Health Evidence Review Commission's Value-based Benefits Subcommittee

August 9, 2018

8:00 AM - 1:00 PM

Clackamas Community College
Wilsonville Training Center, Room 111-112
29373 SW Town Center Loop E, Wilsonville, Oregon, 97070

Section 1.0

Call to Order

AGENDA
VALUE-BASED BENEFITS SUBCOMMITTEE
August 9, 2018
8:00am - 1:00pm
Clackamas Community College
29373 SW Town Center Loop E,
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
A working lunch will be served at approximately 12:00 PM
All times are approximate

#	Time	Item	Presenter	Action Item
1	8:00 AM	**Call to Order, Roll Call, Approval of Minutes**	Kevin Olson	X
3	8:05 AM	**Staff Report**	Darren Coffman Ariel Smits Cat Livingston	
4	8:10 AM	**Straightforward/Consent Agenda** A. Straightforward table B. Straightforward corrections for breast cancer gene testing	Ariel Smits	X
5	8:15 AM	**Advisory Group Reports** A. Behavioral Health Advisory Panel ◦ General recommendations ◦ F39 B. Chronic Pain Taskforce ◦ New chronic pain line proposal	Ariel Smits	X *No action will be taken on CPTF report*
6	9:15 AM	**2019 ICD-10 Code Review** A. Straightforward code placement B. Code issues ◦ Code issues document ◦ Brow ptosis repair ◦ Blepharoplasty	Ariel Smits	X
7	9:45 AM	**2020 Biennial Review** A. Severe acne B. Burn line reorganization	Ariel Smits	*Final decision on biennial review topics not due until March 2019*
8	10:15 AM	**Previous Discussion Items** A. HCPCS "C" code review follow-up: ◦ Drug eluting stents ◦ Eustachian tube inflation B. Severe inflammatory skin disease guideline	Ariel Smits	X

9	10:40 AM	**New Discussion Items, Straightforward** A. Diagnostic indications and the PET guideline B. Absorbable implants for nasal vestibular wall stenosis C. Migraine and botulinum toxin guideline edit D. Computer assist musculoskeletal surgery	Ariel Smits	X
10	11:00 AM	**New Discussion Items, Non-straightforward** A. Prioritization of FDA approved drugs on unfunded lines on the Prioritized List ◦ Human growth hormone deficiency B. Diabetes Prevention Program (DPP) C. Coverage of developmental diagnoses D. Postpartum depression screening E. Revisions to breast reconstruction guideline F. Cardiac MRI	Ariel Smits Cat Livingston	X
11	11:30 AM	**Coverage guidances** A. Single fraction radiation B. Urine drug testing	Wally Shaffer Cat Livingston	X
12	12:55 PM	**Public Comment**		
13	1:00 PM	**Adjournment**	Kevin Olson	

Note: Public comment will be taken on each topic per HERC policy at the time at which that topic is discussed.

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on May 17, 2018

For specific coding recommendations and guideline wording, please see the text of the 5/17/2018 VbBS minutes.

RECOMMENDED CODE MOVEMENT (effective 10/1/2018 unless otherwise noted)

- Place the HCPCS "C" codes on various lines or other files
- Add the diagnosis codes for sagging eyelids to a covered line to allow pairing with corrective procedures when certain criteria set forth in a guideline are met
- Add procedure codes for repair of sagging lower eyelids to an uncovered line for when coverage criteria are not met
- Add stimulation of a tongue nerve for obstructive sleep apnea to an uncovered line
- Add several diagnosis codes for incisional hernias to the uncovered hernia line and leave on the covered hernia line with the hernia guideline defining when the code is included on the upper line
- Add the procedure code for robotic assist for surgery to an uncovered line
- Add procedure codes for UV light therapy to several covered and uncovered lines and delete from inappropriate lines. Add codes for home light therapy to one covered and two uncovered lines. Delete laser therapy from one line with no appropriate diagnoses. Add a code for home lights for treatment of neonatal jaundice to a covered line.
- Add procedure codes for transurethral prostatic lifts to a covered line
- Add several procedure codes for genetic expression profiling to the breast cancer line
- Add the procedure code for chiropractic manipulation of non-spinal regions to a non-covered line
- Make various straightforward coding changes

RECOMMENDED GUIDELINE CHANGES (effective 10/1/2018 unless otherwise noted)

- Add a new statement of intent regarding care of patients with chronic pain
- Edit the hernia guideline to include incarcerated incisional hernias on the uncovered hernia line
- Add a new guideline to define what is a vital site for burns to help clarify which diagnoses are covered on various burn lines
- Edit the guideline for treatment of benign prostatic hypertrophy to add prostatic urethral lifts as a covered treatment
- Edit the biomarkers for cancer guideline to allow certain evidence-based tests and exclude others for various types of cancer
- Make various straightforward guideline note changes

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VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
May 17, 2018
8:00 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, Vice Chair; Vern Saboe, DC; Gary Allen, DMD; Adriane Irwin, PharmD; Susan Williams, MD (via phone until 8:45, then in person); Mark Gibson (via phone until 12:00 pm).

Members Absent: None.

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Jason Gingerich; Daphne Peck; Wally Shaffer, MD.

Also Attending: K. Renae Wentz, MD, (Oregon Health Authority); Adam Obley, MD & Craig Mosbaek (Center for Evidence-based Medicine); Dr. Julie Dhossche and Dr. Tracy Funk (OHSU); Dr. Darin Vaughan (via phone); Arti Baig and Mike Willett (Pfizer); Laura Jeffcoat (Abbvie).

- **Roll Call/Minutes Approval/Staff Report**

  The meeting was called to order at 8:05 am and roll was called. Minutes from the March 8, 2018 VbBS meeting were reviewed and approved with Adriane Irwin's name spelling corrected. Smits reviewed the errata; there were no comments or concerns.

  Gingerich briefly reviewed the data pull regarding changes in services resulting from the new back lines. More extensive discussion of this data was held at the May HERC meeting.

- **Topic: Straightforward/Consent Agenda**

  Discussion: There was no discussion about the consent agenda items.

  Recommended Actions:
  1) Remove 20910 (Cartilage graft; costochondral) from lines 160 TRAUMATIC AMPUTATION OF ARM(S), HAND(S), THUMB(S), AND FINGER(S) (COMPLETE)(PARTIAL) WITH AND WITHOUT COMPLICATION, 641 TMJ DISORDERS
     a. Advise HSD to add 20910 to the Ancillary File
  2) Remove 93285 (Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis…), 93290 and 93291 (Interrogation device evaluation (in person) with analysis…) from line 98 HEART FAILURE
  3) Remove 97810-97840 (Acupuncture) from line 204 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE
  4) Add 11400-11446 (Excision, benign lesion) to line 541 FOREIGN BODY GRANULOMA OF MUSCLE, SKIN AND SUBCUTANEOUS TISSUE
  5) Modify GN 106 PREVENTIVE SERVICES as shown in Appendix A
  6) Modify GN 108 CONTINUOUS GLUCOSE MONITORING as shown in Appendix A

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7) Remove CPT 99339-99340 from line 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER and line 549 SOMATIC SYMPTOMS AND RELATED DISORDERS
    a. CPT 99339-99340 Individual physician supervision of a patient (patient not present) in home, domiciliary or rest home (eg, assisted living facility) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of related laboratory and other studies, communication (including telephone calls) for purposes of assessment or care decisions with health care professional(s), family member(s), surrogate decision maker(s) (eg, legal guardian) and/or key caregiver(s) involved in patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month
8) Remove CPT 28200-29202 (Repair, tendon, flexor, foot) and CPT 28208-28210 (Repair, tendon, extensor, foot) from line 165 PREVENTIVE FOOT CARE IN HIGH RISK PATIENTS
9) Remove inpatient CPT codes from line 165 PREVENTIVE FOOT CARE IN HIGH RISK PATIENTS
    a. CPT 99184 Initiation of selective head or total body hypothermia in the critically ill neonate, includes appropriate patient selection by review of clinical, imaging and laboratory data, confirmation of esophageal temperature probe location, evaluation of amplitude EEG
    b. CPT 99217 Observation care discharge day management
    c. CPT 99356-99357 Prolonged service in the inpatient or observation setting
    d. CPT 99358-99359 Prolonged evaluation and management service before and/or after direct patient care
    e. CPT 99360 Standby service, requiring prolonged attendance

MOTION: To approve the recommendations stated in the consent agenda. CARRIES 7-0.

- **Topic: Chronic Pain Taskforce Interim Report**

Discussion: Smits introduced the summary document with interim recommendations. The first item of discussion was the new proposed statement of intent on treatment of chronic pain. Members asked about the purpose and effect of such a statement of intent. Staff replied that the intent was to try to move the medical community towards a better method of care for these patients, and the statement of intent could help guide CCO's toward providers who should be contracted with for caring for patients with chronic pain. Wentz noted that the SOI would be useful for reviewers at HSD and for administrative law judges in hearings on service denials. The group approved the proposed SOI with the suggested addition of "covered" services.

The next item of discussion was the proposed edits to the opioid guideline for neck and back pain. There was extensive discussion about the length of the taper that should be recommended. One year as proposed by the Taskforce was considered too long. Hodges noted that her CCO uses a 3-month taper for short acting opioids and 6 months for long acting opioids. Livingston noted that the CDC recommends a 10% per week taper, but that this is not backed by strong evidence. A strong evidence base on optimal length of taper does not really exist. Coffman noted that the proposed wording would allow short tapers as it indicated that the taper should be no more than 1 year, but did not restrict shorter tapers. HERC staff was asked to look at the evidence base for optimal length

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of taper. The decision was to send the opioid guideline back to the CPTF for further input on optimal length of taper and bring back the topic to the August 2018 VbBS meeting.

Recommended Actions:

1) Adopt a new statement of intent regarding treatment of chronic pain as shown in Appendix C
2) HERC staff will bring back the opioid guideline for back and neck conditions to the Chronic Pain Taskforce for further consideration and bring back revised recommended edits to the August 2018 VbBS meeting

MOTION: To recommend the addition of the new statement of intent as presented. CARRIES 6-0. *(Abstained: Irwin)*

- **Topic: HCPCS "C" Code Review**

Discussion: Smits reviewed the table of C codes and placement recommendations. Hodges requested that the drug eluting stent codes (HCPCS C9600-9608) be further reviewed. HERC staff will compile an evidence review and discuss with a cardiologist and bring back these materials for discussion in August 2018. There was no other discussion of the general code recommendations or the recommended wording for GN173 changes.

Blue light cystoscopy was discussed separately. Gibson asked about the relative cost difference between normal cystoscopy and the blue light version. Smits identified a 2013 cost effectiveness study that found long-term (5 year) lower overall costs with blue light/HAL cystoscopy. There was discussion about adding a guideline to limit use to HAL (versus 5-ALA), but this was decided against.

Balloon continence devices were also discussed separately. The VbBS changed the rationale in the GN173 entry to "Harms outweigh benefits" as there were demonstrated benefits but the harms were more significant.

The Eustachian tube inflation topic was tabled to August 2018 at the request of Johnson and Johnson, due to the imminent publication of data on effectiveness that should be considered.

Recommended Actions:

1) HCPCS "C" code placement recommendations as presented in Appendix B
2) Modify GN173 INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS as shown in Appendix A
3) Advise HSD to add HCPCS C9738 (Adjunctive blue light cystoscopy with fluorescent imaging agent) to the Diagnostic Procedures File and remove from the Ancillary File
4) Drug eluting stents and Eustachian tube inflation will be further reviewed and brought back to the August 2018 VbBS meeting

Note: Later discussion at the May VbBS meeting regarding prostatic urethral lifts resulted in changes to recommended placement of HCPCS C9739-C9740 (Cystourethroscopy, with insertion of transprostatic implant). These codes were not added to line 660 but rather line 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION. The addition of these codes to GN173 INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT

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BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS was reversed. These changes are reflected in the HCPCS "C" code table in Appendix B and in the entries to GN173 in Appendix A

MOTION: To recommend the code and guideline note changes as presented. CARRIES 7-0.

- **Topic: Coverage of developmental diagnoses**

  Recommended Actions: This topic was tabled until the August 2018 VbBS meeting.

- **Topic: Dermatochalasis and blepharoplasty**

  Discussion: Smits reviewed the summary document. There was minimal discussion.

  Recommended Actions:
  1) Add ICD-10 H02.83 (dermatochalasis) to line 469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT and remove from line 567 BLEPHARITIS
  2) Add line 351 STRABISMUS DUE TO NEUROLOGIC DISORDER to GN130 BLEPHAROPLASTY
  3) Add CPT 15820-15821 (Blepharoplasty, lower eyelid) to line 660 and modify GN173 as shown in Appendix A

  MOTION: To recommend the code and guideline note changes as presented. CARRIES 7-0.

- **Topic: Hypoglossal nerve stimulation for OSA**

  Discussion: Smits reviewed the summary document. There was minimal discussion, other than a request to add "evidence of harms" to the rationale in GN173.

  Recommended Actions:
  1) Add hypoglossal nerve stimulation (CPT 64568 Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator) to line 660/GN173 as shown in Appendix A

  MOTION: To recommend the code and guideline note changes as presented. CARRIES 7-0.

- **Topic: Incisional hernias**

  Discussion: Smits reviewed the summary document. There was minimal discussion.

  Recommended Actions:
  1) Add the following ICD-10 codes to line 522 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER OR DIAPHRAGMATIC HERNIA) and keep on line 168 COMPLICATED HERNIAS; UNCOMPLICATED INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER; PERSISTENT HYDROCELE

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a. K43.0 (Incisional hernia with obstruction, without gangrene)
b. K43.3 (Parastomal hernia with obstruction, without gangrene)
c. K43.6 (Other and unspecified ventral hernia with obstruction, without gangrene)
d. K46.0 (Unspecified abdominal hernia with obstruction, without gangrene)

2) Modify GN24 COMPLICATED HERNIAS as shown in Appendix A

MOTION: To recommend the code and guideline note changes as presented. CARRIES 7-0.

- **Topic: Robotic assisted surgery**

Discussion: Smits reviewed the summary document. There was minimal discussion. It was noted that these robots are extremely expensive.

Recommended Actions:

1) Add HCPCS S2900 (Surgical techniques requiring use of robotic surgical system) to line 500 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS and modify GN172 as shown in Appendix A
    a. Advise HSC to remove HCPCS S2900 from the Ancillary File

MOTION: To recommend the code and guideline note changes as presented. CARRIES 7-0.

- **Topic: Severe inflammatory skin disease guideline**

Discussion: Smits introduced the summary document. There was significant concern about deleting the guideline sections outlining step therapy. Hodges noted that these sections are very helpful to the CCOs. Smits responded that P&T can be more nimble and responsive for changes in medication evidence, new agents, etc. Coffman noted that there are many other conditions on the Prioritized List that have PA criteria for medications but are not in guidelines. The decision was to have HERC staff work with P&T staff to review the medication step therapy in the guideline and update the guideline to comply with P&T PA criteria. Drs. Dhossche and Funk offered to assist staff with revisions as well. Staff will revise the guideline and bring back to the August 2018 VbBS meeting.

Recommended Actions:

1) Staff to work with P&T staff and experts to revise the inflammatory skin disease guideline and bring back revised recommendations to the August 2018 VbBS meeting

- **Topic: PUVA and UVB and other light therapy**

Discussion: Smits introduced the summary document. Hodges had questions about whether light boxes would fall under the same rules as other DME. Wentz indicated that they would. Smits will work with HSD staff when they re-write the rules regarding light boxes and will make the CCO medical directors aware of proposed new rules.

Coffman noted that GN23 would allow inflammatory skin disease affecting <10% BSA to be on the covered inflammatory skin disease line if the hand, feet, or mucous membranes are affected. The

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staff recommendations were modified to keep laser therapy on line 424, with GN23 restricting use to just hands, feet or mucous membranes and American Dermatology Association guidelines restricting use to <10% BSE.

Recommended Actions:

1) Add CPT 96900, 96910, 96912 and 96913 (PUVA and UVB therapy) to line 158 HODGKIN'S LYMPHOMA TX: MEDICAL THERAPY
2) Remove PUVA and UVB therapy (CPT 96900, 96910, 96912 and 96913) from the following lines
    a. 56 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE
    b. 102 HEMOLYTIC DISEASE DUE TO ISOIMMUNIZATION, ANEMIA DUE TO TRANSPLACENTAL HEMORRHAGE, AND FETAL AND NEONATAL JAUNDICE
    c. 213 BULLOUS DERMATOSES OF THE SKIN
    D. 358 BODY INFESTATIONS (E.G., LICE, SCABIES)
    E. 373 ACNE CONGLOBATA (SEVERE CYSTIC ACNE)
    f. 407 EPIDERMOLYSIS BULLOSA
    g. 487 DERMATOPHYTOSIS OF NAIL, GROIN, AND FOOT AND OTHER DERMATOMYCOSIS
    h. 520 ROSACEA; ACNE
    i. 530 MILD ECZEMA
    j. 543 SYMPTOMATIC URTICARIA
3) Add ultraviolet light therapy (CPT 96900, 96910, 96912 and 96913) to the following lines which contain appropriate diagnoses
    a. 313 DISORDERS INVOLVING THE IMMUNE SYSTEM
    b. 506 CIRCUMSCRIBED SCLERODERMA
    c. 654 DERMATOLOGICAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
4) Remove laser therapy (CPT 96920-96922) from line 206 SUPERFICIAL ABSCESSES AND CELLULITIS
5) Add home light therapy (HCPCS A4633, E0691-E0694) to the following lines and advise HSD to remove HCPCS A4633, E0691-E0694 from the Ancillary File and address its exclusion in OARs
    A. 424 SEVERE INFLAMMATORY SKIN DISEASE
    B. 531 CONTACT DERMATITIS AND NON-INFECTIOUS OTITIS EXTERNA
    C. 539 MILD PSORIASIS; DERMATOPHYTOSIS: SCALP, HAND, BODY
6) Add home bili-light therapy (HCPCS E0202 (Phototherapy (bilirubin) light with photometer)) to line 102 HEMOLYTIC DISEASE DUE TO ISOIMMUNIZATION, ANEMIA DUE TO TRANSPLACENTAL HEMORRHAGE, AND FETAL AND NEONATAL JAUNDICE
    A. Advise HSC to remove HCPCS E0202 from the Ancillary File

MOTION: To recommend the code changes as presented. CARRIES 7-0.

- **Topic: Severe Acne Biennial Review**

Discussion: Smits reviewed the summary document. A presentation was given by Dr. Julie Dhossche from OHSU Dermatology on the impact of acne on mental health conditions in patients and the effectiveness of therapy. Dr. Funk from OHSU dermatology also was present to answer questions in person. They recommended coverage of severe acne.

Dr. Darin Vaughan was on the phone and gave verbal testimony is support of the coverage of acne. He argued in support of treatment of moderate and mild forms of acne. He noted that even

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moderate acne has consequences with mental health and treatment can have a positive impact. There is strong evidence in support of the effectiveness of acne treatments. There is a lack of equity for OHP patients, as all private insurance covers this condition.

There was discussion of the importance of coverage for acne fulminans. There is no specific code for this severe form of acne. The VbBS desired that acne fulminans be included on the same line as acne conglobata.

There was general agreement among VbBS members that the more severe form of acne should be covered. The staff proposal of a new line for severe acne, separate from the acne conglobata line, was considered the more desirable approach. It was felt that the effects on mental health with treatment of severe acne supported coverage. There was discussion about the prevalence of severe acne. It was felt to be about 10% of the population with acne.

There was discussion about whether step therapy medications should be covered, or just isotretinoin. Dr. Funk indicated that some patients with severe acne benefit from some topical or other oral medications, and recommended considering them for coverage.

There was discussion about the risk of isotretinoin in pregnancy. Funk replied that the strict FDA requirements for prescribing minimize this risk.

HERC staff was directed to work with P&T staff and dermatology experts to find a way to specify that acne fulminans is on the acne conglobata line. Staff recommendation #2 should be further revised, reviewed with the CCO medical directors, and brought back in August for further discussion.

Recommended Actions:

1) Staff to work with P&T staff and dermatology experts on proposal for new line and guideline, circulate the proposal to the CCO medical directors for comment, and bring back to the August VbBS meeting for further discussion.

- **Topic: Burn line vital site definition and possible burn line reorganization**

Discussion: Smits introduced the summary document. The staff proposal for the addition of a new guideline to define "vital site" in two of the burn line titles was approved with minimal discussion.

There was extensive discussion about the second staff proposal, which would combine several of the existing burn lines as a biennial review change. The members wanted to ensure that moderate burns that do not require skin grafting would have therapy available to them. The way the current burn lines are organized, it appears that severe burns (full thickness burns, partial thickness burns >30% of body surface area or requiring skin grafts and/or involving vital sites) are covered. However, moderate burns (partial thickness burns <30% body surface area not involving vital sites or requiring grafting) appear to be included on the uncovered lines. These burns may still need topical burn creams, dressing changes, or other therapy. Staff was directed to define severe burns and to define moderate burns, and to ensure that all burns other than first degree or otherwise minor burns were in the covered region of the Prioritized List. The ICD-10 codes are generally not helpful, and therefore a guideline may need to be added. Williams requested that staff mock up two new burn

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lines, one for severe and one for moderate, as these two lines would likely have very different scoring/line placement.

Staff will mock up severe, moderate, and mild burn lines, as well as propose a new guideline with definitions for severe and moderate burns. Staff will consult with burn experts, such as at the burn center at Legacy, to assist in creating these definitions and ensuring that all burns requiring treatment are included in the upper lines. Another possibility is to move all the ICD-10 codes for second and third degree burns to covered lines, and not having a guideline. Staff will also consult with HSD staff to see whether DME such as medication-impregnated wound dressings are subject to prior authorization. This topic will be brought back to the August 2018 VbBS meeting for further discussion.

Recommended Actions:

1) Add a new guideline defining "vital site" in the burn line titles as shown in Appendix C
2) Staff will work with experts and bring back a revised recommendation for burn line reorganization to a future VbBS meeting

MOTION: To recommend the guideline note changes as presented. CARRIES 7-0.

- **Topic: Coverage Guidance—Prostatic urethral lift for treatment of benign prostatic hypertrophy**

Discussion: Obley reviewed the evidence. Shaffer reviewed the recommended changes to the Prioritized List. There was minimal discussion.

Recommended Actions:

1) Add the following codes to Line 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
    a. CPT 52441-52442 (Cystourethroscopy, with insertion of permanent adjustable transprostatic implant)
    b. HCPCS C9739-C9740 (Cystourethroscopy, with insertion of permanent adjustable transprostatic implant)
2) Revise Guideline Note 145 TREATMENTS FOR BENIGN PROSTATE ENLARGEMENT WITH LOWER URINARY TRACT SYMPTOMS as shown in Appendix A
3) Remove the entry on Prostatic Urethral Lifts from Guideline Note 173 INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS and remove CPT 52441 and 52442 from line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

MOTION: To approve the recommended changes to the Prioritized List based on the draft Prostatic Urethral Lift for Treatment of Benign Prostatic Hypertrophy coverage guidance scheduled for review by HERC at their May 2018 meeting. CARRIES 7-0.

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- **Topic: Coverage Guidance—Gene expression profiling for breast cancer**

Discussion: Obley reviewed the evidence. Shaffer reviewed the recommended changes to the Prioritized List. Discussion centered around whether the other breast cancer tests were of equivalent utility to Oncotype DX. Olson and Shaffer felt that these tests are of equivalent utility.

Recommended Actions:

1) Add the following codes to line 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER and remove from line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
    a. CPT 81520 (Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes (50 content and 8 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence risk score)
    b. CPT 81521 (Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes, utilizing fresh frozen or formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk of distant metastasis)
2) Add HCPCS S3854 (Gene expression profiling panel for use in the management of breast cancer treatment) to both lines 191 and 660
    a. Advise HSD to remove from the Ancillary File
3) Revise Guideline Note 148 BIOMARKER TESTS OF CANCER TISSUE as shown in Appendix A
4) Add CPT 81525 (Oncology (colon), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence score) and 88120 & 88121 (Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis) to line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
5) Modify GN173 INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS as shown in Appendix A

MOTION: To approve the recommended changes to the Prioritized List based on the draft Genome Expression Profiling for Breast Cancer coverage guidance scheduled for review by HERC at their May, 2018 meeting. CARRIES 7-0.

- **Topic: Chiropractic manipulation for non-axial indications**

Discussion: Smits introduced the summary document. There was minimal discussion.

Recommended Actions:

1) Add CPT 98943 (Chiropractic manipulative treatment (CMT); extraspinal, 1 or more regions) to line 605 SPRAINS AND STRAINS OF ADJACENT MUSCLES AND JOINTS, MINOR
    a. Advise HSD to remove CPT 98943 from the Ancillary File

MOTION: To recommend the code changes as presented. CARRIES 6-0 (Gibson absent).

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- **Public Comment:**

  No additional public comment was received.

- **Issues carried over for next meeting:**
  - Opioid for back and neck pain guideline
  - Drug eluting stents
  - Eustachian tube inflation
  - Coverage of developmental diagnoses
  - Severe inflammatory skin disease guideline
  - Severe acne
  - Burn line reorganization

- **Next meeting:**

  August 9, 2018 at Clackamas Community College, Wilsonville Training Center, Wilsonville Oregon, Rooms 111-112.

- **Adjournment:**

  The meeting adjourned at 12:55 PM.

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Appendix A

Revised Guideline Notes

GUIDELINE NOTE 24, COMPLICATED HERNIAS

Lines 168,522

Complicated hernias are included on Line 168 if they cause symptoms of intestinal obstruction and/or strangulation. Incarcerated hernias (defined as non-reducible by physical manipulation) are also included on Line 168, excluding incarcerated ventral hernias. Incarcerated ventral hernias (including incarcerated abdominal incisional hernias) are included on Line 522, because the chronic incarceration of large ventral hernias does not place the patient at risk for impending strangulation. ICD-10 K43.0, K43.3, K43.6 and K46.0 are included on line 522 when used to designate incarcerated abdominal incisional hernias without intestinal obstruction or gangrene.

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Lines 3,619

Included on Line 3 are the following preventive services:

A) US Preventive Services Task Force (USPSTF) "A" and "B" Recommendations in effect and issued prior to January 1, 2016.
   1) http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/
   2) USPSTF "D" recommendations are not included on this line or any other line of the Prioritized List.

B) American Academy of Pediatrics (AAP) Bright Futures Guidelines:
   1) http://brightfutures.aap.org. Periodicity schedule available at http://www.aap.org/en-us/professional-resources/practice-support/Periodicity/Periodicity%20Schedule_FINAL.pdf.
   2) Screening for lead levels is defined as blood lead level testing and is indicated for Medicaid populations at 12 and 24 months. In addition, blood lead level screening of any child between ages 24 and 72 months with no record of a previous blood lead screening test is indicated.

C) Health Resources and Services Administration (HRSA) Women's Preventive Services - Required Health Plan Coverage Guidelines as retrieved from **http://www.hrsa.gov/womensguidelines/** on 1/1/2017.

D) Immunizations as recommended by the Advisory Committee on Immunization Practices (ACIP): http://www.cdc.gov/vaccines/schedules/hcp/index.html or approved for the Oregon Immunization Program: http://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Documents/DMAPvactable.pdf

GUIDELINE NOTE 108, CONTINUOUS GLUCOSE MONITORING

Line 8

Real-time (personal) continuous glucose monitoring (CGM) is included on Line 8 for:

A) Adults with type 1 diabetes mellitus not on insulin pump management:
   1) Who have received or will receive diabetes education specific to the use of CGM AND

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2) Who have used the device for at least 50% of the time at their first follow-up visit AND
3) Who have baseline HbA1c levels greater than or equal to 8.0%, frequent or severe hypoglycemia, or impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM).

B) Adults with type 1 diabetes on insulin pump management (including the CGM-enabled insulin pump):
1) Who have received or will receive diabetes education specific to the use of CGM AND
2) Who have used the device for at least 50% of the time at their first follow-up visit

C) Women with type 1 diabetes who are pregnant or who plan to become pregnant within six months without regard to HbA1c levels.

D) Children and adolescents under age 21 with type 1 diabetes:
1) Who have received or will receive diabetes education specific to the use of CGM AND
2) Who have used the device for at least 50% of the time at their first follow-up visit

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx

GUIDELINE NOTE 145, TREATMENTS FOR BENIGN PROSTATE ENLARGEMENT WITH LOWER URINARY TRACT SYMPTOMS

Line 327

For men with lower urinary tract symptoms (LUTS) due to benign prostate enlargement, ~~coverage of~~ surgical procedures ~~is recommended~~ are included on these lines only if symptoms are severe, and if drug treatment and conservative management options have been unsuccessful or are not appropriate.

Prostatic urethral lift procedures (CPT 52441, 52442, HCPCS C9739, C9740) are included on Line 327 when the following criteria are met:

- Age 50 or older
- Estimated prostate volume < 80 cc
- International Prostate Symptom Score (IPSS) ≥ 13
- No obstructive median lobe of the prostate identified on cystoscopy at the time of the procedure

The following interventions for benign prostate enlargement are not included on Line 327 due to lack of evidence of effectiveness:
• Botulinum toxin
• HIFU (High Intensity Focused Ultrasound)
• TEAP (Transurethral Ethanol Ablation of the Prostate)
~~• Prostatic urethral lifts~~
• Laser coagulation (for example, VLAP/ILC)
• Prostatic artery embolization

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx.

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GUIDELINE NOTE 148, BIOMARKER TESTS OF CANCER TISSUE

Lines 157,184,191,230,263,271,329

The use of multiple molecular testing to select targeted cancer therapy (CPT 81504) is included on line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS ~~the Services recommended for non-coverage table~~.

~~For breast cancer, Oncotype Dx testing (CPT 81519, HCPCS S3854) is included on Line 191 only for early stage breast cancer when used to guide adjuvant chemotherapy treatment decisions for women who are lymph node negative. Oncotype Dx is not included on this line for lymph node-positive breast cancer. Mammaprint, ImmunoHistoChemistry 4 (IHC4), and Mammostrat for breast cancer are included on the Services recommended for noncoverage table.~~

For early stage breast cancer, the following breast cancer genome profile tests are included on Line 191 when the listed criteria are met. One test per primary breast cancer is covered when the patient is willing to use the test results in a shared decision-making process regarding adjuvant chemotherapy. Lymph nodes with micrometastases less than 2 mm in size are considered node negative.

- Oncotype DX Breast Recurrence Score (CPT 81519) for breast tumors that are estrogen receptor positive, HER2 negative, and either lymph node negative, or lymph node positive with 1-3 involved nodes.
- EndoPredict (using CPT 81599) and Prosigna (CPT 81520 or PLA 0008M) for breast tumors that are estrogen receptor positive, HER2 negative, and lymph node negative.
- MammaPrint (using CPT 81521 or HCPCS S3854) for breast tumors that are estrogen receptor or progesterone receptor positive, HER2 negative, lymph node negative, and only in those cases categorized as high clinical risk.

EndoPredict, Prosigna, and MammaPrint are not included on Line 191 for early stage breast cancer with involved axillary lymph nodes. Oncotype DX Breast Recurrence Score is not included on Line 191 for breast cancer involving four or more axillary lymph nodes or more extensive metastatic disease.

Oncotype DX Breast DCIS Score (CPT 81479) and Breast Cancer Index (may use CPT 81479, 81599, 84999, S3854) are included on Line 660.

For melanoma, BRAF gene mutation testing (CPT 81210) is included on Line 230 MALIGNANT MELANOMA OF SKIN.

For lung cancer, epidermal growth factor receptor (EGFR) gene mutation testing (CPT 81235) is included on Line 263 CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS only for non-small cell lung cancer. KRAS gene mutation testing (CPT 81275) is not included on Line 263.

For colorectal cancer, KRAS gene mutation testing (CPT 81275) is included on Line 157. BRAF (CPT 81210) and Oncotype DX (81525) are not included on Line 157. Microsatellite instability (MSI) is included on ~~the Services recommended for noncoverage table~~ line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

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For bladder cancer, Urovysion (88120, 88121) testing is included on ~~Services recommended for noncoverage table~~ line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

For prostate cancer, Oncotype DX Genomic Prostate Score (81479), Prolaris Score Assay (81541), and Decipher RP (81479) are included on Line 660.

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx.

GUIDELINE NOTE 172, INTERVENTIONS WITH MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS FOR CERTAIN CONDITIONS

Line 500

The following interventions are prioritized on Line 500 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS:

Procedure Code	Intervention Description	Rationale	Last Review
S2900	Surgical techniques requiring use of robotic surgical system	More cost-effective treatments are available	May, 2018

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

The following Interventions are prioritized on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
15820-15821	Blepharoplasty, lower eyelid	No clinically important benefit	May, 2018
19294 C9726	Intraoperative radiation therapy (IORT) concurrent with partial Mastectomy Placement and removal (if performed) of applicator into breast for intraoperative radiation therapy, add-on to primary breast procedure	Unproven treatment	November, 2017
22867-22870 C1821	Insertion of interlaminar/ interspinous process stabilization/ distraction device, without fusion, including image guidance when performed, with open decompression, lumbar Interspinous process distraction device (implantable)	Insufficient evidence of effectiveness	November, 2016

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C9733	Non-ophthalmic fluorescent vascular angiography	Unproved therapy	December, 2012
~~52441-52442~~ ~~C9739-9740~~	~~Cystourethroscopy, with insertion of permanent adjustable transprostatic implant~~ ~~Cystourethroscopy, with insertion of transprostatic implant~~	~~No evidence of effectiveness~~	~~March, 2015~~ ~~Coverage Guidance~~
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator for hypoglossal nerve stimulation for treatment of obstructive sleep apnea	Insufficient evidence of effectiveness and evidence of harm	May, 2018
81479	• Oncotype DX Breast DCIS Score • Breast Cancer Index • Oncotype DX Genomic Prostate Score • Decipher RP for prostate cancer	Unproven intervention	May, 2018 (breast) Coverage Guidance Blog (Breast) January, 2018 (prostate)
~~81521~~	~~Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes~~	~~Unproven intervention~~	~~August, 2015~~
81504	Biomarker tests for tumor tissue: • Mammostrat and ImmunoHistoCHemistry 4 (IHC4) for breast cancer • Microsatellite instability (MSI) for colorectal cancer • Urovysion for bladder cancer (88120, 88121) • Multiple molecular testing to select targeted cancer therapy	Insufficient evidence of effectiveness. More costly than equally effective therapies for this condition	August, 2015 Coverage Guidance Blog (other than breast) May, 2018 Coverage Guidance Blog (Breast)
81525	Oncotype DX for colon cancer	Insufficient evidence of effectiveness	November, 2015
88120, 88121	Urovysion for bladder cancer	Insufficient evidence of effectiveness	
C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed	Harms outweigh benefits	May, 2018

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C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (hifu), including imaging guidance	No evidence of effectiveness	March, 2015 Coverage Guidance Blog
HEALTH TECHNOLOGIES CURRENTLY UNDER REVIEW			
~~81520~~	~~Gene expression profiling algorithm for breast cancer mRNA gene expression profiling by hybrid capture of 58 genes (50 content and 8 housekeeping),~~	~~Under review by HTAS~~	~~N/A~~

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C2617	Stent, non-coronary, temporary, without delivery system	Ancillary procedures	Ancillary procedures
C2618	Probe/needle, cryoablation	Ancillary procedures	Ancillary procedures
C2619	Pacemaker, dual chamber, non rate-responsive (implantable)	Ancillary procedures	69 Acute and subacute ischemic heart disease, myocardial infarction 111 Congenital heart block; other obstructive anomalies of heart 189 Chronic ischemic heart disease 281 Life-threatening cardiac arrhythmias 285 Complications of a procedure always requiring treatment 347 Cardiac arrhythmias
C2620	Pacemaker, single chamber, non rate-responsive (implantable)	Ancillary procedures	69, 111, 189, 281, 285, 347
C2621	Pacemaker, other than single or dual chamber (implantable)	Ancillary procedures	69, 111, 189, 281, 285, 347
C2622	Prosthesis, penile, non-inflatable	Ancillary procedures	521 SEXUAL DYSFUNCTION
C2623	Catheter, transluminal angioplasty, drug-coated, non-laser	Ancillary procedures	Ancillary procedures
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components		Ancillary procedures
C2625	Stent, non-coronary, temporary, with delivery system	Ancillary procedures	Ancillary procedures
C2626	Infusion pump, non-programmable, temporary (implantable)	Ancillary procedures	Ancillary procedures
C2627	Catheter, suprapubic/cystoscopic	Ancillary procedures	Ancillary procedures
C2628	Catheter, occlusion	Ancillary procedures	Ancillary procedures

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C2629	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, laser	Ancillary procedures	Ancillary procedures
C2630	Catheter, electrophysiology, diagnostic/ablation, other than 3d or vector mapping, cool-tip	Ancillary procedures	Ancillary procedures
C2631	Repair device, urinary, incontinence, without sling graft	Ancillary procedures	Ancillary procedures
C2634	Brachytherapy source, non-stranded, high activity, iodine-125, greater than 1.01 mci (nist), per source	Ancillary procedures	Ancillary procedures
C2635	Brachytherapy source, non-stranded, high activity, palladium-103, greater than 2.2 mci (nist), per source	Ancillary procedures	Ancillary procedures
C2636	Brachytherapy linear source, non-stranded, palladium-103, per 1 mm	Ancillary procedures	Ancillary procedures
C2637	Brachytherapy source, non-stranded, ytterbium-169, per source	Ancillary procedures	Ancillary procedures
C2638	Brachytherapy source, stranded, iodine-125, per source	Ancillary procedures	Ancillary procedures
C2639	Brachytherapy source, non-stranded, iodine-125, per source	Ancillary procedures	Ancillary procedures
C2640	Brachytherapy source, stranded, palladium-103, per source	Ancillary procedures	Ancillary procedures
C2641	Brachytherapy source, non-stranded, palladium-103, per source	Ancillary procedures	Ancillary procedures
C2642	Brachytherapy source, stranded, cesium-131, per source	Ancillary procedures	Ancillary procedures
C2643	Brachytherapy source, non-stranded, cesium-131, per source	Ancillary procedures	Ancillary procedures
C2644	Brachytherapy source, cesium-131 chloride solution, per millicurie		Ancillary procedures

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C2645	Brachytherapy planar source, palladium-103, per square millimeter	Ancillary procedures	Ancillary procedures
C2698	Brachytherapy source, stranded, not otherwise specified, per source	Ancillary procedures	Ancillary procedures
C2699	Brachytherapy source, non-stranded, not otherwise specified, per source	Ancillary procedures	Ancillary procedures
C5271	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area	Ancillary procedures	57 Burn, full thickness greater than 10% of body surface 72 Burn, partial thickness greater than 30% of body surface or with vital site; full thickness, less than 10% of body surface 181 Conditions involving exposure to natural elements (e.g., lightning strike, heatstroke) 197 Burn, partial thickness without vital site requiring grafting, up to 30% of body surface 379 Chronic ulcer of skin
C5272	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	Ancillary procedures	57,72,181,197,379
C5273	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	Ancillary procedures	57,72,181,197,379

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C5274	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)	Ancillary procedures	57,72,181,197,379
C5275	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area	Ancillary procedures	57,72,181,197,379
C1713	Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)	Ancillary procedures	Ancillary procedures
C1714	Catheter, transluminal atherectomy, directional	Ancillary procedures	Ancillary procedures
C1715	Brachytherapy needle	Ancillary procedures	Ancillary procedures
C1716	Brachytherapy source, non-stranded, gold-198, per source	Ancillary procedures	Ancillary procedures
C1717	Brachytherapy source, non-stranded, high dose rate iridium-192, per source	Ancillary procedures	Ancillary procedures
C1719	Brachytherapy source, non-stranded, non-high dose rate iridium-192, per source	Ancillary procedures	Ancillary procedures

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C1721	Cardioverter-defibrillator, dual chamber (implantable)	Ancillary procedures	69 Acute and subacute ischemic heart disease, myocardial infarction 98 Heart failure 99 Cardiomyopathy 111 Congenital heart block; other obstructive anomalies of heart 189 Chronic ischemic heart disease 281 Life-threatening cardiac arrhythmias 347 Cardiac arrhythmias
C1722	Cardioverter-defibrillator, single chamber (implantable)	Ancillary procedures	69,98,99,111,189,281,347
C1724	Catheter, transluminal atherectomy, rotational	Ancillary procedures	Ancillary procedures
C1725	Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)	Ancillary procedures	Ancillary procedures
C1726	Catheter, balloon dilatation, non-vascular	Ancillary procedures	Ancillary procedures
C1727	Catheter, balloon tissue dissector, non-vascular (insertable)	Ancillary procedures	Ancillary procedures
C1728	Catheter, brachytherapy seed administration	Ancillary procedures	Ancillary procedures
C1729	Catheter, drainage	Ancillary procedures	Ancillary procedures
C1730	Catheter, electrophysiology, diagnostic, other than 3d mapping (19 or fewer electrodes)	Ancillary procedures	Ancillary procedures
C1731	Catheter, electrophysiology, diagnostic, other than 3d mapping (20 or more electrodes)	Ancillary procedures	Ancillary procedures

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C1732	Catheter, electrophysiology, diagnostic/ablation, 3d or vector mapping	Ancillary procedures	Ancillary procedures
C1733	Catheter, electrophysiology, diagnostic/ablation, other than 3d or vector mapping, other than cool-tip	Ancillary procedures	Ancillary procedures
C1749	Endoscope, retrograde imaging/illumination colonoscope device (implantable)	Ancillary procedures	Ancillary procedures
C1750	Catheter, hemodialysis/peritoneal, long-term	Ancillary procedures	59 End stage renal disease 339 CHRONIC KIDNEY DISEASE
C1751	Catheter, infusion, inserted peripherally, centrally or midline (other than hemodialysis)	Ancillary procedures	Ancillary procedures
C1752	Catheter, hemodialysis/peritoneal, short-term	Ancillary procedures	59 End stage renal disease 103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS 127 Acute kidney injury 148 ACQUIRED HEMOLYTIC ANEMIAS 222 Disorders of fluid, electrolyte, and acid-base balance 339 Chronic kidney disease
C1753	Catheter, intravascular ultrasound	Ancillary procedures	Ancillary procedures
C1754	Catheter, intradiscal	Ancillary procedures	476 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT NEUROLOGIC INJURY OR STRUCTURAL INSTABILITY
C1755	Catheter, intraspinal	Ancillary procedures	Ancillary procedures
C1756	Catheter, pacing, transesophageal	Ancillary procedures	Ancillary procedures

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C1757	Catheter, thrombectomy/embolectomy	Ancillary procedures	Ancillary procedures
C1758	Catheter, ureteral	Ancillary procedures	Ancillary procedures
C1759	Catheter, intracardiac echocardiography	Ancillary procedures	Ancillary procedures
C1760	Closure device, vascular (implantable/insertable)	Ancillary procedures	Ancillary procedures
C1762	Connective tissue, human (includes fascia lata)	Ancillary procedures	Ancillary procedures
C1763	Connective tissue, non-human (includes synthetic)	Ancillary procedures	Ancillary procedures
C1764	Event recorder, cardiac (implantable)	Diagnostic procedures	Diagnostic procedures
C1765	Adhesion barrier	Ancillary procedures	Ancillary procedures
C1766	Introducer/sheath, guiding, intracardiac electrophysiological, steerable, other than peel-away	Ancillary procedures	Ancillary procedures

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C1767	Generator, neurostimulator (implantable), non-rechargeable	Ancillary procedures	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 Parkinson's disease 292 Neurological dysfunction in posture and movement caused by chronic conditions 346 Conditions of the back and spine with urgent surgical indications 361 Scoliosis 440 Trigeminal and other nerve disorders 527 Conditions of the back and spine without urgent surgical indications 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C1768	Graft, vascular	Ancillary procedures	Ancillary procedures
C1769	Guide wire	Ancillary procedures	Ancillary procedures
C1770	Imaging coil, magnetic resonance (insertable)	Ancillary procedures	Ancillary procedures
C1771	Repair device, urinary, incontinence, with sling graft	Ancillary procedures	Ancillary procedures
C1772	Infusion pump, programmable (implantable)	Ancillary procedures	Ancillary procedures
C1773	Retrieval device, insertable (used to retrieve fractured medical devices)	Ancillary procedures	Ancillary procedures
C1776	Joint device (implantable)	Ancillary procedures	Ancillary procedures
C1777	Lead, cardioverter-defibrillator, endocardial single coil (implantable)	Ancillary procedures	69,98,99,111,189,281,347

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C1778	Lead, neurostimulator (implantable)	Ancillary procedures	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 Parkinson's disease 292 Neurological dysfunction in posture and movement caused by chronic conditions 346 Conditions of the back and spine with urgent surgical indications 361 Scoliosis 440 Trigeminal and other nerve disorders 527 Conditions of the back and spine without urgent surgical indications 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C1779	Lead, pacemaker, transvenous vdd single pass	Ancillary procedures	69, 111, 189, 281, 285, 347
C1780	Lens, intraocular (new technology)	Ancillary procedures	Ancillary procedures
C1781	Mesh (implantable)	Ancillary procedures	Ancillary procedures
C1782	Morcellator	Ancillary procedures	Ancillary procedures
C1783	Ocular implant, aqueous drainage assist device	Ancillary procedures	Ancillary procedures
C1784	Ocular device, intraoperative, detached retina	Ancillary procedures	Ancillary procedures
C1785	Pacemaker, dual chamber, rate-responsive (implantable)	Ancillary procedures	69,111,189,281,285,300
C1786	Pacemaker, single chamber, rate-responsive (implantable)	Ancillary procedures	69,111,189,281,285,300

HCPCS code	Code description	Current Placement	Recommended Placement
C1787	Patient programmer, neurostimulator	Ancillary procedures	Ancillary procedures
C1788	Port, indwelling (implantable)	Ancillary procedures	Ancillary procedures
C1789	Prosthesis, breast (implantable)	Ancillary procedures	191 Cancer of breast; at high risk of breast cancer 312 Gender dysphoria/transexualism 634 Galactorrhea, mastodynia, atrophy, benign neoplasms and unspecified disorders of the breast
C1813	Prosthesis, penile, inflatable	Ancillary procedures	521 SEXUAL DYSFUNCTION
C1814	Retinal tamponade device, silicone oil	Ancillary procedures	Ancillary procedures
C1815	Prosthesis, urinary sphincter (implantable)	Ancillary procedures	71 Neurological dysfunction in breathing, eating, swallowing, bowel, or bladder control caused by chronic conditions; attention to ostomies 87 Congenital anomalies of genitourinary system 327 Functional and mechanical disorders of the genitourinary system including bladder outlet obstruction
C1816	Receiver and/or transmitter, neurostimulator (implantable)	Ancillary procedures	174, 250, 292, 346, 361, 440, 527, 660
C1817	Septal defect implant system, intracardiac	Ancillary procedures	Ancillary procedures
C1818	Integrated keratoprosthesis	Ancillary procedures	296 CATARACT
C1819	Surgical tissue localization and excision device (implantable)	Ancillary procedures	Ancillary procedures
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system	Ancillary procedures	174, 250, 292, 346, 361, 440, 527, 660

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C1821	Interspinous process distraction device (implantable)	Ancillary procedures	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system	Ancillary procedures	174, 250, 292, 346, 361, 440, 527, 660
C1830	Powered bone marrow biopsy needle	Ancillary procedures	Ancillary procedures
C1840	Lens, intraocular (telescopic)	Ancillary procedures	Ancillary procedures
C1841	Retinal prosthesis, includes all internal and external components	Ancillary procedures	Ancillary procedures
C1874	Stent, coated/covered, with delivery system	Ancillary procedures	Ancillary procedures
C1875	Stent, coated/covered, without delivery system	Ancillary procedures	Ancillary procedures
C1876	Stent, non-coated/non-covered, with delivery system	Ancillary procedures	Ancillary procedures
C1877	Stent, non-coated/non-covered, without delivery system	Ancillary procedures	Ancillary procedures
C1878	Material for vocal cord medialization, synthetic (implantable)	Ancillary procedures	66 Laryngeal stenosis or paralysis with airway complications 516 Paralysis of vocal cords or larynx
C1880	Vena cava filter	Ancillary procedures	1 Pregnancy 79 Phlebitis and thrombophlebitis, deep 214 Acute pulmonary heart disease and pulmonary emboli 280 Budd-Chiari syndrome, and other venous embolism and thrombosis

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C1881	Dialysis access system (implantable)	Ancillary procedures	59 End stage renal disease 103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS 127 Acute kidney injury 148 ACQUIRED HEMOLYTIC ANEMIAS 222 Disorders of fluid, electrolyte, and acid-base balance 339 Chronic kidney disease
C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable)	Ancillary procedures	39,98,99,111,189,281,347
C1883	Adapter/extension, pacing lead or neurostimulator lead (implantable)	Ancillary procedures	Ancillary procedures
C1884	Embolization protective system	Ancillary procedures	Ancillary procedures
C1885	Catheter, transluminal angioplasty, laser	Ancillary procedures	Ancillary procedures
C1886	Catheter, extravascular tissue ablation, any modality (insertable)	Ancillary procedures	Ancillary procedures
C1887	Catheter, guiding (may include infusion/perfusion capability)	Ancillary procedures	Ancillary procedures
C1888	Catheter, ablation, non-cardiac, endovascular (implantable)	Ancillary procedures	Ancillary procedures
C1889	Implantable/insertable device for device intensive procedure, not otherwise classified	Ancillary procedures	Ancillary procedures
C1891	Infusion pump, non-programmable, permanent (implantable)	Ancillary procedures	Ancillary procedures
C1892	Introducer/sheath, guiding, intracardiac electrophysiological, fixed-curve, peel-away	Ancillary procedures	Ancillary procedures

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C1893	Introducer/sheath, guiding, intracardiac electrophysiological, fixed-curve, other than peel-away	Ancillary procedures	Ancillary procedures
C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser	Ancillary procedures	Ancillary procedures
C1895	Lead, cardioverter-defibrillator, endocardial dual coil (implantable)	Ancillary procedures	69,98,99,111,189,281,347
C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)	Ancillary procedures	69,98,99,111,189,281,347
C1897	Lead, neurostimulator test kit (implantable)	Ancillary procedures	174, 250, 292, 346, 361, 440, 527, 660
C1898	Lead, pacemaker, other than transvenous vdd single pass	Ancillary procedures	69,111,189,281,285,300
C1899	Lead, pacemaker/cardioverter-defibrillator combination (implantable)	Ancillary procedures	69,98,99,111,189,281,347
C1900	Lead, left ventricular coronary venous system	Ancillary procedures	Ancillary procedures
C2613	Lung biopsy plug with delivery system	Ancillary procedures	Ancillary procedures
C2614	Probe, percutaneous lumbar discectomy	Ancillary procedures	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C2615	Sealant, pulmonary, liquid	Ancillary procedures	Ancillary procedures
C2616	Brachytherapy source, non-stranded, yttrium-90, per source	Ancillary procedures	500

Appendix B
C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C5276	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)	Ancillary procedures	57 Burn, full thickness greater than 10% of body surface 72 Burn, partial thickness greater than 30% of body surface or with vital site; full thickness, less than 10% of body surface 181 Conditions involving exposure to natural elements (e.g., lightning strike, heatstroke) 197 Burn, partial thickness without vital site requiring grafting, up to 30% of body surface 379 Chronic ulcer of skin
C5277	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children	Ancillary procedures	57,72,181,197,379
C5278	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)	Ancillary procedures	57,72,181,197,379
C8900	Magnetic resonance angiography with contrast, abdomen	Ancillary procedures	Diagnostic Procedures File

HCPCS code	Code description	Current Placement	Recommended Placement
C8901	Magnetic resonance angiography without contrast, abdomen	Ancillary procedures	Diagnostic Procedures File
C8902	Magnetic resonance angiography without contrast followed by with contrast, abdomen	Ancillary procedures	Diagnostic Procedures File
C8903	Magnetic resonance imaging with contrast, breast; unilateral	Ancillary procedures	Diagnostic Procedures File
C8904	Magnetic resonance imaging without contrast, breast; unilateral	Ancillary procedures	Diagnostic Procedures File
C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral	Ancillary procedures	Diagnostic Procedures File
C8906	Magnetic resonance imaging with contrast, breast; bilateral	Ancillary procedures	Diagnostic Procedures File
C8907	Magnetic resonance imaging without contrast, breast; bilateral	Ancillary procedures	Diagnostic Procedures File
C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral	Ancillary procedures	Diagnostic Procedures File
C8909	Magnetic resonance angiography with contrast, chest (excluding myocardium)	Ancillary procedures	Diagnostic Procedures File
C8910	Magnetic resonance angiography without contrast, chest (excluding myocardium)	Ancillary procedures	Diagnostic Procedures File
C8911	Magnetic resonance angiography without contrast followed by with contrast, chest (excluding myocardium)	Ancillary procedures	Diagnostic Procedures File
C8912	Magnetic resonance angiography with contrast, lower extremity	Ancillary procedures	Diagnostic Procedures File
C8913	Magnetic resonance angiography without contrast, lower extremity	Ancillary procedures	Diagnostic Procedures File

Appendix B
C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C8914	Magnetic resonance angiography without contrast followed by with contrast, lower extremity	Ancillary procedures	Diagnostic Procedures File
C8918	Magnetic resonance angiography with contrast, pelvis	Ancillary procedures	Diagnostic Procedures File
C8919	Magnetic resonance angiography without contrast, pelvis	Ancillary procedures	Diagnostic Procedures File
C8920	Magnetic resonance angiography without contrast followed by with contrast, pelvis	Ancillary procedures	Diagnostic Procedures File
C8921	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; complete	Ancillary procedures	Diagnostic Procedures File
C8922	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; follow-up or limited study	Ancillary procedures	Diagnostic Procedures File
C8923	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode recording, when performed, complete, without spectral or color doppler echocardiography	Ancillary procedures	Diagnostic Procedures File
C8924	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode recording, when performed, follow-up or limited study	Ancillary procedures	Diagnostic Procedures File

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C8925	Transesophageal echocardiography (tee) with contrast, or without contrast followed by with contrast, real time with image documentation (2d) (with or without m-mode recording); including probe placement, image acquisition, interpretation and report	Ancillary procedures	Diagnostic Procedures File
C8926	Transesophageal echocardiography (tee) with contrast, or without contrast followed by with contrast, for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report	Ancillary procedures	Diagnostic Procedures File
C8927	Transesophageal echocardiography (tee) with contrast, or without contrast followed by with contrast, for monitoring purposes, including probe placement, real time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to therapeutic measures on an immediate time basis	Ancillary procedures	Diagnostic Procedures File

Appendix B
C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C8928	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report	Ancillary procedures	Diagnostic Procedures File
C8929	Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode recording, when performed, complete, with spectral doppler echocardiography, and with color flow doppler echocardiography	Ancillary procedures	Diagnostic Procedures File
C8930	Transthoracic echocardiography, with contrast, or without contrast followed by with contrast, real-time with image documentation (2d), includes m-mode recording, when performed, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report; including performance of continuous electrocardiographic monitoring, with physician supervision	Ancillary procedures	Diagnostic Procedures File
C8931	Magnetic resonance angiography with contrast, spinal canal and contents	Ancillary procedures	Diagnostic Procedures File

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C8932	Magnetic resonance angiography without contrast, spinal canal and contents	Ancillary procedures	Diagnostic Procedures File
C8933	Magnetic resonance angiography without contrast followed by with contrast, spinal canal and contents	Ancillary procedures	Diagnostic Procedures File
C8934	Magnetic resonance angiography with contrast, upper extremity	Ancillary procedures	Diagnostic Procedures File
C8935	Magnetic resonance angiography without contrast, upper extremity	Ancillary procedures	Diagnostic Procedures File
C8936	Magnetic resonance angiography without contrast followed by with contrast, upper extremity	Ancillary procedures	Diagnostic Procedures File
C8957	Intravenous infusion for therapy/diagnosis; initiation of prolonged infusion (more than 8 hours), requiring use of portable or implantable pump	Ancillary procedures	Ancillary procedures
C9014	Injection, cerliponase alfa, 1 mg		Ancillary procedures
C9015	Injection, c-1 esterase inhibitor (human), haegarda, 10 units		Ancillary procedures
C9016	Injection, triptorelin extended release, 3.75 mg		Ancillary procedures
C9024	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine		Ancillary procedures
C9028	Injection, inotuzumab ozogamicin, 0.1 mg		Ancillary procedures
C9029	Injection, guselkumab, 1 mg		Ancillary procedures
C9113	Injection, pantoprazole sodium, per vial	Ancillary procedures	Ancillary procedures

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C9132	Prothrombin complex concentrate (human), kcentra, per i.u. of factor ix activity	Ancillary procedures	Ancillary procedures
C9248	Injection, clevidipine butyrate, 1 mg	Ancillary procedures	Ancillary procedures
C9250	Human plasma fibrin sealant, vapor-heated, solvent-detergent (artiss), 2 ml	Ancillary procedures	Ancillary procedures
C9254	Injection, lacosamide, 1 mg	Ancillary procedures	Ancillary procedures
C9257	Injection, bevacizumab, 0.25 mg	Ancillary procedures	Ancillary procedures
C9275	Injection, hexaminolevulinate hydrochloride, 100 mg, per study dose	Ancillary procedures	Ancillary procedures
C9285	Lidocaine 70 mg/tetracaine 70 mg, per patch	Ancillary procedures	Ancillary procedures
C9290	Injection, bupivacaine liposome, 1 mg	Ancillary procedures	Ancillary procedures
C9293	Injection, glucarpidase, 10 units	Ancillary procedures	Ancillary procedures
C9352	Microporous collagen implantable tube (neuragen nerve guide), per centimeter length	Ancillary procedures	Ancillary procedures
C9353	Microporous collagen implantable slit tube (neurawrap nerve protector), per centimeter length	Ancillary procedures	Ancillary procedures
C9354	Acellular pericardial tissue matrix of non-human origin (veritas), per square centimeter	Ancillary procedures	Ancillary procedures
C9355	Collagen nerve cuff (neuromatrix), per 0.5 centimeter length	Ancillary procedures	Ancillary procedures

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C9356	Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (tenoglide tendon protector sheet), per square centimeter	Ancillary procedures	Ancillary procedures
C9358	Dermal substitute, native, non-denatured collagen, fetal bovine origin (surgimend collagen matrix), per 0.5 square centimeters	Ancillary procedures	Ancillary procedures
C9359	Porous purified collagen matrix bone void filler (integra mozaik osteoconductive scaffold putty, integra os osteoconductive scaffold putty), per 0.5 cc	Ancillary procedures	Ancillary procedures
C9360	Dermal substitute, native, non-denatured collagen, neonatal bovine origin (surgimend collagen matrix), per 0.5 square centimeters	Ancillary procedures	Ancillary procedures
C9361	Collagen matrix nerve wrap (neuromend collagen nerve wrap), per 0.5 centimeter length	Ancillary procedures	Ancillary procedures
C9362	Porous purified collagen matrix bone void filler (integra mozaik osteoconductive scaffold strip), per 0.5 cc	Ancillary procedures	Ancillary procedures
C9363	Skin substitute, integra meshed bilayer wound matrix, per square centimeter	Ancillary procedures	Ancillary procedures
C9364	Porcine implant, permacol, per square centimeter	Ancillary procedures	Ancillary procedures
C9399	Unclassified drugs or biologicals	Ancillary procedures	Ancillary procedures
C9447	Injection, phenylephrine and ketorolac, 4 ml vial		Ancillary procedures

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C9460	Injection, cangrelor, 1 mg	Ancillary procedures	Ancillary procedures
C9482	Injection, sotalol hydrochloride, 1 mg	Ancillary procedures	Ancillary procedures
C9488	Injection, conivaptan hydrochloride, 1 mg	New (added) Codes	Ancillary procedures
C9492	Injection, durvalumab, 10 mg	New (added) Codes	Ancillary procedures
C9493	Injection, edaravone, 1 mg	New (added) Codes	Ancillary procedures
C9497	Loxapine, inhalation powder, 10 mg	Ancillary procedures	Ancillary procedures
C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	Ancillary procedures	Tabled
C9601	Percutaneous transcatheter placement of drug-eluting intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	Ancillary procedures	Tabled
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	Ancillary procedures	Tabled

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C9603	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	Ancillary procedures	Tabled
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel	Ancillary procedures	Tabled
C9605	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)	Ancillary procedures	Tabled

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C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C9606	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel	Ancillary procedures	Tabled
C9607	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel	Ancillary procedures	Tabled
C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)	Ancillary procedures	Tabled
C9725	Placement of endorectal intracavitary applicator for high intensity brachytherapy	Ancillary procedures	All radiation therapy lines

Appendix B

C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C9726	Placement and removal (if performed) of applicator into breast for intraoperative radiation therapy, add-on to primary breast procedure	Ancillary procedures	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C9727	Insertion of implants into the soft palate; minimum of three implants	Ancillary procedures	64 Congenital anomalies of upper alimentary tract, excluding tongue 287 Cancer of oral cavity, pharynx, nose and larynx 300 Cleft palate and/or cleft lip 321 Dermatologic hemangiomas, complicated 625 Benign neoplasms of skin and other soft tissues
C9728	Placement of interstitial device(s) for radiation therapy/surgery guidance (e.g., fiducial markers, dosimeter), for other than the following sites (any approach): abdomen, pelvis, prostate, retroperitoneum, thorax, single or multiple	Ancillary procedures	Ancillary procedures
C9733	Non-ophthalmic fluorescent vascular angiography	Excluded File (travel vaccines etc.)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance	Ancillary procedures	
C9738	Adjunctive blue light cystoscopy with fluorescent imaging agent (list separately in addition to code for primary procedure)		Diagnostic Procedures File
C9739	Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants	Excluded File (travel vaccines etc.)	327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION

Appendix B

C Code Recommended Placement - May 2018

HCPCS code	Code description	Current Placement	Recommended Placement
C9740	Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants	Excluded File (travel vaccines etc.)	327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
C9741	Right heart catheterization with implantation of wireless pressure sensor in the pulmonary artery, including any type of measurement, angiography, imaging supervision, interpretation, and report	Diagnostic procedures	
C9744	Ultrasound, abdominal, with contrast	Ancillary procedures	Diagnostic Procedure File
C9745	Nasal endoscopy, surgical; balloon dilation of eustachian tube		Tabled
C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed		660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C9747	Ablation of prostate, transrectal, high intensity focused ultrasound (hifu), including imaging guidance		660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C9748	Transurethral destruction of prostate tissue; by radiofrequency water vapor (steam) thermal therapy		327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
C9898	Radiolabeled product provided during a hospital inpatient stay	Ancillary procedures	Ancillary procedures
C9899	Implanted prosthetic device, payable only for inpatients who do not have inpatient coverage	Ancillary procedures	Ancillary procedures

Appendix C

New Guideline Notes

STATEMENT OF INTENT XXX, TREATMENT OF CHRONIC PAIN

It is the intent of the Commission that covered chronic pain conditions be treated in a multidisciplinary fashion, with a focus on active therapies, improving function, and demedicalizing the condition. Care should include education on sleep, nutrition, stress reduction, mood, exercise, and knowledge of pain. All providers seeing chronic pain patients should be trained in pain science (e.g. a contemporary understanding of the central and peripheral nervous system in chronic pain), motivational interviewing, culturally sensitive care, and trauma-informed care. Care should be provided as outlined in the Oregon Pain Management Commission pain management module: http://www.oregon.gov/oha/HPA/CSI-PMC/Pages/module.aspx.

GUIDELINE NOTE XXX, VITAL SITE DEFINITION FOR BURN LINES

Lines 72, 197

A burn to a "vital site" is defined as a burn involving the face, eyes, ears, hands, feet, or perineum that may result in functional impairment.

DRAFT

Section 2.0

Staff Report

Errata
August 2018

1) In guideline note 141 LARYNGEAL STENOSIS OR PARALYSIS, DYSPHONIA, a reference to line 66 was corrected (previously, it referenced line 70, an incorrect line). The corrected guideline reads:

GUIDELINE NOTE 141, LARYNGEAL STENOSIS OR PARALYSIS; DYSPHONIA

Lines 66,516

Laryngeal and vocal cord paralysis (ICD-10-CM J38.01 and J38.02) are included on Line 66 if associated with recurrent aspiration pneumonia (unilateral or bilateral) or airway obstruction (bilateral). Vocal cord paralysis is included on ~~Line 70~~Line 66 for children 18 and under with dysphonia or dysphagia persisting for at least twelve months. Treatment of hoarseness and dysphonia in adults are included only on Line 516. Laryngeal stenosis (ICD-10-CM J38.6) is included on Line 66 only if it causes airway obstruction; otherwise it is included on Line 516.

2) During the review of serum allergy testing in November, 2017, the code used to represent "Allergen specific IgE; qualitative, multiallergen screen (eg, disk, sponge, card)" was mistakenly listed at 86006 when it is in fact 86005. The placement of 86005 is still line 660. The coding on line 660 and the related GN173 entries were corrected as shown below.

GUIDELINE NOTE 173, TREATMENTS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS; UNPROVEN TREATMENTS

The following treatments are prioritized on Line 660, CONDITIONS FOR WHICH CERTAIN TREATMENTS HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS; UNPROVEN TREATMENTS for the conditions listed here:

CPT/HCPCS code	INTERVENTION	Rationale	Date of last Review
86005	Allergen specific IgE qualitative, multiallergen screen	~~No clinically important benefit~~ Harms outweigh benefits	November, 2017
~~86006~~	~~Allergen specific IgE, multiallergen screen~~	~~Harms outweigh benefits~~	~~November, 2017~~

3) Guideline Note 90 contains a CPT code that is no longer valid and has been replaced with an updated code. CPT 97127 is "Therapeutic interventions that focus on cognitive function (eg, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (eg, managing time or schedules, initiating, organizing and sequencing tasks), direct (one-on-one) patient contact."

GUIDELINE NOTE 90, COGNITIVE REHABILITATION

Lines 92,178,196,202,285,317,345,377

Once physical stabilization from acute brain injury has occurred, as determined by an attending physician, cognitive rehabilitation (CPT 97127 ~~97532~~) is included on this line for a three-month period. This three-month period does not have to be initiated immediately following stabilization from the injury. For up to 3 years following the acute event, an additional 6 visits of

cognitive rehabilitation are included on this line each time the patient has a major change in status resulting in a significantly improved prognosis. Cognitive rehabilitation is not included on this line for those in a vegetative state or for those who are unable or unwilling to participate in therapy.

Section 3.0

Consent Agenda-

Straightforward Items

Consent Agenda Issues—August 2018

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
Z45.42	Encounter for adjustment and management of neuropacemaker (brain) (peripheral nerve) (spinal cord)	250 PARKINSON'S DISEASE	Neurostimulators were added to the Parksinson's line in January 2018. However, one of the management diagnosis codes was not added in error.	Add ICD-10 Z45.42 to line 250
N43.4	Spermatocele of epididymis	327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION 542 HYDROCELE	The ICD-10 urology reviewers suggested placing the N43.4 series of codes on line 542 HYDROCELE as they do not require treatment. It appears that this code series was never removed from line 327 in error. They currently also appear on line 542	Remove ICD-10 N43.4 series from line 327
G0270-G0271	Medical nutrition therapy, reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition, or treatment regimen	1 PREGNANCY 8 TYPE 1 DIABETES MELLITUS 27 TYPE 2 DIABETES MELLITUS 320 OBESITY IN ADULTS AND CHILDREN; OVERWEIGHT STATUS IN ADULTS WITH CARDIOVASCULAR RISK FACTORS	G0270-G027 currently appear on lines 1,8,27. They should also appear on line 320.	Add G0270-G0271 to line 320
H0023	Behavioral health outreach service (planned approach to reach a targeted population)	4 SUBSTANCE USE DISORDER	H0023 was added to all mental health lines in 2009 but left off line 4 is error.	Add H0023 to line 4
N18.5	Chronic kidney disease, stage 5	59 END STAGE RENAL DISEASE 339 CHRONIC KIDNEY DISEASE	HSD requested that N18.5 be paired with a variety of dialysis management codes. Stage 5 kidney disease is another name for end stage renal disease. N18.5 is currently on line 339, but should be moved to line 59 where it will pair with all needed CPT codes.	Add N18.5 to line 59 Remove N18.5 from line 339

Consent Agenda Issues—August 2018

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
50389 50432 50435 50695	Removal of nephrostomy tube, requiring fluoroscopic guidance (eg, with concurrent indwelling ureteral stent) Placement of nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation Exchange nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation; new access, with separate nephrostomy catheter	25 VESICOURETERAL REFLUX	HSD requested pairing of 50389, 50432, 50435 and 50695 with ICD-10 N13.8 (Other obstructive and reflux uropathy). 50432 and 50435 are on lines 180,231,275,352. 50389 is on lines 180,231,352. 50695 is on lines 47,49,80,180,271,352.	Add 50389, 50432, 50435 and 50695 to line 25

Consent Agenda Issues—August 2018

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
11004 11006 11042 13131-13133 15004-15005 55150	Debridement of skin, subcutaneous tissue, muscle and fascia for necrotizing soft tissue infection; external genitalia and perineum Debridement of skin, subcutaneous tissue, muscle and fascia for necrotizing soft tissue infection; external genitalia, perineum and abdominal wall, with or without fascial closure Debridement, subcutaneous tissue (includes epidermis and dermis, if performed); first 20 sq cm or less Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits Resection of scrotum	47 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS	HSD requested that 11004 and 11006, 11042, 13131-1313, 15004-15005, 55150 pair with ICD 10 N49.3 (Fournier gangrene). These CPT codes are on multiple lines.	Add 11004, 11006, 11042, 13131-1313, 15004-15005 and 55150 to line 47
57420-57421	Colposcopy of the entire vagina, with cervix if present;	25 DYSPLASIA OF CERVIX AND CERVICAL CARCINOMA IN SITU, CERVICAL CONDYLOMA	HSD requested that vaginal dysplasia pair with vaginal colposcopy. The vaginal dysplasia ICD10 codes are on line 25.	Add 57420-57421 to line 25

Consent Agenda Issues—August 2018

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
49020 49322 49406- 49407	Drainage of peritoneal abscess or localized peritonitis, exclusive of appendiceal abscess, open Laparoscopy, surgical; with aspiration of cavity or cyst (eg, ovarian cyst) Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); peritoneal or retroperitoneal	51 ACUTE PELVIC INFLAMMATORY DISEASE	HSD requested that 49020, 49322 and 49406 pair with acute female pelvic peritonitis. These codes are all on several lines.	Add 49020, 49322 and 49406-49407 to line 51

Breast Cancer Genome Expression Profiling
August 2018 Corrections

At the May 2018 meetings, VBBS and HERC adopted coding and guideline note changes regarding breast cancer gene expression profiling. On further review, HERC staff have found several errors and corrections.

HERC Staff Recommendations:

1) Revise Guideline Note 148 as shown below
    a. Minor edits to add line 660 and to remove "multiple molecular testing" and add "tissue of origin testing" in the first paragraph

GUIDELINE NOTE 148, BIOMARKER TESTS OF CANCER TISSUE
Lines 157,184,191,230,263,271,329,660

The use of ~~multiple molecular testing~~ tissue of origin testing ~~to select targeted cancer therapy~~ (e.g. CPT 81504) is included on line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

For early stage breast cancer, the following breast cancer genome profile tests are included on Line 191 when the listed criteria are met. One test per primary breast cancer is covered when the patient is willing to use the test results in a shared decision-making process regarding adjuvant chemotherapy. Lymph nodes with micrometastases less than 2 mm in size are considered node negative.

- Oncotype DX Breast Recurrence Score (CPT 81519) for breast tumors that are estrogen receptor positive, HER2 negative, and either lymph node negative, or lymph node positive with 1-3 involved nodes.
- EndoPredict (using CPT 81599) and Prosigna (CPT 81520 or PLA 0008M) for breast tumors that are estrogen receptor positive, HER2 negative, and lymph node negative.
- MammaPrint (using CPT 81521 or HCPCS S3854) for breast tumors that are estrogen receptor or progesterone receptor positive, HER2 negative, lymph node negative, and only in those cases categorized as high clinical risk.

EndoPredict, Prosigna, and MammaPrint are not included on Line 191 for early stage breast cancer with involved axillary lymph nodes. Oncotype DX Breast Recurrence Score is not included on Line 191 for breast cancer involving four or more axillary lymph nodes or more extensive metastatic disease.

Oncotype DX Breast DCIS Score (CPT 81479) and Breast Cancer Index (may use CPT 81479, 81599, 84999, S3854) are included on Line 660.

For melanoma, BRAF gene mutation testing (CPT 81210) is included on Line 230 MALIGNANT MELANOMA OF SKIN.

For lung cancer, epidermal growth factor receptor (EGFR) gene mutation testing (CPT 81235) is included on Line 263 CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS only for non-small cell lung cancer. KRAS gene mutation testing (CPT 81275) is not included on Line 263.

Breast Cancer Genome Expression Profiling
August 2018 Corrections

For colorectal cancer, KRAS gene mutation testing (CPT 81275) is included on Line 157. BRAF (CPT 81210) and Oncotype DX (81525) are not included on Line 157. Microsatellite instability (MSI) is included on line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

For bladder cancer, Urovysion (88120, 88121) testing is included on line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

For prostate cancer, Oncotype DX Genomic Prostate Score (81479), Prolaris Score Assay (81541), and Decipher RP (81479) are included on Line 660.

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx.

2) Modify GN173 as shown below
   a. The new entries are shown first. There was significant reorganization to make the table more readable and usable. The entries for breast and prostate cancer tests billed with dump codes were put into separate rows so that the correct coverage guidance can be referenced for each. The cost-test relationship was corrected in some instances. An entry for 18301 was added (this code was missed on the May 2018 review)
   b. The entries accepted in May, 2018 are shown second. These entries would be deleted.

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

Line 660

The following Interventions are prioritized on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
Breast Cancer Gene Expression tests billed with nonspecific codes (e.g. 81479, 81599, 84999, S3854)	• Mammostrat • Oncotype DX Breast DCIS Score • Breast Cancer Index • IHC4	Unproven Intervention	May, 2018 (breast cancer) Coverage Guidance Blog (Breast)
Prostate Cancer Gene Expression tests billed with nonspecific codes (e.g. 81479, 81599, 84999, S3854)	• Oncotype DX Genomic Prostate Score • Decipher RP for prostate cancer	Unproven Intervention	January, 2018 (prostate) Coverage Guidance Blog (Prostate)

Breast Cancer Genome Expression Profiling
August 2018 Corrections

81301	Microsatellite instability (MSI) for colorectal cancer	Unproven Intervention	August, 2015 Coverage Guidance Blog
81504	Oncology (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores)	Unproven Intervention	August, 2015
81525	Oncotype DX for colon cancer	Insufficient evidence of effectiveness	November, 2015
88120, 88121	Urovysion for bladder cancer	-Insufficient evidence of effectiveness	

To be deleted and replaced with above:

Procedure Code	Intervention Description	Rationale	Last Review
~~81479~~	~~• Oncotype DX Breast DCIS Score~~ ~~• Breast Cancer Index~~ ~~• Oncotype DX Genomic Prostate Score~~ ~~• Decipher RP for prostate cancer~~	~~Unproven Intervention~~	~~May, 2018 (breast)~~ ~~Coverage Guidance Blog (Breast)~~ ~~January, 2018 (prostate)~~
~~81504~~	~~Biomarker tests for tumor tissue:~~ ~~• Mammostrat and ImmunoHistoCHemistry 4 (IHC4) for breast cancer~~ ~~• Microsatellite instability (MSI) for colorectal cancer~~ ~~• Urovysion for bladder cancer (88120, 88121)~~ ~~• Multiple molecular testing to select targeted cancer therapy~~	~~Insufficient evidence of effectiveness. More costly than equally effective therapies for this condition~~	~~August, 2015~~ ~~Coverage Guidance Blog~~ ~~May, 2018~~ ~~Coverage Guidance Blog (Breast)~~

Section 4.0

Taskforce report

BHAP Recommendations to the August 2018 VBBS/HERC Meetings

The Behavioral Health Advisory Panel (BHAP) met on June 25, 2018, and made various recommendations to VBBS/HERC. The recommendations requiring HERC approval are listed below.

1) 2019 ICD-10 behavioral health code placement: the BHAP recommendations are included in the ICD-10 review materials for discussion later in this meeting. All issues were considered straightforward other than the placement of **Z13.39** (Encounter for screening examination for other mental health and behavioral disorders) and **F53.0** (postpartum depression), which are included in the issues document.

2) Add HCPCS H2014 (Skills training and development, per 15 minutes) to line 121 ABUSE AND NEGLECT
    a. Several providers have requested that H2014 pair with the ICD-10 Z69 series (Encounter for mental health services for victim of abuse) which is on line 121. H2014 is on 30+ lines on the Prioritized List.

3) F39: see separate issues document

4) Inpatient and ER code clean-up for various behavioral health lines:

Line	**BHAP recommendation**
204 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE	Add ER CPT codes Remove inpatient CPT codes (only include on line 7 MAJOR DEPRESSION, RECURRENT; MAJOR DEPRESSION, SINGLE EPISODE, SEVERE)
290 ACUTE STRESS DISORDER	Add ER CPT codes
391 PANIC DISORDER; AGORAPHOBIA	Add ER CPT codes
448 REACTIVE ATTACHMENT DISORDER OF INFANCY OR EARLY CHILDHOOD	Remove inpatient CPT codes
468 ENCOPRESIS NOT DUE TO A PHYSIOLOGICAL CONDITION	Remove inpatient CPT codes
521 SEXUAL DYSFUNCTION	Remove inpatient and ER CPT codes

Note: BHAP requested additional information on utilization of inpatient CPT codes for line 448. HERC staff queried the claims database, and only 4 patients were found in the past year (FFS and CCO) who had a diagnosis on line 448 as their primary diagnosis paired with inpatient CPT codes.

6. Add CPT 96118 (Neuropsychological testing (eg, Halstead-Reitan Neuropsychological Battery, Wechsler Memory Scales and Wisconsin Card Sorting Test), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report) to line 173 POSTTRAUMATIC STRESS DISORDER with the guideline shown below.

GUIDELINE NOTE XXX NEUROPSYCHOLOGICAL TESTING FOR PTSD
Line 173
Neuropsychological testing is included on this line only when there is question of cognitive deficit or impairment and such testing is required to assist in making the correct diagnosis.

7. Add CPT 96119 (Neuropsychological testing… administered by technician, per hour of technician time, face-to-face) and 96120 (Neuropsychological testing (eg, Wisconsin Card Sorting Test), administered by a computer, with qualified health care professional interpretation and report) to any line with 96118 (Neuropsychological testing (eg, Halstead-Reitan Neuropsychological Battery, Wechsler Memory Scales and Wisconsin Card Sorting Test), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report) –see list below– and remove from line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS and remove entry to GN173. BHAP felt that technician or computer testing was a more cost-effective use of resources during a neuropsychological evaluation than requiring a psychologist or physician to perform these tests.

a. 92 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
b. 173 POSTTRAUMATIC STRESS DISORDER (pending decision on #6 above)
c. 193 AUTISM SPECTRUM DISORDERS
d. 202 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS

Unspecified Mood Disorder

Question: Should restrictions be placed on the utilization of ICD-10 F39 (Unspecified mood disorder)?

Question source: Lea Forsman; OHA behavioral health team

Issue: Until 2015, F39 (Unspecified mood [affective] disorder) had a guideline note restricting use to children 18 years and under, with pairings allowed only with a few procedure codes (see the historical GN28 below). This guideline was removed in 2015 due to concerns that under the ACA, such restrictions would be considered age discrimination without a medical justification. Additionally, HERC staff felt that mental health parity rules would not allow restriction of use of the F39 code to only a few services. F39 is currently on line 204 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE.

Historical guideline removed 2016

GUIDELINE NOTE 28, MOOD DISORDERS IN CHILDREN AGE EIGHTEEN AND UNDER

Line 207

The use of ICD-10-CM code F39 Unspecified Mood [Affective] Disorder is appropriate only for children 18 years old and under who have functional impairment caused by significant difficulty with emotional regulation.

Use of ICD-10-CM F39 is limited to pairings with the following procedure codes:

- Assessment and Screening: 90791, 90792, H0002, H0031, H0032, T1023
- Family interventions and supports: 90832-90838, 90846, 90847, 90849, 90887, H0038, H0045, H2021, H2022, H2027, S5151, S9125, T1005
- Individual Counseling and Therapy: 90785, 90832-90838, 99201-99215, H0004
- Group therapy: 90785, 90832-90838, 90853, 99201-99215, H2032
- Medication management: 99201-99215
- Case Management: 90882, T1016
- Interpreter Service: T1013

The OHA behavioral health team has seen a significant increase in the use of F39 since the removal of this guideline, paired with a variety of testing and treatment codes. They are concerned that it is being inappropriately used when more specific diagnoses can be reached. The behavioral health team is requesting the consideration of the addition of a guideline to govern the use of F39, limiting use of this code to:

- When a person is in the diagnostic phase of a workup
- When a person is seen in an urgent/emergency care setting where the focus is on directing the person to the correct provider
- For children who are younger and those who are non-verbal
- In cases where it is not possible to give a more specific diagnosis due to cultural/stigma considerations

BHAP discussed this topic at their June 2018 meeting. It was noted that this code is often used when a patient is developing a disorder, but has not had enough symptoms to meet diagnostic criteria for any specific disorder. Bradshaw, however, noted that he sees this diagnosis used for years on end and no more specific diagnosis is ever made. There was agreement that this diagnosis could be overused.

Unspecified Mood Disorder

Savicki recalled that this diagnosis had a guideline to initially restrict to kids due to not wanting to give diagnosis to kids like bipolar disorder or other disorder which might lead to overtreatment, etc. Cobb reflected that overuse might not be a problem if it reflects more people getting into initial treatment.

BHAP requested that HERC staff reach out to the OHA team to get additional information about the overutilization they reported. Is the overuse just more initial diagnoses of more patients, or is it being used for a long time for single patients, which would be sloppy coding. Staff reached out to the OHA behavioral health team and did a utilization review (below).

BHAP members were divided on the need for a guideline for F39. In general, members were supportive of a guideline; however, some felt that there should be somewhat broad leeway for clinicians to see a patient multiple times to determine an exact diagnosis. Rural areas may have more need for this code due to a relative lack of behavioral health workforce to assist in making a definitive diagnosis.

Utilization data:
2017 data, FFS and CCO
Of 4220 individuals. 1 had 106 unique dates of service (DOS). 14 had >30; 142 had >10, 358 had >5, 967 had 3 or more. 2472 had 1, 781 had 2. Therefore 77% of patients had this diagnosis used 1 or 2 times
The majority of claims were for outpatient clinic visits. Psychotherapy, lab tests, ER visits, and inpatient treatment were also billed with this code.

BHAP/HERC staff recommendation:

1) Consider adopting a new guideline for line 204 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE

GUIDELINE NOTE XXX UNSPECIFIED MOOD DISORDER
Line 204
ICD-10 F39 (Unspecified mood [affective] disorder) is included on line 204 only when

1) A person is in the diagnostic phase of a workup, OR
2) A person is seen in an urgent/emergency care setting where the focus is on directing the person to the correct provider, OR
3) Used for services for pre-verbal children or patients who are non-verbal, OR
4) It is not possible to give a more specific diagnosis due to cultural/stigma considerations.

The Chronic Pain Taskforce report to the Value Based Benefits Subcommittee

August 9, 2018

Oregon Health Authority

Chronic Pain Task Force report

- No decisions to be made on this report today
- Next CPTF meeting September 20, 2018
- Any implementation would begin January 1, 2020

Chronic Pain Taskforce

- Taskforce membership
  - Pain specialists
  - Chiropractor
  - Acupuncturist
  - Physical therapist
  - Primary care physician
  - Medicaid managed care plan medical director
  - Psychologist
  - Addictions specialist
  - Pharmacist
  - Patient/advocate
- Many also on Oregon Pain Management Commission
- Series of public meetings held in 2017-2018
- Evidence review
  - Literature reviews, expert guidelines, expert input

Conditions (ICD-10-CM):

(Caveat: *ICD-10-CM nomenclature does not align with current understanding of pain conditions)*

ICD-10-CM	Description
G89.21	Chronic pain due to trauma
G89.28	Other chronic postprocedural pain
G89.4	Chronic pain syndrome
G89.9	Other chronic pain
M79.7	Fibromyalgia

*No change to other chronic pain diagnoses on List

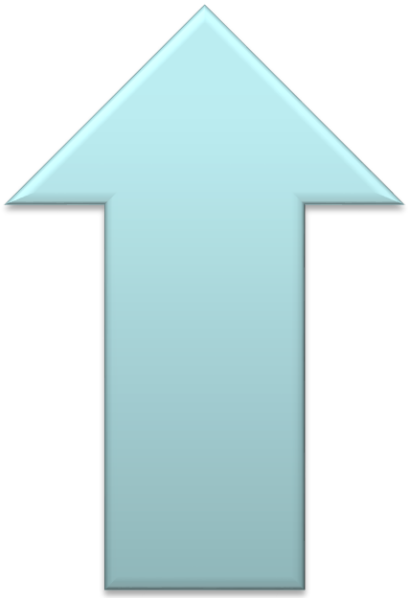
Current Coverage

- Per prioritization:
  - No coverage without comorbid condition
- In reality:
  - Non-specialty office visits
  - Non-PA'd medications
    - Primarily opioids

Non-Pharmacologic Treatments

Increased Coverage:

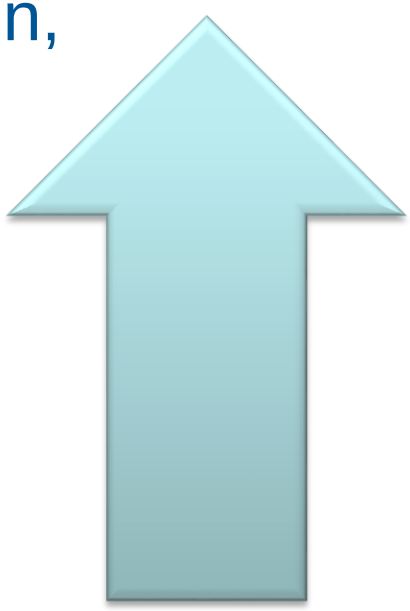
- Cognitive behavioral therapy
- Acupuncture
- Health and behavior assessment
- Physical/Occupational therapy
- Pain education
- Yoga, mindfulness based stress reduction, massage, supervised exercise, intensive interdisciplinary rehab (if available)



Oregon Health Authority

Non-Opioid Medications

- Tylenol, NSAIDS, duloxetine, pregabalin, antidepressants, etc.
  - FDA approved for chronic, non-neuropathic pain
  - Require active therapy (including psychotherapy)
  - Re-evaluate every 90 days for continued functional benefit unless efficacy established



General Questions for Feedback to the CPTF

- Overall comments, concerns, and suggestions
- Regarding the proposed new line:
  - Should fibromyalgia be included?
  - Any other diagnoses or procedures that should be included or removed?
    - G89.0 (central pain syndrome), others?
- Regarding the proposed new guideline:
  - How to clarify that not all chronic pain conditions are included (e.g. rheumatoid arthritis, cancer pain, etc.)
  - Other concerns with proposed coverage?

Opioid Guideline

- Proposed changes to the opioid guideline
  - Same restrictions as back pain
  - Limited prescribing up to 90 days after initial injury/surgery
    - Should this be included as all conditions are chronic by definition?
  - Removal of “flare” for these conditions as well as back pain

Oregon Health Authority

Guideline Note 60: Opioid Medications

During the first 6 weeks after injury, ~~flare~~, surgery:

-Prescription limited to 7 days, and
-Short acting opioids only, and
-First line pharmacologic therapies are ineffective, and
-Treatment plan includes exercise, and
-Opioid risk assessment

Opioid use after 6 weeks, up to 90 days:

-Functional assessment – 30% improvement,
-Spinal manipulation, physical therapy, yoga, or acupuncture,
-Opioid Risk mitigation:
  -PDMP
  -Screen for opioid use disorder
  -Urine drug test
-Prescriptions limited to 7 days and short acting only

Opioids after 90 days:

- Not Covered without new injury, ~~flare~~, surgery

Oregon Health Authority

Opioids/Taper

- Evidence for opioids and chronic pain
  - Good evidence of harms.
  - Very low quality evidence of no benefit
  - Better evidence of no benefit for fibromyalgia.
  - Very limited evidence of good outcomes from taper programs
- Large numbers of patient comments opposing taper requirements, reporting benefits of opioids
- Implementation concerns

Summary of Written Public Testimony

- Alternative therapies are not adequate or do not work
- Benefits of long-term opioid therapy:
  - improved function, ability to work or care for self/family
- Harms of involuntary taper from long-term opioid therapy:
  - reduced function and ability to work
  - increased pain
  - increased risk of suicide
  - increased use of illicit opioids/drugs
- Patients on chronic opioids are not addicts
- The proposed taper policy is an overreaction to a few bad patients/doctors/illegal drug users
- Stories of bad experiences with forced tapers
- Opioid tapers should be decided between doctors and patients, not payers
- This discriminates against low-income patients/OHP patients

Feedback & Questions

Oregon Health Authority

Chronic Pain Taskforce
Report to the Health Evidence Review Commission

The Chronic Pain Taskforce met a total of 5 times, and has created a proposal for HERC consideration for the creation of a new line for chronic pain conditions as part of the 2020 Biennial Review of the Prioritized List. The Taskforce has reviewed a significant amount of evidence regarding effective treatments for chronic pain. The Taskforce has concluded that effective treatments include:

1) Pain education, which should include but not be limited to sleep, nutrition, stress reduction/mood, exercise, and knowledge of pain as a biopsychosocial phenomenon
2) Cognitive behavioral therapy (CBT)/acceptance and commitment therapy (ACT)
3) Yoga, mindfulness training, massage, supervised exercise therapy (land-based and aquatic), intensive interdisciplinary rehabilitation
4) Physical therapy and acupuncture
5) Certain non-opioid medications

The Taskforce is proposing adding a new line to the Prioritized List to contain diagnoses including chronic pain syndrome and fibromyalgia. The treatments include office visits, ER visits, and the services noted above. A new guideline is proposed to accompany this line. The Taskforce feels that this guideline should be separate from the back line guideline as there are significant differences between the two. The Taskforce scored this line in the funded region of the Prioritized List. To accompany the changes needed for this new line, the Taskforce suggested minor changes to the back line guideline and acupuncture guideline.

The Taskforce strongly felt that fibromyalgia should be included on the new line for certain chronic pain conditions. An **AHRQ 2017 draft review, which was made final in June, 2018 (**https://effectivehealthcare.ahrq.gov/sites/default/files/cer-209-evidence-summary-non-pharma-chronic-pain.pdf**)** found that for fibromyalgia:

1) Exercise had a small effect on function compared to no treatment in the short and intermediate term, but not long term (SOE low to moderate) and a small effect on pain in the short term (SOE moderate)
2) CBT was found to have improvement in short-term pain compared to no treatment (SOE low) and improvement in function compared to control (SOE: low for short term and intermediate term).
3) Acupuncture improved function in the short and intermediate term (SOE: moderate) but had no clear impact on pain
4) Multidisciplinary treatment was associated with a slight improvement in function in the short, intermediate, and long term (SOE: low for short, intermediate and long term). Multidisciplinary treatment was associated with a slight improvement in pain at intermediate term, but not short or long term (SOE: low for short, intermediate and long term).
5) Mindfulness based stress reduction therapy had no clear benefit on function or pain

As the majority of treatments proposed for the new line for certain chronic pain conditions showed some benefit for fibromyalgia, the CPTF felt that there was support for inclusion on the new line.

The Taskforce also reviewed the opioid guideline for back and neck conditions. The VBBS had previous directed HERC staff to review the evidence for opioid taper length. This evidence review is included below. The summary of the evidence review is that there is no agreed upon evidence-based opioid taper length. The Taskforce strongly feels that the taper length included in the guideline should be “no

more than 1 year," which would allow faster taper for patients who are able, and slower tapers for those patients who require more time. The Taskforce also recommends removing language allowing short term opioids for "flares of chronic conditions" as evidence published in the last few years has shown that it is not helpful and likely is harmful to increase or start opioids for pain flares. Rather, patients should be directed to other, more active therapies, for dealing with flares of pain.

Opioid tapering evidence

1) **MED 2017**, Tapering or Discontinuing Opioid Use among Patients with Chronic Noncancer Pain
    a. Data do not currently support assessment of comparative effectiveness of the different models of care or opioid tapering protocols
    b. Based on clinical practice guidelines, there is no one-size-fits-all method for tapering opioid doses, and providers should work with patients to develop an individualized tapering plan that addresses their specific needs.
    c. Most patients experience fewer withdrawal symptoms with a slow taper that reduces doses over months or years.
    d. Guidelines varied on their recommendations for how much to reduce the dose and how often (e.g., weekly, biweekly, or monthly)
2) Canadian Agency for Drugs and Technology in Health **CADTH 2017**, evidence summary for reduction or discontinuation of opioids https://www.cadth.ca/sites/default/files/pdf/htis/2017/RB1078%20-%20Opioid%20Tapering%20Final.pdf
    a. N=6 evidence based guidelines
    b. General recommendation based on 3 guidelines: It is recommended to treat patients with individualized treatment plans that suit their specific needs.
    c. The only specific tapering recommendation found was the Agency for Healthcare Research and Quality guideline, which recommended a gradual taper of approximately 10% per week. This recommendation was based on expert opinion.
3) **Frank 2017**, systematic review of patient outcomes with opioid tapers (http://annals.org/aim/fullarticle/2643842/patient-outcomes-dose-reduction-discontinuation-long-term-opioid-therapy-systematic)
    a. N=67 studies (11 RCTs, 56 observational studies)
        i. Study quality was good for 3 studies, fair for 13 studies, and poor for 51 studies.
    b. overall quality of evidence was very low.
    c. Among 40 studies examining patient outcomes after dose reduction (very low overall quality of evidence), improvement was reported in pain severity (8 of 8 fair-quality studies), function (5 of 5 fair-quality studies), and quality of life (3 of 3 fair-quality studies).
    d. **Conclusion:** Very low quality evidence suggests that several types of interventions may be effective to reduce or discontinue LTOT and that pain, function, and quality of life may improve with opioid dose reduction.

Chronic Pain Taskforce
Report to the Health Evidence Review Commission

HERC staff request for VBBS/HERC feedback on CPTF proposal:

This feedback will be discussed at the September 20, 2018 CPTF meeting

1) Overall comments, concerns, and suggestions
2) Regarding the proposed new line:
    a. Should fibromyalgia be included?
        i. If so, how should the current fibromyalgia guideline be incorporated into the chronic pain and/or opioid guideline?

GUIDELINE NOTE 135, FIBROMYALGIA

Line 528

Fibromyalgia (ICD-10-CM M79.7) treatment should consist of a multi-modal approach, which should include two of more of the following:

A) medications other than opioids
B) exercise advice/programs
C) cognitive behavioral therapy

Care should be provided in the primary care setting. Referrals to specialists are generally not required. Use of opioids should be avoided due to evidence of harm in this condition.

    b. Any other diagnoses or procedures that should be included or removed?
        i. G89.0 (central pain syndrome), others?
3) Regarding the proposed new guideline:
    a. Should the CPTF consider wording to be changed in the guideline to indicate that only chronic pain conditions that have ICD-10 diagnosis codes on the new line are governed by this guideline?
        i. Possible title wording change: GUIDELINE NOTE XXX, CHRONIC PAIN THERAPY FOR CONDITIONS INCLUDED ON LINE XXX
        ii. Possible wording change: "~~Chronic pain~~ conditions are included on line XXX when symptoms have been present for at least 3 months and have not responded to conservative management."
        iii. This clarifies that not all chronic pain conditions are included (e.g. rheumatoid arthritis, cancer pain, etc.). Should this be stated explicitly?
4) Feedback on the line scoring
5) Feedback on the prioritization of the revised line for chronic fatigue syndrome
6) Regarding the proposed changes to the opioid guideline:
    a. Should additional pain diagnoses/lines be added to this guideline?
    b. If not, should the CPTF consider additional wording for the guideline to clarify that it only applies to the diagnoses on the back/neck pain line and the specific diagnoses on the proposed chronic pain/fibromyalgia line?
        i. Possible title wording change (suggested wording change in purple): GUIDELINE NOTE 60, OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE AND CERTAIN CHRONIC PAIN CONDITIONS INCLUDED ON LINE XXX

c. Discuss whether the selected affected chronic pain conditions (by definition >90 days in duration) should have 90 days of opioids as a provided treatment
d. Discussion about the opioid taper section

Qualitative summary of a sample of written public testimony from patients and experts (most common themes):

1) Alternative therapies have been tried in the past and didn't work or had adverse effects; these therapies are beneficial but not sufficient to address pain adequately
2) Benefits of long-term opioid therapy:
    a) improved function
    b) improved ability to work or care for self/family
3) Harms of involuntary taper from long-term opioid therapy:
    a) reduced function
    b) increased pain
    c) reduced ability to work
    d) increased disability
    e) increased risk of suicide
    f) increased use of illicit opioids/drugs
4) Patients on chronic opioids are not addicts
5) The proposed taper policy is an overreaction to a few bad patients/doctors/illegal drug users
6) Stories of bad experiences with forced tapers
7) Opioid tapers should be decided between doctors and patients, not payers
8) This discriminates against low-income patients/OHP patients

Chronic Pain Taskforce
Report to the Health Evidence Review Commission

Taskforce recommendations:

1) Create a new line for selected chronic pain conditions including fibromyalgia for the 2020 Biennial Review as shown below
2) Adopt a new guideline for this line as shown below
3) Score this new line as shown below
4) Modify line 528 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS as shown below
    i. Remove all diagnoses other than chronic fatigue syndrome and modify line title
5) Modify GUIDELINE NOTE 56, NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE as shown below
    i. Matches changes in the new chronic pain conditions guideline
    ii. Also delete table at the end. Out of date, newer reviews do not have summary tables that are usable
6) Modify GUIDELINE NOTE 60, OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE as shown below
    i. Adds chronic pain syndrome/fibromyalgia line to the guideline
    ii. Modifies the paragraph on tapering for chronic opioid use
    iii. Removes flares of chronic pain as an indication for opioids
7) Modify GUIDELINE NOTE 92, ACUPUNCTURE as shown below
    i. Adds the new chronic pain syndrome/fibromyalgia line to the guideline

LINE: XXX
CONDITION: CHRONIC PAIN SYNDROME AND FIBROMYALGIA
TREATMENT: LIMITED PHYSICAL MODALITIES, COGNITIVE BEHAVIORAL THERAPY, MEDICAL THERAPY
ICD-10: G89.21 (Chronic pain due to trauma), G89.28 (Other chronic postprocedural pain), G89.29 (Other chronic pain), G89.4 (Chronic pain syndrome), M79.7 (fibromyalgia)
CPT: 90785, 90832-90840, 90853 (psychotherapy—for CBT and ACT), 96150-96155 (Health and behavior assessment and intervention), 97110-97124, 97140-97168, 97530, 97535 (PT/OT), 97810-97814 (acupuncture), 98966-98969, 99051, 99060,99070,99078,99201-99215,99281-99285,99304-99337, 99340-99404,99408-99449,99487-99490,99495,99496,99605-99607 (medical office visits, including ER and SNF)
HCPCS: G0157-G0160 (PT/OT assistant), G0396-G0397 (alcohol and substance abuse screening), G0463-G0467,G0469,G0470 (FQHC care), G0490, G0511-G0513 (RFQHC care),G0514 (prolonged office visit)

GUIDELINE NOTE XXX, CHRONIC PAIN THERAPY

Lines XXX

The specified chronic pain conditions are included on line XXX when symptoms have been present for at least 3 months and have not responded to conservative management.

The following treatments are included on line XXX:

- Office evaluation, consultation and education.
    - Pain education, if done, should include but not be limited to sleep, nutrition, stress reduction/mood, exercise, and knowledge of pain as a biopsychosocial phenomenon. All providers seeing chronic pain patients should be trained in pain science (e.g. a contemporary understanding of the central and peripheral nervous system in chronic

pain), motivational interviewing, culturally sensitive care, and trauma informed care. Care should be multidisciplinary and focus on active therapies.

- Cognitive behavioral therapy (CBT)/acceptance and commitment therapy (ACT). The necessity for CBT and/or ACT should be re-evaluated every 90 days and coverage will only be continued if there is documented evidence of decreasing depression or anxiety symptomatology, improved ability to work/function, increased self-efficacy, or other clinically significant, objective improvement.
- The following therapies, when available, may be provided: yoga, mindfulness training, massage, supervised exercise therapy (land-based and aquatic), intensive interdisciplinary rehabilitation. HCPCS S9451 is only included on Line XXX for the provision of yoga or supervised exercise therapy.
- A total of 30 visits per year of any combination of the following therapies when available and medically appropriate. These therapies are only included on these lines if provided by a provider licensed to provide the therapy and when there is documentation of measurable clinically significant progress toward the therapy plan of care goals and objectives using evidence-based objective tools. Once the pre-determined goals of care have been achieved, an additional two visits may be authorized for maintenance therapy to maintain these improvements. These 30 visits count toward the visit totals in GUIDELINE NOTE 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE if the patient has comorbid back or spine conditions.
    1) Rehabilitative therapy (physical and/or occupational therapy), if provided according to Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES. Rehabilitation services provided under this guideline also count towards visit totals in Guideline Note 6. CPT 97124 is included in this category.
    2) Acupuncture

Non-opioid medications are only included on Line XXX if all of the following apply:

1) The medication is FDA approved or supported by compendia for treatment of chronic, non-neuropathic pain
2) The patient is also being treated with active therapy (e.g. physical therapy, CBT) or is continuing maintenance of self-management strategies learned from such therapy.
3) The benefit of non-opioid medication is re-evaluated at least every 90 days and medications are only continued if there is documented evidence of improvement of function of at least fifteen percent as compared to baseline based on a validated tool (e.g. Oswestry, SF-MPQ, and MSPQ). Less frequent monitoring may be appropriate for certain medications after safety and efficacy are established.

Opioids are included on this line according to GUIDELINE NOTE 60, OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE AND CHRONIC PAIN.

Chronic Pain Taskforce
Report to the Health Evidence Review Commission

Line Scoring

Line XXX CHRONIC PAIN SYNDROME AND FIBROMYALGIA
Category: 7
HL: 4
Suffering: 3
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 2
Effectiveness: 2
Need for service: 0.8
Net cost: 2
Score: 288
Approximate line placement: 443

Line 528 CHRONIC FATIGUE SYNDROME
Category: 7
HL: 4
Suffering: 3
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 0
Effectiveness: 1
Need for service: 0.8
Net cost: 2
Score: 112
Line placement: 528

Line 401 CONDITIONS OF THE BACK AND SPINE
Category: 7
HL: 4
Suffering: 3
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 2
Effectiveness: 3
Need for service: 0.8
Net cost: 2
Score: 438
Approximate line placement: 401

Line: 528

Condition: ~~FIBROMYALGIA,~~ CHRONIC FATIGUE SYNDROME~~, AND RELATED DISORDERS~~ (See Guideline Notes 64,65,135)
Treatment: MEDICAL THERAPY
ICD-10: ~~G89.21,G89.28-G89.29,G89.4,M79.7,~~R53.82
CPT: 90785,90832-90840,90846-90853,93792,93793,98966-98969,99051,99060,99070,99078, 99201-99215,99281-99285,99341-99378,99381-99404,99408-99449,99487-99490,99495-99498,99605-99607
HCPCS: G0248-G0250,G0396,G0397,G0463-G0467,G0490,G0511,G0513,G0514

GUIDELINE NOTE 56, NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE

Lines 361,401

Patients seeking care for back pain should be assessed for potentially serious conditions ("red flag" symptoms requiring immediate diagnostic testing), as defined in Diagnostic Guideline D4. Patients lacking red flag symptoms should be assessed using a validated assessment tool (e.g. STarT Back Assessment Tool) in order to determine their risk level for poor functional prognosis based on psychosocial indicators.

For patients who are determined to be low risk on the assessment tool, the following services are included on these lines:

- Office evaluation and education,
- Up to four total visits, consisting of the following treatments: OMT/CMT, acupuncture, and PT/OT. Massage, if available, may be provided as part of these four total visits.
- First line medications: NSAIDs, acetaminophen, and/or muscle relaxers (not including benzodiazepines). Opioids may be considered as a second line treatment, subject to the limitations on coverage of opioids in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE. See evidence table.

For patients who are determined to be medium- or high risk on the validated assessment tool, as well as patients undergoing opioid tapers as in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE, the following treatments are included on these lines:

- Office evaluation, consultation and education
- Cognitive behavioral therapy/acceptance and commitment therapy. The necessity for cognitive behavioral therapy/acceptance and commitment therapy should be re-evaluated every 90 days and coverage will only be continued if there is documented evidence of decreasing depression or anxiety symptomatology, improved ability to work/function, increased self-efficacy, or other clinically significant, objective improvement.
- Prescription and over-the-counter medications; opioid medications subject to the limitations on coverage of opioids in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE. See evidence table.
- The following evidence-based therapies, when available, may be provided: yoga, massage, supervised exercise therapy, intensive interdisciplinary rehabilitation. HCPCS S9451 is only included on Line 401 for the provision of yoga or supervised exercise therapy.
- A total of 30 visits per year of any combination of the following evidence-based therapies when available and medically appropriate. These therapies are only included on these lines if provided by a provider licensed to provide the therapy and when there is documentation of measurable clinically significant progress toward the therapy plan of care goals and objectives using evidence based objective tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ). These 30 visits count toward the visit totals in GUIDELINE NOTE XXX CHRONIC PAIN THERAPY if the patient has comorbid chronic pain conditions.
    3) Rehabilitative therapy (physical and/or occupational therapy), if provided according to Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES. Rehabilitation services provided under this guideline also count towards visit totals in Guideline Note 6. CPT 97124 is included in this category.
    4) Chiropractic or osteopathic manipulation

5) Acupuncture

Mechanical traction (CPT 97012) is not included on these lines, due to evidence of lack of effectiveness for treatment of back and neck conditions.

The development of this guideline note was informed by HERC coverage guidances on Low Back Pain Non-Pharmacologic, Non-Invasive Intervention, Low Back Pain, Pharmacological and Herbal Therapies. See http://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx.

Delete table below

Evidence Table of Effective Treatments for the Management of Low Back Pain [delete table]

Intervention Category*	Intervention	Acute < 4 Weeks	Subacute & Chronic > 4 Weeks
Self-care	Advice to remain active	●	●
	Books, handout	●	●
	Application of superficial heat	●	
Nonpharmacologic therapy	Spinal manipulation	●	●
	Exercise therapy		●
	Massage		●
	Acupuncture		●
	Yoga		●
	Cognitive-behavioral therapy		●
	Progressive relaxation		●
Pharmacologic therapy (Carefully consider risks/harms)	Acetaminophen	●	●
	NSAIDs	●(▲)	●(▲)
	Skeletal muscle relaxants	●	
	Antidepressants (TCA)		●
	*Benzodiazepines***	●(▲)	●(▲)
	*Tramadol, opioids***	●(▲)	●(▲)
Interdisciplinary therapy	Intensive interdisciplinary rehabilitation		●

- Interventions supported by grade B evidence (at least fair-quality evidence of moderate benefit, or small benefit but no significant harms, costs, or burdens). No intervention was supported by grade "A" evidence (good-quality evidence of substantial benefit).

▲ *Carries greater risk of harms than other agents in table.*

NSAIDs = nonsteroidal anti-inflammatory drugs; TCA = tricyclic antidepressants.

*These are general categories only. Individual care plans need to be developed on a case by case basis. For more detailed information please see: http://www.annals.org/content/147/7/478.full.pdf

**Associated with significant risks related to potential for abuse, addiction and tolerance. This evidence evaluates effectiveness of these agents with relatively short term use studies. Chronic use of these agents may result in significant harms.

GUIDELINE NOTE 60, OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE AND SELECT CHRONIC PAIN CONDITIONS

Lines 346,361,401,527,XXX

Opioid medications are only included on these lines under the following criteria:

For acute injury~~, acute flare of chronic pain,~~ or after surgery:

1) During the first 6 weeks opioid treatment is included on these lines ONLY:
   a) When each prescription is limited to 7 days of treatment, AND
   b) For short acting opioids only, AND
   c) When one or more alternative first line pharmacologic therapies such as NSAIDs, acetaminophen, and muscle relaxers (not including benzodiazepines) have been tried and found not effective or are contraindicated, AND
   d) When prescribed with a plan to keep active (home or prescribed exercise regime) and with consideration of additional therapies such as spinal manipulation, physical therapy, yoga, or acupuncture, AND
   e) There is documented verification that the patient is not high risk for opioid misuse or abuse.
2) Treatment with opioids after 6 weeks, up to 90 days after the initial injury/~~flare/~~surgery is included on these lines ONLY:
   a) With documented evidence of improvement of function of at least thirty percent as compared to baseline based on a validated tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
   b) When prescribed in conjunction with therapies such as spinal manipulation, physical therapy, yoga, or acupuncture.
   c) With verification that the patient is not high risk for opioid misuse or abuse. Such verification may involve
      i) Documented verification from the state's prescription monitoring program database that the controlled substance history is consistent with the prescribing record
      ii) Use of a validated screening instrument to verify the absence of a current substance use disorder (excluding nicotine) or a history of prior opioid misuse or abuse
      iii) Administration of a baseline urine drug test to verify the absence of illicit drugs and non-prescribed opioids.
   d) Each prescription must be limited to 7 days of treatment and for short acting opioids only

3) Chronic opioid treatment (>90 days) after the initial injury/~~flare/~~surgery is not included on these lines except for the taper process described below.

Transitional coverage for patients on long-term opioid therapy ~~as of July 1, 2016~~:

For patients ~~on covered chronic~~ receiving long-term opioid therapy ~~as of July 1, 2016, opioid medication is included on these lines only from July 1, 2016 to December 31, 2016. During the period from January 1, 2017 to December 31, 2017~~, continued coverage of opioid medications requires an individual treatment plan ~~developed by January 1, 2017~~ which includes a taper with an end to opioid therapy no later than one year from the start of the taper ~~no later than January 1, 2018~~. Taper plans must include nonpharmacological treatment strategies for managing the patient's pain ~~based on Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE~~. If a patient has

developed dependence and/or addiction related to their opioids, treatment is ~~available~~ included on Line 4 SUBSTANCE USE DISORDER**.**

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,5,202,361,401,409,461,538

Inclusion of acupuncture (CPT 97810-97814) on the Prioritized List has the following limitations:

Line 1 PREGNANCY

Acupuncture pairs on Line 1 for the following conditions and codes.

Hyperemesis gravidarum

ICD-10-CM: O21.0, O21.1

Acupuncture pairs with hyperemesis gravidarum when a diagnosis is made by the maternity care provider and referred for acupuncture treatment for up to 12 sessions of acupressure/acupuncture per pregnancy.

Breech presentation

ICD-10-CM: O32.1

Acupuncture (and moxibustion) is paired with breech presentation when a referral with a diagnosis of breech presentation is made by the maternity care provider, the patient is between 33 and 38 weeks gestation, for up to 6 sessions per pregnancy.

Back and pelvic pain of pregnancy

ICD-10-CM: O99.89

Acupuncture is paired with back and pelvic pain of pregnancy when referred by maternity care provider/primary care provider for up to 12 sessions per pregnancy.

Line 5 TOBACCO DEPENDENCE

Acupuncture is included on this line for a maximum of 12 sessions per quit attempt up to two quit attempts per year; additional sessions may be authorized if medically appropriate.

Line 202 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS

Acupuncture is paired with the treatment of post-stroke depression only. Treatments may be billed to a maximum of 30 minutes face-to-face time and limited to 12 total sessions per year, with documentation of meaningful improvement; patients may have additional visits authorized beyond these limits if medically appropriate.

Line 361 SCOLIOSIS

Acupuncture is included on this line with visit limitations as in Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE.

Line 401 CONDITIONS OF THE BACK AND SPINE

Acupuncture is included on this line with visit limitations as in Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE.

Line 409 MIGRAINE HEADACHES

Acupuncture pairs on Line 409 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), for up to 12 sessions per year.

Line XXX CHRONIC PAIN SYNDROME AND FIBROMYALGIA

Acupuncture is included on this line with visit limitations as in Guideline Note XXX CHRONIC PAIN THERAPY AND FIBROMYALGIA

Line 461 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 461 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions per year.

*Line 538 TENSION HEADACHES

Acupuncture is included on Line 538 for treatment of tension headaches (ICD-10-CM G44.2), for up to 12 sessions per year.

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx.

*Below the current funding line.

Section 5.0

New Codes

2019 ICD-10-CM
New Codes

Code	Code Description	Notes	Placement Recommendation
C43.111	Malignant melanoma of right upper eyelid, including canthus		230 MALIGNANT MELANOMA OF SKIN
C43.112	Malignant melanoma of right lower eyelid, including canthus		230 MALIGNANT MELANOMA OF SKIN
C43.121	Malignant melanoma of left upper eyelid, including canthus		230 MALIGNANT MELANOMA OF SKIN
C43.122	Malignant melanoma of left lower eyelid, including canthus		230 MALIGNANT MELANOMA OF SKIN
C4A.111	Merkel cell carcinoma of right upper eyelid, including canthus	C4A.10 (Merkel cell carcinoma of unspecified eyelid, including canthus) is on line 276	276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C4A.112	Merkel cell carcinoma of right lower eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C4A.121	Merkel cell carcinoma of left upper eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C4A.122	Merkel cell carcinoma of left lower eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1021	Unspecified malignant neoplasm of skin of right upper eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1022	Unspecified malignant neoplasm of skin of right lower eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1091	Unspecified malignant neoplasm of skin of left upper eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1092	Unspecified malignant neoplasm of skin of left lower eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1121	Basal cell carcinoma of skin of right upper eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA

Code	Code Description	Notes	Placement Recommendation
C44.1122	Basal cell carcinoma of skin of right lower eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1191	Basal cell carcinoma of skin of left upper eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1192	Basal cell carcinoma of skin of left lower eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1221	Squamous cell carcinoma of skin of right upper eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1222	Squamous cell carcinoma of skin of right lower eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1291	Squamous cell carcinoma of skin of left upper eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1292	Squamous cell carcinoma of skin of left lower eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.131	Sebaceous cell carcinoma of skin of unspecified eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1321	Sebaceous cell carcinoma of skin of right upper eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1322	Sebaceous cell carcinoma of skin of right lower eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1391	Sebaceous cell carcinoma of skin of left upper eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1392	Sebaceous cell carcinoma of skin of left lower eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1921	Other specified malignant neoplasm of skin of right upper eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA

Code	Code Description	Notes	Placement Recommendation
C44.1922	Other specified malignant neoplasm of skin of right lower eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1991	Other specified malignant neoplasm of skin of left upper eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
C44.1992	Other specified malignant neoplasm of skin of left lower eyelid, including canthus		276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA
D03.111	Melanoma in situ of right upper eyelid, including canthus	D03.1 (Melanoma in situ of unspecified eyelid, including canthus) is on line 230	230 MALIGNANT MELANOMA OF SKIN
D03.112	Melanoma in situ of right lower eyelid, including canthus		230 MALIGNANT MELANOMA OF SKIN
D03.121	Melanoma in situ of left upper eyelid, including canthus		230 MALIGNANT MELANOMA OF SKIN
D03.122	Melanoma in situ of left lower eyelid, including canthus		230 MALIGNANT MELANOMA OF SKIN
D04.111	Carcinoma in situ of skin of right upper eyelid, including canthus	D04.10 (Carcinoma in situ of skin of unspecified eyelid, including canthus) is on line 243	243 DERMATOLOGICAL PREMALIGNANT LESIONS AND CARCINOMA IN SITU
D04.112	Carcinoma in situ of skin of right lower eyelid, including canthus		243 DERMATOLOGICAL PREMALIGNANT LESIONS AND CARCINOMA IN SITU
D04.121	Carcinoma in situ of skin of left upper eyelid, including canthus		243 DERMATOLOGICAL PREMALIGNANT LESIONS AND CARCINOMA IN SITU
D04.122	Carcinoma in situ of skin of left lower eyelid, including canthus		243 DERMATOLOGICAL PREMALIGNANT LESIONS AND CARCINOMA IN SITU
D22.111	Melanocytic nevi of right upper eyelid, including canthus	D22.10 (Melanocytic nevi of unspecified eyelid, including canthus) is on lines 493,625	493 ECTROPION AND BENIGN NEOPLASM OF EYE 625 BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES
D22.112	Melanocytic nevi of right lower eyelid, including canthus		493,625

Code	Code Description	Notes	Placement Recommendation
D22.121	Melanocytic nevi of left upper eyelid, including canthus		493,625
D22.122	Melanocytic nevi of left lower eyelid, including canthus		493,625
D23.111	Other benign neoplasm of skin of right upper eyelid, including canthus	D23.10 (Other benign neoplasm of skin of unspecified eyelid, including canthus) is on lines 493, 625	493,625
D23.112	Other benign neoplasm of skin of right lower eyelid, including canthus		493,625
D23.121	Other benign neoplasm of skin of left upper eyelid, including canthus		493,625
D23.122	Other benign neoplasm of skin of left lower eyelid, including canthus		493,625

Code	Code Description	Notes	Placement Recommendation
E72.81	Disorders of gamma aminobutyric acid metabolism	E72.8 (Other disorders of fatty-acid metabolism) has been broken down into sub codes. E72.8 was found on lines 71,177,242,292,345,377	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 177 DISORDERS OF AMINO-ACID TRANSPORT AND METABOLISM (NON PKU); HEREDITARY FRUCTOSE INTOLERANCE 242 ACUTE AND SUBACUTE NECROSIS OF LIVER; SPECIFIED INBORN ERRORS OF METABOLISM (E.G., MAPLE SYRUP URINE DISEASE, TYROSINEMIA) TX LIVER TRANSPLANT 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS
E72.89	Other specified disorders of amino-acid metabolism		71,177,242,292,345,300

2019 ICD-10-CM
New Codes

Code	Code Description	Notes	Placement Recommendation
E75.26	Sulfatase deficiency	See issues document	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
E78.41	Elevated Lipoprotein(a)	See issues document	650 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
E78.49	Other hyperlipidemia		221 DYSLIPIDEMIAS
E88.02	Plasminogen deficiency	Similar codes are on line 454	454 DISORDERS OF PLASMA PROTEIN METABOLISM
F12.23	Cannabis dependence with withdrawal	Reviewed by BHAP	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL
F12.93	Cannabis use, unspecified with withdrawal	Reviewed by BHAP	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL
F53.0	Postpartum depression	See issues document	7 MAJOR DEPRESSION, RECURRENT; MAJOR DEPRESSION, SINGLE EPISODE, SEVERE
F53.1	Puerperal psychosis	Reviewed by BHAP Replaced code F53 Peurperal psychosis was on line 277	277 OTHER PSYCHOTIC DISORDERS
F68.A	Factitious disorder imposed on another	Reviewed by BHAP	549 SOMATIC SYMPTOMS AND RELATED DISORDERS

Code	Code Description	Notes	Placement Recommendation
G51.31	Clonic hemifacial spasm, right	Replaced code G51.3 (Clonic hemifacial spasm) was on line 483	483 BELL'S PALSY, EXPOSURE KERATOCONJUNCTIVITIS
G51.32	Clonic hemifacial spasm, left		483 BELL'S PALSY, EXPOSURE KERATOCONJUNCTIVITIS
G51.33	Clonic hemifacial spasm, bilateral		483 BELL'S PALSY, EXPOSURE KERATOCONJUNCTIVITIS
G51.39	Clonic hemifacial spasm, unspecified		483 BELL'S PALSY, EXPOSURE KERATOCONJUNCTIVITIS
G71.00	Muscular dystrophy, unspecified	Replaced code G71.0 (Muscular dystrophy) was on lines 71,292,345,377	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS
G71.01	Duchenne or Becker muscular dystrophy		71,292,345,377
G71.02	Facioscapulohumeral muscular dystrophy		71,292,345,377
G71.09	Other specified muscular dystrophies		71,292,345,377
H01.00A	Unspecified blepharitis right eye, upper and lower eyelids		567 BLEPHARITIS
H01.00B	Unspecified blepharitis left eye, upper and lower eyelids		567 BLEPHARITIS

Code	Code Description	Notes	Placement Recommendation
H01.01A	Ulcerative blepharitis right eye, upper and lower eyelids		567 BLEPHARITIS
H01.01B	Ulcerative blepharitis left eye, upper and lower eyelids		567 BLEPHARITIS
H01.02A	Squamous blepharitis right eye, upper and lower eyelids		567 BLEPHARITIS
H01.02B	Squamous blepharitis left eye, upper and lower eyelids		567 BLEPHARITIS
H02.151	Paralytic ectropion of right upper eyelid		493 ECTROPION AND BENIGN NEOPLASM OF EYE
H02.152	Paralytic ectropion of right lower eyelid		493 ECTROPION AND BENIGN NEOPLASM OF EYE
H02.153	Paralytic ectropion of right eye, unspecified eyelid		493 ECTROPION AND BENIGN NEOPLASM OF EYE
H02.154	Paralytic ectropion of left upper eyelid		493 ECTROPION AND BENIGN NEOPLASM OF EYE
H02.155	Paralytic ectropion of left lower eyelid		493 ECTROPION AND BENIGN NEOPLASM OF EYE
H02.156	Paralytic ectropion of left eye, unspecified eyelid		493 ECTROPION AND BENIGN NEOPLASM OF EYE
H02.159	Paralytic ectropion of unspecified eye, unspecified eyelid		493 ECTROPION AND BENIGN NEOPLASM OF EYE
H02.20A	Unspecified lagophthalmos right eye, upper and lower eyelids	Other lagophthalmos diagnoses on line 469. GN130 governs coverage of surgical repair.	469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT
H02.20B	Unspecified lagophthalmos left eye, upper and lower eyelids		469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT
H02.20C	Unspecified lagophthalmos, bilateral, upper and lower eyelids		469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT
H02.21A	Cicatricial lagophthalmos right eye, upper and lower eyelids		469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT

Code	Code Description	Notes	Placement Recommendation
H02.21B	Cicatricial lagophthalmos left eye, upper and lower eyelids		469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT
H02.21C	Cicatricial lagophthalmos, bilateral, upper and lower eyelids		469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT
H02.22A	Mechanical lagophthalmos right eye, upper and lower eyelids		469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT
H02.22B	Mechanical lagophthalmos left eye, upper and lower eyelids		469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT
H02.22C	Mechanical lagophthalmos, bilateral, upper and lower eyelids		469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT
H02.23A	Paralytic lagophthalmos right eye, upper and lower eyelids		469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT
H02.23B	Paralytic lagophthalmos left eye, upper and lower eyelids		469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT
H02.23C	Paralytic lagophthalmos, bilateral, upper and lower eyelids		469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT
H02.881	Meibomian gland dysfunction right upper eyelid	See issues document	508 DYSFUNCTION OF NASOLACRIMAL SYSTEM IN ADULTS; LACRIMAL SYSTEM LACERATION
H02.882	Meibomian gland dysfunction right lower eyelid		508 DYSFUNCTION OF NASOLACRIMAL SYSTEM IN ADULTS; LACRIMAL SYSTEM LACERATION
H02.883	Meibomian gland dysfunction of right eye, unspecified eyelid		508 DYSFUNCTION OF NASOLACRIMAL SYSTEM IN ADULTS; LACRIMAL SYSTEM LACERATION
H02.884	Meibomian gland dysfunction left upper eyelid		508 DYSFUNCTION OF NASOLACRIMAL SYSTEM IN ADULTS; LACRIMAL SYSTEM LACERATION
H02.885	Meibomian gland dysfunction left lower eyelid		508 DYSFUNCTION OF NASOLACRIMAL SYSTEM IN ADULTS; LACRIMAL SYSTEM LACERATION
H02.886	Meibomian gland dysfunction of left eye, unspecified eyelid		508 DYSFUNCTION OF NASOLACRIMAL SYSTEM IN ADULTS; LACRIMAL SYSTEM LACERATION
H02.889	Meibomian gland dysfunction of unspecified eye, unspecified eyelid		508 DYSFUNCTION OF NASOLACRIMAL SYSTEM IN ADULTS; LACRIMAL SYSTEM LACERATION
H02.88A	Meibomian gland dysfunction right eye, upper and lower eyelids		508 DYSFUNCTION OF NASOLACRIMAL SYSTEM IN ADULTS; LACRIMAL SYSTEM LACERATION

Code	Code Description	Notes	Placement Recommendation
H02.88B	Meibomian gland dysfunction left eye, upper and lower eyelids		508 DYSFUNCTION OF NASOLACRIMAL SYSTEM IN ADULTS; LACRIMAL SYSTEM LACERATION
H10.821	Rosacea conjunctivitis, right eye	See issues document	499 CHRONIC CONJUNCTIVITIS, BLEPHAROCONJUNCTIVITIS
H10.822	Rosacea conjunctivitis, left eye		499 CHRONIC CONJUNCTIVITIS, BLEPHAROCONJUNCTIVITIS
H10.823	Rosacea conjunctivitis, bilateral		499 CHRONIC CONJUNCTIVITIS, BLEPHAROCONJUNCTIVITIS
H10.829	Rosacea conjunctivitis, unspecified eye		499 CHRONIC CONJUNCTIVITIS, BLEPHAROCONJUNCTIVITIS
H57.811	Brow ptosis, right	See issues document	393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN 469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT
H57.812	Brow ptosis, left		393, 469
H57.813	Brow ptosis, bilateral		393, 469
H57.819	Brow ptosis, unspecified		393, 469
H57.89	Other specified disorders of eye and adnexa	Previous code H57.8 (Other specified disorders of eye and adnexa) was on line 652	652 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

2019 ICD-10-CM
New Codes

Code	Code Description	Notes	Placement Recommendation
I63.81	Other cerebral infarction due to occlusion or stenosis of small artery	Previous code I63.8 (Other cerebral infarction) was on lines 71,292,317,345,377	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 317 Stroke 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS
I63.89	Other cerebral infarction		71,292,317,345,377
I67.850	Cerebral autosomal dominant arteriopathy with subcortical infarcts and leukoencephalopathy	an inherited condition that causes stroke and other impairments	71,292,317,345,377
I67.858	Other hereditary cerebrovascular disease	Similar code I67.89 (Other cerebrovascular disease) is on lines 71,292,317,345,377	71,292,317,345,377
K35.20	Acute appendicitis with generalized peritonitis, without abscess	Other acute appendicitis diagnoses found on line 47	47 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS
K35.21	Acute appendicitis with generalized peritonitis, with abscess		47 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS
K35.30	Acute appendicitis with localized peritonitis, without perforation or gangrene		47 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS
K35.31	Acute appendicitis with localized peritonitis and gangrene, without perforation		47 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS

Code	Code Description	Notes	Placement Recommendation
K35.32	Acute appendicitis with perforation and localized peritonitis, without abscess		47 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS
K35.33	Acute appendicitis with perforation and localized peritonitis, with abscess		47 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS
K35.890	Other acute appendicitis without perforation or gangrene		47 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS
K35.891	Other acute appendicitis without perforation, with gangrene		47 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS
K61.31	Horseshoe abscess	Previous code K61.3 (Ischiorectal abscess) found on line 206	206 SUPERFICIAL ABSCESSES AND CELLULITIS
K61.39	Other ischiorectal abscess		206 SUPERFICIAL ABSCESSES AND CELLULITIS
K61.5	Supralevator abscess	Other abscess codes on line 206	206 SUPERFICIAL ABSCESSES AND CELLULITIS
K82.A1	Gangrene of gallbladder in cholecystitis	Cholecystitis found on line 55	55 COMPLICATED STONES OF THE GALLBLADDER AND BILE DUCTS; CHOLECYSTITIS
K82.A2	Perforation of gallbladder in cholecystitis		55 COMPLICATED STONES OF THE GALLBLADDER AND BILE DUCTS; CHOLECYSTITIS
K83.01	Primary sclerosing cholangitis	Previous code K83.0 (Cholangitis) found on line 55	55 COMPLICATED STONES OF THE GALLBLADDER AND BILE DUCTS; CHOLECYSTITIS
K83.09	Other cholangitis		55 COMPLICATED STONES OF THE GALLBLADDER AND BILE DUCTS; CHOLECYSTITIS
M79.10	Myalgia, unspecified site	Previous code M79.1 (Myalgia) was on line 601	601 DISORDERS OF SOFT TISSUE
M79.11	Myalgia of mastication muscle		601 DISORDERS OF SOFT TISSUE
M79.12	Myalgia of auxiliary muscles, head and neck		601 DISORDERS OF SOFT TISSUE
M79.18	Myalgia, other site		601 DISORDERS OF SOFT TISSUE
N35.016	Post-traumatic urethral stricture, male, overlapping sites	Other urethral stricture codes are on line 327	327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION

Code	Code Description	Notes	Placement Recommendation
N35.116	Postinfective urethral stricture, not elsewhere classified, male, overlapping sites		327
N35.811	Other urethral stricture, male, meatal		327
N35.812	Other urethral bulbous stricture, male		327
N35.813	Other membranous urethral stricture, male		327
N35.814	Other anterior urethral stricture, male, anterior		327
N35.816	Other urethral stricture, male, overlapping sites		327
N35.819	Other urethral stricture, male, unspecified site		327
N35.82	Other urethral stricture, female		327
N35.911	Unspecified urethral stricture, male, meatal		327
N35.912	Unspecified bulbous urethral stricture, male		327
N35.913	Unspecified membranous urethral stricture, male		327
N35.914	Unspecified anterior urethral stricture, male		327
N35.916	Unspecified urethral stricture, male, overlapping sites		327
N35.919	Unspecified urethral stricture, male, unspecified site		327
N35.92	Unspecified urethral stricture, female		327
N99.116	Postprocedural urethral stricture, male, overlapping sites		327

Code	Code Description	Notes	Placement Recommendation
O30.131	Triplet pregnancy, trichorionic/triamniotic, first trimester		1 PREGNANCY
O30.132	Triplet pregnancy, trichorionic/triamniotic, second trimester		1 PREGNANCY
O30.133	Triplet pregnancy, trichorionic/triamniotic, third trimester		1 PREGNANCY
O30.139	Triplet pregnancy, trichorionic/triamniotic, unspecified trimester		1 PREGNANCY
O30.231	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, first trimester		1 PREGNANCY
O30.232	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, second trimester		1 PREGNANCY
O30.233	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, third trimester		1 PREGNANCY
O30.239	Quadruplet pregnancy, quadrachorionic/quadra-amniotic, unspecified trimester		1 PREGNANCY
O30.831	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, first trimester		1 PREGNANCY
O30.832	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, second trimester		1 PREGNANCY

Code	Code Description	Notes	Placement Recommendation
O30.833	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, third trimester		1 PREGNANCY
O30.839	Other specified multiple gestation, number of chorions and amnions are both equal to the number of fetuses, unspecified trimester		1 PREGNANCY
O86.00	Infection of obstetric surgical wound, unspecified	Previous code O86.0 (Infection of obstetric surgical wound) was on line 285	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
O86.01	Infection of obstetric surgical wound, superficial incisional site		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
O86.02	Infection of obstetric surgical wound, deep incisional site		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
O86.03	Infection of obstetric surgical wound, organ and space site		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
O86.04	Sepsis following an obstetrical procedure		182 SEPTICEMIA
O86.09	Infection of obstetric surgical wound, other surgical site		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
P02.70	Newborn affected by fetal inflammatory response syndrome	Previous code P02.7 (Newborn affected by chorioamnionitis) was on line 2	2 BIRTH OF INFANT
P02.78	Newborn affected by other conditions from chorioamnionitis		2 BIRTH OF INFANT
P04.11	Newborn affected by maternal antineoplastic chemotherapy	Previous code P04.1 (Newborn affected by other maternal medication) was on line 2	2 BIRTH OF INFANT
P04.12	Newborn affected by maternal cytotoxic drugs		2 BIRTH OF INFANT
P04.13	Newborn affected by maternal use of anticonvulsants		2 BIRTH OF INFANT

Code	Code Description	Notes	Placement Recommendation
P04.14	Newborn affected by maternal use of opiates		2 BIRTH OF INFANT
P04.15	Newborn affected by maternal use of antidepressants		2 BIRTH OF INFANT
P04.16	Newborn affected by maternal use of amphetamines		2 BIRTH OF INFANT
P04.17	Newborn affected by maternal use of sedative-hypnotics		2 BIRTH OF INFANT
P04.1A	Newborn affected by maternal use of anxiolytics		2 BIRTH OF INFANT
P04.18	Newborn affected by other maternal medication		2 BIRTH OF INFANT
P04.19	Newborn affected by maternal use of unspecified medication		2 BIRTH OF INFANT
P04.40	Newborn affected by maternal use of unspecified drugs of addiction	Similar codes with specified drugs of addiction are on line 2	2 BIRTH OF INFANT
P04.42	Newborn affected by maternal use of hallucinogens		2 BIRTH OF INFANT
P04.81	Newborn affected by maternal use of cannabis		2 BIRTH OF INFANT
P04.89	Newborn affected by other maternal noxious substances	Previous code P04.8 (Newborn affected by other maternal noxious substances) was on line 2	2 BIRTH OF INFANT

Code	Code Description	Notes	Placement Recommendation
P35.4	Congenital Zika virus disease	Other congenital viral diseases are on lines 15,71,292,345,377	15 Congenital infectious diseases 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS
P74.21	Hypernatremia of newborn	Previous code P74.2 (Disturbances of sodium balance of newborn) was on line 24	24 ENDOCRINE AND METABOLIC DISTURBANCES SPECIFIC TO THE FETUS AND NEWBORN
P74.22	Hyponatremia of newborn		24 ENDOCRINE AND METABOLIC DISTURBANCES SPECIFIC TO THE FETUS AND NEWBORN
P74.31	Hyperkalemia of newborn	Previous code P74.3 (Disturbances of potassium balance of newborn) was on line 24	24 ENDOCRINE AND METABOLIC DISTURBANCES SPECIFIC TO THE FETUS AND NEWBORN
P74.32	Hypokalemia of newborn		24 ENDOCRINE AND METABOLIC DISTURBANCES SPECIFIC TO THE FETUS AND NEWBORN
P74.41	Alkalosis of newborn	Previous code P74.4 (Other transitory electrolyte disturbances of newborn) was on line 24	24 ENDOCRINE AND METABOLIC DISTURBANCES SPECIFIC TO THE FETUS AND NEWBORN
P74.421	Hyperchloremia of newborn		24 ENDOCRINE AND METABOLIC DISTURBANCES SPECIFIC TO THE FETUS AND NEWBORN

Code	Code Description	Notes	Placement Recommendation
P74.422	Hypochloremia of newborn		24 ENDOCRINE AND METABOLIC DISTURBANCES SPECIFIC TO THE FETUS AND NEWBORN
P74.49	Other transitory electrolyte disturbance of newborn		24 ENDOCRINE AND METABOLIC DISTURBANCES SPECIFIC TO THE FETUS AND NEWBORN
Q51.20	Other doubling of uterus, unspecified	Previous code Q51.2 (Other doubling of uterus) was on line 578	578 CONGENITAL ANOMALIES OF FEMALE GENITAL ORGANS EXCLUDING VAGINA
Q51.21	Other complete doubling of uterus		578 CONGENITAL ANOMALIES OF FEMALE GENITAL ORGANS EXCLUDING VAGINA
Q51.22	Other partial doubling of uterus		578 CONGENITAL ANOMALIES OF FEMALE GENITAL ORGANS EXCLUDING VAGINA
Q51.28	Other doubling of uterus, other specified		578 CONGENITAL ANOMALIES OF FEMALE GENITAL ORGANS EXCLUDING VAGINA
Q93.51	Angelman syndrome	Genetic condition with only supportive treatments	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS
Q93.59	Other deletions of part of a chromosome	Previous code Q93.5 (Other deletions of part of a chromosome) was on lines 71,292,345,377	71,292,345,377

Code	Code Description	Notes	Placement Recommendation
Q93.82	Williams syndrome	Genetic condition with only supportive treatments. Specific conditions, such as heart conditions, could be treated under the specific diagnosis	71,292,345,377
R82.991	Hypocitraturia		Diagnostic Workup File (DWF)
R82.992	Hyperoxaluria		Diagnostic Workup File (DWF)
R82.993	Hyperuricoscuria		Diagnostic Workup File (DWF)
R82.994	Hypercalciuria		Diagnostic Workup File (DWF)
R82.998	Other abnormal findings in urine		Diagnostic Workup File (DWF)
R93.811	Abnormal radiologic findings on diagnostic imaging of right testicle		Diagnostic Workup File (DWF)
R93.812	Abnormal radiologic findings on diagnostic imaging of left testicle		Diagnostic Workup File (DWF)
R93.813	Abnormal radiologic findings on diagnostic imaging of testicles, bilateral		Diagnostic Workup File (DWF)
R93.819	Abnormal radiologic findings on diagnostic imaging of unspecified testicle		Diagnostic Workup File (DWF)
R93.89	Abnormal findings on diagnostic imaging of other specified body structures		Diagnostic Workup File (DWF)
T43.641A	Poisoning by ecstasy, accidental (unintentional), initial encounter		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T43.641D	Poisoning by ecstasy, accidental (unintentional), subsequent encounter		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T43.641S	Poisoning by ecstasy, accidental (unintentional), sequela		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T43.642A	Poisoning by ecstasy, intentional self-harm, initial encounter		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS

Code	Code Description	Notes	Placement Recommendation
T43.642D	Poisoning by ecstasy, intentional self-harm, subsequent encounter		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T43.642S	Poisoning by ecstasy, intentional self-harm, sequela		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T43.643A	Poisoning by ecstasy, assault, initial encounter		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T43.643D	Poisoning by ecstasy, assault, subsequent encounter		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T43.643S	Poisoning by ecstasy, assault, sequela		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T43.644A	Poisoning by ecstasy, undetermined, initial encounter		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T43.644D	Poisoning by ecstasy, undetermined, subsequent encounter		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T43.644S	Poisoning by ecstasy, undetermined, sequela		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T74.51XA	Adult forced sexual exploitation, confirmed, initial encounter	Reviewed by BHAP	121 ABUSE AND NEGLECT
T74.51XD	Adult forced sexual exploitation, confirmed, subsequent encounter	Reviewed by BHAP	121 ABUSE AND NEGLECT
T74.51XS	Adult forced sexual exploitation, confirmed, sequela	Reviewed by BHAP	121 ABUSE AND NEGLECT
T74.52XA	Child sexual exploitation, confirmed, initial encounter	Reviewed by BHAP	121 ABUSE AND NEGLECT
T74.52XD	Child sexual exploitation, confirmed, subsequent encounter	Reviewed by BHAP	121 ABUSE AND NEGLECT
T74.52XS	Child sexual exploitation, confirmed, sequela	Reviewed by BHAP	121 ABUSE AND NEGLECT
T74.61XA	Adult forced labor exploitation, confirmed, initial encounter	Reviewed by BHAP	121 ABUSE AND NEGLECT
T74.61XD	Adult forced labor exploitation, confirmed, subsequent encounter	Reviewed by BHAP	121 ABUSE AND NEGLECT

Code	Code Description	Notes	Placement Recommendation
T74.61XS	Adult forced labor exploitation, confirmed, sequela	Reviewed by BHAP	121 ABUSE AND NEGLECT
T74.62XA	Child forced labor exploitation, confirmed, initial encounter	Reviewed by BHAP	121 ABUSE AND NEGLECT
T74.62XD	Child forced labor exploitation, confirmed, subsequent encounter	Reviewed by BHAP	121 ABUSE AND NEGLECT
T74.62XS	Child forced labor exploitation, confirmed, sequela	Reviewed by BHAP	121 ABUSE AND NEGLECT
T76.51XA	Adult forced sexual exploitation, suspected, initial encounter	Reviewed by BHAP	121 ABUSE AND NEGLECT
T76.51XD	Adult forced sexual exploitation, suspected, subsequent encounter	Reviewed by BHAP	121 ABUSE AND NEGLECT
T76.51XS	Adult forced sexual exploitation, suspected, sequela	Reviewed by BHAP	121 ABUSE AND NEGLECT
T76.52XA	Child sexual exploitation, suspected, initial encounter	Reviewed by BHAP	121 ABUSE AND NEGLECT
T76.52XD	Child sexual exploitation, suspected, subsequent encounter	Reviewed by BHAP	121 ABUSE AND NEGLECT
T76.52XS	Child sexual exploitation, suspected, sequela	Reviewed by BHAP	121 ABUSE AND NEGLECT
T76.61XA	Adult forced labor exploitation, suspected, initial encounter	Reviewed by BHAP	121 ABUSE AND NEGLECT
T76.61XD	Adult forced labor exploitation, suspected, subsequent encounter	Reviewed by BHAP	121 ABUSE AND NEGLECT
T76.61XS	Adult forced labor exploitation, suspected, sequela	Reviewed by BHAP	121 ABUSE AND NEGLECT
T76.62XA	Child forced labor exploitation, suspected, initial encounter	Reviewed by BHAP	121 ABUSE AND NEGLECT
T76.62XD	Child forced labor exploitation, suspected, subsequent encounter	Reviewed by BHAP	121 ABUSE AND NEGLECT
T76.62XS	Child forced labor exploitation, suspected, sequela	Reviewed by BHAP	121 ABUSE AND NEGLECT

Code	Code Description	Notes	Placement Recommendation
T81.40XA	Infection following a procedure, unspecified, initial encounter		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
T81.40XD	Infection following a procedure, unspecified, subsequent encounter		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
T81.40XS	Infection following a procedure, unspecified, sequela		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
T81.41XA	Infection following a procedure, superficial incisional surgical site, initial encounter		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
T81.41XD	Infection following a procedure, superficial incisional surgical site, subsequent encounter		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
T81.41XS	Infection following a procedure, superficial incisional surgical site, sequela		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
T81.42XA	Infection following a procedure, deep incisional surgical site, initial encounter		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
T81.42XD	Infection following a procedure, deep incisional surgical site, subsequent encounter		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
T81.42XS	Infection following a procedure, deep incisional surgical site, sequela		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
T81.43XA	Infection following a procedure, organ and space surgical site, initial encounter		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
T81.43XD	Infection following a procedure, organ and space surgical site, subsequent encounter		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
T81.43XS	Infection following a procedure, organ and space surgical site, sequela		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT

Code	Code Description	Notes	Placement Recommendation
T81.44XA	Sepsis following a procedure, initial encounter		182 SEPTICEMIA
T81.44XD	Sepsis following a procedure, subsequent encounter		182 SEPTICEMIA
T81.44XS	Sepsis following a procedure, sequela		182 SEPTICEMIA
T81.49XA	Infection following a procedure, other surgical site, initial encounter		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
T81.49XD	Infection following a procedure, other surgical site, subsequent encounter		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
T81.49XS	Infection following a procedure, other surgical site, sequela		285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
Y07.6	Multiple perpetrators of maltreatment and neglect		Informational Diagnosis File
Z04.81	Encounter for examination and observation of victim following forced sexual exploitation	Reviewed by BHAP	121 ABUSE AND NEGLECT
Z04.82	Encounter for examination and observation of victim following forced labor exploitation	Reviewed by BHAP	121 ABUSE AND NEGLECT
Z04.89	Encounter for examination and observation for other specified reasons		Diagnostic Workup File (DWF)
Z13.30	Encounter for screening examination for mental health and behavioral disorders, unspecified	Reviewed by BHAP	Informational Diagnosis File
Z13.31	Encounter for screening for depression	Reviewed by BHAP	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
Z13.32	Encounter for screening for maternal depression	Reviewed by BHAP	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

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New Codes

Code	Code Description	Notes	Placement Recommendation
Z13.39	Encounter for screening examination for other mental health and behavioral disorders	See issues document	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
Z13.40	Encounter for screening for unspecified developmental delays	Previous code Z13.4 (Encounter for screening for certain developmental disorders in childhood) was on line 3 Reviewed by BHAP	Informational Diagnosis File
Z13.41	Encounter for autism screening	Reviewed by BHAP	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
Z13.42	Encounter for screening for global developmental delays (milestones)	Reviewed by BHAP	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
Z13.49	Encounter for screening for other developmental delays	Reviewed by BHAP	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
Z20.821	Contact with and (suspected) exposure to Zika virus	Similar code Z20.828 (Contact with and (suspected) exposure to other viral communicable diseases) is on line 3	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
Z28.83	Immunization not carried out due to unavailability of vaccine		Informational Diagnosis File
Z62.813	Personal history of forced labor or sexual exploitation in childhood		Informational Diagnosis File
Z83.430	Family history of elevated lipoprotein(a)		Informational Diagnosis File
Z83.438	Family history of other disorder of lipoprotein metabolism and other lipidemia	Family history of hypercholesterolemia is on the DWF.	Informational Diagnosis File
Z91.42	Personal history of forced labor or sexual exploitation		Informational Diagnosis File

2019 ICD-10 Code Placement Issues

1) **E75.26**, Sulfatase deficiency
    a. Definition: Sulfatase deficiency is a very rare autosomal recessive lysosomal storage disease[1] caused by a deficiency in multiple sulfatase enzymes, or in formylglycine-generating enzyme, which activates sulfatases. It is similar to mucopolysaccharidosis.
    b. Similar codes: Sulfatase deficiency was coded by E75.29 (Other sphingolipidosis) which was on lines 71,292,345,377. The E76 series (mucopolysaccharidoses) are on lines 60,71,292,345,377,650. Per the NIH website on rare diseases, treatment includes physical therapy and supportive services.
    c. <u>HERC staff recommendations:</u>
        i. Add ICD-10 E75.26 (Sulfatase deficiency) to lines 71,292,345, and 377 as the only treatment is supportive care
            1. 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
            2. 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
            3. 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS
            4. 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION

2) **E78.41**, Elevated Lipoprotein(a)
    A. Definition: lipoprotein(a) is being investigated as an independent risk factor for developing vascular disease, separate from traditional cholesterol measurements. Although therapies that lower lipoprotein(a) levels exist, mainly niacin based medications, these interventions have not been shown to reduce cardiovascular risk in modern clinical trials. The CPT code for measuring lipoprotein(a) levels (CPT 83695) was reviewed as a new CPT code in January, 2014 and added to line 660/GN173 as having no evidence of effectiveness.
    B. Other codes:
        I. CPT 83695 (Lipoprotein (a)) is on line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
    C. <u>HERC staff recommendation</u>:
        I. Add ICD-10 E78.41, Elevated Lipoprotein(a) to line 650 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

3) **F53.0** Postpartum depression
   A. Definition: a range of mental health disorders ranging from mild depression to severe depression, with psychosis possible. Puerperal psychosis has its own ICD-10 code (F53.1). Postpartum depression may be treated in a primary care home, maternity care office, or in a mental health setting.
   B. Coding: no mental health treatment codes appear on line 1 PREGNANCY
   c. Possible lines for placement:
      1. 7 MAJOR DEPRESSION, RECURRENT; MAJOR DEPRESSION, SINGLE EPISODE, SEVERE
      2. 204 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE
   D. BHAP discussion/recommendation: It was decided that since this illness is a spectrum of severity, it should be placed on the higher severity depression line (line 7) to match the higher severity range possible with this diagnosis. Additionally, it was noted that postpartum depression affects the infant's health as well as the mother, which was more reason to place this diagnosis on a high priority line.
   E. <u>HERC staff/BHAP recommendation</u>:
      I. Add F53.0 (Postpartum depression) to line 7 MAJOR DEPRESSION, RECURRENT; MAJOR DEPRESSION, SINGLE EPISODE, SEVERE

4) **H02.88** Meibomian gland dysfunction eyelid
   a. Definition: Meibomian gland dysfunction is blockage or some other abnormality of the meibomian glands so they don't secrete enough oil into the tears. Because the tears then evaporate too quickly, MGD is a leading cause of dry eye syndrome. It also is associated with an eyelid problem called blepharitis (inflammation of the eyelid).
   b. This condition was previously coded under H02.89 (Other specified disorders of eyelid) which is on lines 483 BELL'S PALSY, EXPOSURE KERATOCONJUNCTIVITIS and 652 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
   c. Similar codes: H04.12 (Dry eye syndrome) is on line 508 DYSFUNCTION OF NASOLACRIMAL SYSTEM IN ADULTS; LACRIMAL SYSTEM LACERATION. H01.0 (Blepharitis) is on line 567 BLEPHARITIS.
   d. <u>HERC staff recommendation</u>:
      i. Place H02.88 (Meibomian gland dysfunction eyelid) on line 508 DYSFUNCTION OF NASOLACRIMAL SYSTEM IN ADULTS; LACRIMAL SYSTEM LACERATION

5) **H10.82** Rosacea conjunctivitis
   a. Definition: Ocular rosacea is inflammation that causes redness, burning and itching of the eyes. It often develops in people who have rosacea. Treatment is good eye care as well as medications used to treat rosacea (oral tetracycline, etc.). The condition is chronic.
   b. Similar codes: H10.4 (Chronic conjunctivitis) is on line 499 CHRONIC CONJUNCTIVITIS, BLEPHAROCONJUNCTIVITIS. L71.8 (Other rosacea) is on line 520 ROSACEA; ACNE.

c. HERC staff recommendation:
    i. Place H10.82 (Rosacea conjunctivitis) on line 499 CHRONIC CONJUNCTIVITIS, BLEPHAROCONJUNCTIVITIS

6) **Z13.39** Encounter for screening examination for other mental health and behavioral disorders
    a. Definition: screening for mental health disorders other than depression, postpartum depression, and developmental delay/autism
    b. BHAP discussion: HERC staff initially proposed placement on the Diagnostic Work Up File, but BHAP did not feel that this code belonged there, as that would open it up to too broad of possible utilization. The group discussed the possible diagnoses that could be screened for with this diagnosis. Members felt that there were evidence based screening tools for ADHD, anxiety, and OCD. It was noted that the only mental health screening currently recommended by the USPSTF was for depression. The group noted that other, non-USPSTF, screening was included on line 3. It was noted that pediatrics uses even more broad screenings that might fall under this category, such as family violence screens. The final recommendation from BHAP was to place on line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS, and HERC staff will research and summarize USPSTF and other evidence based guidelines for mental health screening that might utilize this code for discussion at the August VBBS meeting.
    c. Additional research:
        i. USPSTF recommended mental health screenings (2018):
            1. Alcohol and drug misuse (B recommendation for adults, I recommendation for adolescents). This would use the SBIRT screening HCPCS codes. There is no specific ICD-10 code for this diagnosis (a general preventive exam diagnosis could be used). Z13.39 is proposed by some coding sources as a possible diagnosis code to use for alcohol and drug misuse screening.
            2. Child abuse or neglect; intimate partner abuse; elder abuse: The diagnosis and billing codes for these issues are included on line 121 ABUSE AND NEGLECT
            3. Depression: would use the new ICD-10 code Z13.31
            4. Suicide risk screening (I recommendation): could use ICD-10 R45.851 (suicidal ideations). However, for screening without symptoms, the Z13.39 code is proposed by some billing source as a code for use for this type of screening
        ii. AAP (2018) recommends regular screening for behavioral and emotional health issues. Many of these have no specific ICD-10 code
        iii. Many clinics screen for anxiety, but there is no specific ICD-10 code for this.
    d. HERC staff/BHAP recommendation:
        I. Add **Z13.39** (Encounter for screening examination for other mental health and behavioral disorders) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

Brow Ptosis
2019 ICD-10 Code Placement Issues

1) **H57.81** Brow ptosis
    a. Definition: Brow ptosis is decent of the brow and brow fat pad and typically occurs with advancing age. Drooping of the eyebrows can occur to such an extent that excess tissue is pushed into the upper eyelid that may cause mechanical blepharoptosis and/or dermatochalasis. In the most severe cases, the drooping can obstruct the visual field and cause positional head changes. There are 2 types of ptosis: acquired and congenital. Ptosis in early childhood can lead to amblyopia. Ptosis may occur because the levator muscle's attachment to the lid is weakening with age. Acquired ptosis can also be caused by a number of different things, such as disease that impairs the nerves, diabetes, injury, tumors, inflammation, or aneurysms. Congenital ptosis may be caused by a problem with nerve innervation or a weak muscle. Drooping eyelids may also be the result of diseases such as myotonic dystrophy or myasthenia gravis. It is considered a cosmetic issue unless the visual field is impacted. The treatment is surgical repair (blepharoptosis).
    b. Coding:
        i. CPT 67900 (Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)) is on lines 351 STRABISMUS DUE TO NEUROLOGIC DISORDER and 469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT.
        ii. ICD-10 Q10.0 (Congenital ptosis) is on lines 393 and 469.
        iii. GN130 details criteria for the similar procedure of blepharoplasty (upper eyelid surgery)

GUIDELINE NOTE 130, BLEPHAROPLASTY

Line 469

Blepharoplasty is covered when 1) visual fields demonstrate an absolute superior defect to within 15 degrees of fixation, 2) upper eyelid position contributes to difficulty tolerating a prosthesis in an anophthalmic socket, 3) essential blepharospasm or hemifacial spasm is present, OR 4) when there is significant ptosis in the downgaze reading position.

    c. Other coverage:
        i. **Aetna 2018**:
            1. Brow ptosis repair for laxity of the forehead muscles causing functional visual impairment is covered when the following criteria are met:
                a. Photographs show the eyebrow below the supra-orbital rim; *and*
                b. Documentation of a visual field test without the brow taped, shows points of visual loss inside the 25-degree circle of the superior field that is corrected when taped, and shows improvement in the superior field with no visual loss inside the 40- degree circle of the superior field; *and*
                c. Brow ptosis is causing a functional impairment of upper/outer visual fields with documented interference with vision or visual field related activities such as difficulty reading due to upper

eyelid drooping, looking through the eyelashes or seeing the upper eyelid skin

2. Aetna considers surgical correction of congenital ptosis medically necessary to allow proper visual development in infants and children when the following criteria are met:
    a. Infant or child has congenital ptosis (present at birth and detected within the first year of life); *and*
    b. Ptosis interferes with field of vision (visual field testing not required); *and*
    c. Child has abnormal head posture (e.g., head tilt or turn, chin up or chin down), amblyopia or strabismus
3. Surgery is considered cosmetic if performed for mild ptosis that is only of cosmetic concern.

ii. Medicare LDC 2015 (https://med.noridianmedicare.com/documents/10546/6990983/Blepharoplasty+Eyelid+Surgery+and+Brow+Lift+LCD/61353f20-a2dc-420b-9a70-542dd57db939**)**

1. For the purposes of this policy, these surgeries [blepharoplasty, blepharoptosis repair, and brow ptosis repair] (either individually or in the minimum combination required to achieve a satisfactory surgical outcome) are functional when overhanging skin or upper lid position secondary to dermatochalasis, blepharochalasis, blepharoptosis, or pseudoptosis is sufficiently low to produce a visually significant field restriction considered by this policy to be approximately 30 degrees or less from fixation. Published literature correlates this amount of field restriction with a Margin Reflex Distance (see below) of 2.0 mm or less.
2. Criteria that must be documented:
    a. A functional deficit or disturbance secondary to eyelid and/or brow abnormalities must be documented, such as interference with vision or visual field that impacts an activity of daily living (such as difficulty reading or driving).
    b. Redundant eyelid tissue hanging over the eyelid margin resulting in pseudoptosis where the “pseudo” margin produces a central "pseudo-MRD" of 2.0 mm or less, or
    c. Redundant eyelid tissue predominantly medially or laterally that clearly obscures the line of sight in corresponding gaze.
    d. Photographs are required to support upper eyelid surgery as reasonable and necessary

iii. Premara 2018 (https://www.premera.com/medicalpolicies/7.01.508.pdf**)**

1. Brow lift (repair of brow ptosis due to laxity of the forehead muscles) is considered medically necessary when ALL of the following criteria are met:
    a. Brow ptosis is causing a functional impairment of upper/outer visual fields with documented complaints of interference with

vision or visual field related activities such as difficulty reading due to upper brow drooping, looking through eyelashes, or seeing the upper eyelid skin **AND**

b. Photographs show the eyebrow below the supraorbital rim **AND**
c. Documentation of visual field testing with the brow untapped shows a superior or peripheral visual field of ≤ 20 degrees that is corrected to normal visual field limits when the eyebrow is taped

2. Blepharoplasty, blepharoptosis repair or brow lift is considered not medically necessary when performed to improve a patient's appearance in the absence of any significant signs or symptoms of a functional visual impairment

iv. Pacificsource criteria:
1. Brow ptosis repair (CPT 67900) may be considered medically necessary if the following are documented:
a. Physical exam and photographs show the eyebrow is below the superior orbital rim, and
b. Clear documentation that the visual field impairment cannot be corrected by an upper lid blepharoplasty alone, and
c. Visual fields show that lifting the brow meets the same criteria as above for blepharoplasty

d. Expert input:
i. Congenital brow ptosis:
1. Dr. Daniel Karr and Dr. Michael Chaing (OHSU pediatric ophthalmology) reviewed the congenital ptosis criteria and worked with HERC staff to come up with the first portion of the guideline criteria outlined below
ii. Acquired brow ptosis:
1. Dr. Roger Dailey (OHSU Oculofacial Plastic & Reconstructive Surgery) reviewed the acquired brow ptosis criteria and worked with HERC staff to create the second portion of the guideline below. This criteria is generally based on Medicare criteria

e. <u>HERC staff recommendation</u>:
i. Place H57.81 (Brow ptosis) on lines 393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN for congenital brow ptosis and on lines 469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT Treatment PTOSIS REPAIR and line 652 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY for acquired brow ptosis
1. Will pair with repair CPT codes
ii. Remove ICD-10 Q10.0 (Congenital ptosis) from line 469 and leave only on line 393
iii. Adopt the following guideline note:

GUIDELINE NOTE XXX BROW PTOSIS

Lines 393,469,652

Brow ptosis repair is included on line 393 for congenital brow ptosis in children only when ALL the following criteria are met:

1) The condition developed within the first year of life, and
2) Ptosis interferes with field of vision, and
3) The child has abnormal head posture (e.g., head tilt or turn, chin up or chin down), amblyopia or strabismus or is at high risk for development of amblyopia.

Brow ptosis repair is included on line 469 for acquired brow ptosis only when ALL the following criteria are present:

1) Brow ptosis is causing a functional impairment of upper/outer visual fields with documented complaints of interference with vision or visual field related activities such as difficulty reading or driving due to upper brow drooping, looking through eyelashes, or seeing the upper eyelid skin, and
2) Photographs show the eyebrow below the supraorbital rim, and
3) Overhanging skin due to brow ptosis is sufficiently low to produce a visually significant field restriction of approximately 30 degrees or less from fixation or a central "pseudo-MRD" of 2.0 mm or less, and
4) The visual field impairment cannot be corrected by an upper lid blepharoplasty alone

Otherwise, brow ptosis repair is included on line 652.

Blepharoplasty

Question: Should the blepharoplasty guideline be clarified and brought into alignment with the CMS coverage criteria?

Question source: Holly Jo Hodges, CCO medical director

Issue: Recently, dermatochalasis was added to a covered line to pair with blepharoplasty. The blepharoplasty guideline was written by the ophthalmology ICD-10 reviewers, but never utilized as the diagnosis code needed for pairing with blepharoplasty was not added to the line in error. In May, 2018, the HERC added the dermatochalsis diagnosis code to the blepharoplasty line. Dr. Hodges requested that the blepharoplasty guideline be reviewed. In particular, the first clause of the guideline was found to be confusing. CMS national coverage determination language has been updated since the ICD-10 ophthalomology review and Dr. Hodges suggested substituting in the current LCD language. The new language requires that the eyelid droop is "sufficiently low to produce a visually significant field restriction considered by this policy to be approximately 30 degrees or less from fixation." Changing the current language requiring "visual fields demonstrate an absolute superior defect to within 15 degrees of fixation" to language requiring "30 degree loss of visual field" will allow ease of reviewing and reduce confusion among ophthalmologists.

HERC staff recommendation:

1) Modify GN130 as shown below

GUIDELINE NOTE 130, BLEPHAROPLASTY

Line 469

Blepharoplasty is covered when 1) ~~visual fields demonstrate an absolute superior defect to within 15 degrees of fixation~~ a minimum of 30 degrees of visual field loss with upper lid skin/margin in repose, 2) upper eyelid position contributes to difficulty tolerating a prosthesis in an anophthalmic socket, 3) essential blepharospasm or hemifacial spasm is present, OR 4) when there is significant ptosis in the downgaze reading position.

FACT SHEET

Blepharoplasty

LCD L33944

Medicare does not cover cosmetic surgery or expenses incurred in connection with such surgery. This exclusion does not appy to surgery in connection with the treatment of an accidental injury or for the improvement of the functioning of a malformed body member. (CMS Publication 100-2, chapter 16, section 120, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c16.pdf)

Any procedure(s) involving blepharoplasty and billed to this contractor MUST be supported by documented patient complaints which justify functional surgery.

This documentation must address the signs and symptoms commonly found in association with ptosis, pseudoptosis, blepharochalasis and/or dermatochalasis.

These include, but are not limited to:

- Significant interference with vision or superior or lateral visual field (i.e.. difficulty seeing objects approaching from the periphery)
- Difficulty reading due to superior visual field loss
- Looking through the eyelashes or seeing the upper eyelid skin

Visual Field Testing

- Demonstrate a significant loss of superior visual field and potential correction of the visual field by the proposed procedure(s).
- A minimum 12 degree OR 30 percent loss of upper field of vision with upper lid skin and/or upper lid margin in repose and elevated (by taping of the lid) to demonstrate potential correction by the proposed procedure or procedures is required.
- Testing of eye(s) both at rest and with lid elevation (taped, manually retracted)
- When planned procedure is for ptosis or the ptosis is concurrent with dermatochalasis; the visual field study should be repeated with the true eyelid taped, so the eyelid margin assumes the correct anatomic position
- Include Patient name, date of testing and eye(s) tested
- When both eyes are tested the test MUST clearly distinguish right (OD) from left (OS)

Visual field studies are not required when the indication for surgery is entropion or extropion.

Documentation

Documentation of Medical Necessity should include but is not limited to:

- Signed Office Visit Record
  - The subjective complaints of the patient must be well documented in the medical record and should support functional impairment of the eyelid (i.e. difficulty with peripheral vision, patient must lift eyelids to read, patient must look through lashes, etc)
- Signed Operative Report

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FACT SHEET

Blepharoplasty

LCD L33944

Additional Information

In cases of induction of visually compromising dermatochalasis by ptosis repair in patient having large dehiscence of the levator aponeurosis documentation must demonstrate:

- Dehiscence of the levator aponeurosis; and
- An operative note indicating the skin excess after the ptosis has been repaired and blepharoplasty is necessary

Please note that ALL services ordered or rendered to Medicare beneficiaries MUST be signed. Signatures may be handwritten or electronically signed; exceptions for stamped signatures are described in MLN Matters article MM8219 (http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8219.pdf). You should NOT add late signatures to a medical record but instead make use of the signature authentication process outlined in MLN Matters article MM6698 (http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM6698.pdf). A sample attestation statement (http://www.cgsmedicare.com/kyb/claims/cert/Attestation_form.pdf) is available on the CGS website. Guidelines regarding signature requirements are located in CMS Publication 100-8, chapter 3, section 3.3.2.4 (http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf).

References:

- LCD L33944 – Blepharoplasty: http://www.cgsmedicare.com/partb/medicalpolicy/index.html
- CMS Publication 100-02, chapter 16, sections 20.2.1, 120: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673.html?DLPage=1&DLSort=0&DLSortDir=ascending
- CMS Publication 100-08, chapter 3, section 3.4.1.1: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673.html?DLPage=1&DLSort=0&DLSortDir=ascending

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Section 6.0

Biennial Review

2020 Biennial Review
Severe Acne

Question: Should severe acne other than acne conglobata be included on a covered line on the Prioritized List? If so, what degree of acne severity should qualify for coverage?

Question sources: Julie Dhossche, MD, resident OHSU Dermatology; Darin Vaughan, MD, pediatrician in Bend; several community dermatology providers

Issue: Adding coverage for severe acne was discussed at the May, 2018 VBBS meeting. At the May meeting, several dermatology experts testified and HERC staff reviewed the evidence for coverage of severe acne. There was general agreement among VbBS members that the more severe forms of acne should be covered. The staff proposal of a new line for severe acne, separate from the acne conglobata line, was considered the more desirable approach. HERC staff was directed to work with the dermatology experts on the proposal to address several areas of concern.

Additionally, VBBS wanted to cover acne fulminans on the same line as acne conglobata. There is no specific ICD-10 code for acne fulminans. Consultation with P&T staff found that P&T could not review medications for conditions such as acne fulminans and develop appropriate PA criteria prior to their November 2018 meeting. The earliest implementation for adding acne fulminans would likely be January 1, 2019.

Current Prioritized List status:

1) Acne conglobata (ICD-10 L70.1) is on line 373 ACNE CONGLOBATA (SEVERE CYSTIC ACNE)
2) All other acne diagnoses (ICD-10 L70.0, L70.2-9) are on line 520 ROSACEA; ACNE

GUIDELINE NOTE 132, ACNE CONGLOBATA

Line 373

Acne conglobata is only included on Line 373 if it involves recurrent abscesses or communicating sinuses.

2020 Biennial Review
Severe Acne

Expert guidelines

American Academy of Dermatology 2016 guideline on treatment of acne https://ac.els-cdn.com/S0190962215026146/1-s2.0-S0190962215026146-main.pdf?_tid=fd86cfc2-fc10-4e3e-9bf1-8984ca556e33&acdnat=1525190517_15f4dda7deb7d000be0af61c08fefc37:

1) Treatments: lists first line and alternative therapies for mild, moderate or severe acne.
2) Definition of mild, moderate or severe acne:
    a. To date, there is no universally agreed-upon grading system, and systems can differ greatly between studies. In addition, interobserver reliability of these scales varies, but has been poor in some studies.

American Academy of Pediatrics 2013 guideline on treatment of acne http://pediatrics.aappublications.org/content/pediatrics/131/Supplement_3/S163.full.pdf:

1) It has been repeatedly demonstrated that acne can have a significant adverse impact on quality of life, and that the level of distress may not correlate directly with acne severity
2) Defining acne severity:
    a. Acne severity may be classified clinically as mild, moderate, or severe based on the number and type of lesions and the amount of skin involved. Although there are numerous grading systems by which to define acne severity, there is no agreed-upon standard, and interpretation is subjective
    b. Typically, patients' assessments do not correlate well with either those of physicians or published severity scales.
3) Various treatment options are reviewed

European evidence based guidelines for the treatment of acne, 2013 https://www.slideshare.net/UtaiSukviwatsirikul/european-evidencebased-s3-guidelines-for-the-treatment-of-acne:

1) Evidence for various therapies reviewed. For nodular/conglobate acne, a high strength of recommendation was given to oral isotretinoin; a medium strength of recommendation was given to systemic antibiotics in combination with azelaic acid. Low strength of recommendation was given or oral anti-androgens in combination with oral antibiotics, and to systemic antibiotics in combination with adapalene and/or benzoyl peroxide

2020 Biennial Review
Severe Acne

HERC staff recommendations:

1) Addition of acne fulminans to line 373 effective January 1, 2019
    i. Change line title for line 373 ACNE CONGLOBATA ~~(SEVERE CYSTIC ACNE)~~ AND ACNE FULMINANS
    ii. Add ICD-10 L70.0 (acne vulgaris) to line 373
    iii. Modify GN 132 as shown below
2) Creation of a new line for severe cystic acne effective January 1, 2020
    i. Create a new line and guideline as shown below
    ii. Score this new line as shown below
    iii. Change the line title for line 520 to ROSACEA; MILD/MODERATE ACNE

GUIDELINE NOTE 132, ACNE CONGLOBATA AND ACNE FULMINANS

Line 373

Acne conglobata is only included on Line 373 if it involves recurrent abscesses or communicating sinuses. ICD-10 L70.0 is included on line 132 only for acne fulminans.

New line

Line XXX SEVERE CYSTIC ACNE

Treatment: MEDICAL AND SURGICAL TREATMENT

a. ICD-10 codes: L70 (acne)
b. CPT/HCPCS codes: all included currently on line 373 ACNE CONGLOBATA (SEVERE CYSTIC ACNE)

GUIDELINE NOTE XXX SEVERE CYSTIC ACNE

Line XXX,520

Acne is only included on Line XXX if it is severe, defined as the presence of the following characteristics: persistent or recurrent inflammatory nodules and cysts AND ongoing scarring. Otherwise, acne diagnoses are included on line 520.

Note that acne with recurrent abscesses or communicating sinuses is covered according to Guideline Note 132 ACNE CONGLOBATA AND ACNE FULMINANS.

Line scoring

Current scoring in parentheses for lines 373 ACNE CONGLOBATA (SEVERE CYSTIC ACNE)/530 ROSACEA; ACNE

Category 7 (7,7)
Impact on Healthy Life Years 1 (2,1)
Impact on Pain and Suffering 3 (3,2)
Population effects 0 (0)
Vulnerable populations 0 (0)
Tertiary prevention 0 (2,0)
Effectiveness 4 (4,4)
Need for treatment 0.8 (1,0.5)
Net cost 3 (3,3)

SCORE 256, PUTS ON LINE 451

Burn Line Reorganization
2020 Biennial Review

Question: Should the multiple burn lines be reorganized?

Question source: VBBS

Issue: The burn lines were discussed at the May 2018 VBBS meeting. At that meeting, a new guideline defining "vital site" in the burn line titles was adopted. During that meeting, it was noted that the current division of burns between the various lines did not agree with current burn treatment standards. The burn lines were created with the initial Prioritized Lists, and have not been significantly altered. The different lines contain many of the same ICD-10 diagnosis codes. Lines are prioritized more highly if they involve full thickness burns, or extensive partial thickness burns. The only non-covered burn line is for minor burns, and contains ICD-10 codes for partial thickness burns of presumably minor percent body surface area. These burns could still benefit from therapy such as topical burn creams or dressings.

There are currently 4 burn lines and 1 line for other types of burns:
57 BURN, FULL THICKNESS GREATER THAN 10% OF BODY SURFACE Treatment: FREE SKIN GRAFT, MEDICAL THERAPY
72 BURN, PARTIAL THICKNESS GREATER THAN 30% OF BODY SURFACE OR WITH VITAL SITE; FULL THICKNESS, LESS THAN 10% OF BODY SURFACE Treatment: FREE SKIN GRAFT, MEDICAL THERAPY
181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE) Treatment: MEDICAL THERAPY, BURN TREATMENT
197 BURN, PARTIAL THICKNESS WITHOUT VITAL SITE REQUIRING GRAFTING, UP TO 30% OF BODY SURFACE Treatment: FREE SKIN GRAFT, MEDICAL THERAPY
602 MINOR BURNS Treatment: MEDICAL THERAPY

On review, HERC staff found that line 57 included all third degree burn diagnoses and multiple treatment codes not found on other burn lines, mostly involving amputations. Lines 72 and 197 had essentially the same treatment CPT codes. The ICD-10 diagnoses codes that differed between lines 72 and 197 mainly appeared to be regarding burns to the face, neck, genitals, foot and palm (on line 72). Most other second degree burn diagnoses appear on both lines 72 and 197. Line 602 had many similar diagnoses to lines 72 and 197, as well as first degree burn diagnoses.

Standard references for defining burn severity state:

> Major burn injury is defined as partial-thickness burns involving more than 25% of total body surface area (TBSA) in adults or 20% of TBSA in children younger than 10 years or adults older than 50 years; full-thickness burns involving more than 10% of TBSA; burns involving the face, eyes, ears, hands, feet, or perineum that may result in functional or cosmetic impairment; burns caused by caustic chemical agents; high-voltage electrical injury; burns complicated by inhalation injury or major trauma; or burns sustained by high-risk patients (those with underlying debilitating diseases).

After the May, 2018 meeting, HERC staff were directed to determine if there were any PAs or other limits on burn dressings or topical burn medications. Staff was also directed to draft up a severe, moderate and mild burn line for consideration at a later VBBS meeting.

P&T staff indicated that burn medications, such as Silvadene, are not subject to PA. They did not feel that the proposed changes would have a significant impact on utilization of medications. HSD staff indicated that dressings are either bundled into visit codes or have unit limits. There is no PA or diagnosis restrictions on burn dressings, including medication-impregnated dressings.

Burn Line Reorganization
2020 Biennial Review

HERC staff recommendations:

1) Reorganize the current burn lines as shown below, effective January 1, 2020
    a. Line 57 remains the same as the severe burn line
    b. Lines 72 and 197 are combined, overlapping diagnoses with line 57 are removed
    c. Line 181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE) remains unchanged
    d. Line 607 remains as is with removal of any second degree burn diagnoses
    e. Delete the newly adopted GUIDELINE NOTE XXX MODERATE/SEVERE BURNS

Line 57 SEVERE BURNS ~~BURN, FULL THICKNESS GREATER THAN 10% OF BODY SURFACE~~ Treatment: FREE SKIN GRAFT, MEDICAL THERAPY
ICD-10 All currently on line 57 (third degree burn and corrosion codes; burns of eyes, trachea, larynx, GI tract, ears)
CPT: all currently on line 57
HCPCS: all currently on line 57

LINE XXX MODERATE BURNS Treatment: FREE SKIN GRAFT, MEDICAL THERAPY
ICD-10: all second degree burn codes [remove all 3rd degree burn codes, L00 (Staphylococcal scalded skin syndrome) and L49.7 (Exfoliation due to erythematous condition involving 70-79 percent of body surface) and leave only on line 57] [Add L55.1 (Sunburn of second degree)]
CPT: all currently on line 72 or 197
HCPCS: all currently on line 72 or 197

Line scoring for LINE XXX MODERATE BURNS
Current scoring in parentheses for lines 72 BURN, PARTIAL THICKNESS GREATER THAN 30% OF BODY SURFACE OR WITH VITAL SITE; FULL THICKNESS, LESS THAN 10% OF BODY SURFACE/ 197 BURN, PARTIAL THICKNESS WITHOUT VITAL SITE REQUIRING GRAFTING, UP TO 30% OF BODY SURFACE

Category 6 (6,6)
Impact on Healthy Life Years 7 (8,7)
Impact on Pain and Suffering 3 (4,2)
Population effects 0 (0,0)
Vulnerable populations 0 (0,1)
Tertiary prevention 3 (4,3)
Effectiveness 4 (4,3)
Need for treatment 1 (1,1)
Net cost 2 (1,2)

SCORE 2080, PUTS ON LINE 127

602 MINOR BURNS Treatment: MEDICAL THERAPY
ICD-10 All first degree and unspecified degree burn codes [remove all 2nd degree burn codes, L00 (Staphylococcal scalded skin syndrome) and L55.1 (Sunburn of second degree)]
CPT: all currently on line 602
HCPCS: all currently on line 602

Section 7.0

Previously Discussed Items

Drug Eluting Cardiac Stents

Question: Should there be any restrictions on the use of drug eluting stents for cardiac procedures on the Prioritized List?

Question source: VBBS

Issue: Drug eluting stents are coded with HCPCS C9600-C9608. The HCPCS "C" codes were reviewed in May, 2018 by VBBS. The HERC staff recommendation was for drug eluting coronary artery stents to be placed on several lines on the Prioritized list. VBBS requested that HERC staff summarize the evidence supporting the use of drug eluting stents and bring this evidence for discussion regarding coverage on the Prioritized List.

Coronary artery disease can be treated surgically with coronary artery bypass grafting (CABG) or with percutaneous insertion of stents into the occluded artery. There are two types of stents, bare-metal stents (BMSs) and stents coated with a drug, usually an immune suppressant, to reduce inflammation or an antimitotic agent to reduce cell proliferation. The drug eluting stents are higher cost than the BMS, but have a lower rate of restenosis and need for revascularization. Newer generation drug eluting stents have less in-stent stenosis and some sources report they are lower cost.

Similar CPT codes (e.g. 92928 Percutaneous transcatheter placement of intracoronary stent(s)) are on 45 CORONARY ARTERY ANOMALY, 69 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION, 98 HEART FAILURE, 189 CHRONIC ISCHEMIC HEART DISEASE, and 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT. Drug eluting stents were reviewed by VBBS/HERC in 2012 as part of new 2013 HCPCS codes review, prior to HERC staff not reviewing any "C" codes. In 2012, placement was recommended on the equivalents of lines 45, 69, 98, and 189. Line 285 would match non-drug eluding stents. However, the 2012 meeting notes recommend that HTAS review this technology at some point and that this review come back to VBBS/HERC.

Drug Eluting Cardiac Stents

Drug eluting stent HCPCS codes

HCPCS Code	Code description
C9600	Percutaneous transcatheter placement of drug eluting intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch
C9601	each additional branch of a major coronary artery
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch
C9603	each additional branch of a major coronary artery
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel
C9605	each additional branch of a major coronary artery
C9606	Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel
C9607	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel
C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft

<u>Evidence</u>

Comparative effectiveness

1) **Stefanini 2013** review of DES vs BMS
    a. In a network meta-analysis involving 38 trials and more than 18,000 patients, there was a marked reduction in the rate of repeat revascularization with both sirolimus-eluting stents and paclitaxel-eluting stents, as compared with bare metal stents. On the basis of this analysis, 7 patients (95% confidence interval [CI], 6 to 8) would need to be treated with sirolimus-eluting stents and 8 patients (95% CI, 7 to 10) with paclitaxel-eluting stents in order to prevent one repeat revascularization as compared with bare-metal stents.
    b. Conclusions: Drug-eluting stents mitigate the risk of restenosis and thus represent an important advance in the percutaneous treatment of coronary artery disease. New drug-eluting stents with thin struts releasing limus-family analogues from durable polymers have further improved clinical outcomes, as compared with early-generation stents releasing sirolimus or paclitaxel. The risk of stent thrombosis has become exceedingly low.

Cost effectiveness

1) **Ferko 2017**, Cost effectiveness analysis of second generation drug eluting stents vs bare metal stents
    a. Analysis of cobalt-chromium everolimus drug eluting stent vs BMS

   b. US Medicare claims data
   c. Higher rates of MI, all cause cardiac mortality, and repeat procedure with BMS
   d. The base-case and secondary analyses reported an additional 0.018 and 0.013 quality-adjusted life years (QALYs) and cost savings of $236 and $288, respectively with Co-Cr EES versus BMS. Results were robust to sensitivity analyses and were most sensitive to the price of clopidogrel. In the probabilistic sensitivity analysis, Co-Cr EES was associated with a greater than 99% chance of being cost saving or cost effective (at a cost per QALY threshold of $50,000) versus BMS.
   e. Conclusions: Using data from a recent patient level meta-analysis and contemporary cost data, this analysis found that PCI with Co-Cr EES is more effective and less costly than PCI with BMS.
2) **Baschet 2016**, cost effectiveness analysis of drug eluting stents vs bare metal stents
   a. French national health insurance data
   b. DES are dominant over BMS, with an increase in event-free survival and a cost-reduction of €184, primarily due to a diminution of second revascularisations, and an absence of myocardial infarction and stent thrombosis. No differences in overall survival were predicted These results are robust for uncertainty on one-way deterministic and probabilistic sensitivity analyses. Using a cost-effectiveness threshold of €7000 per major cardiac event-free year gained, DES has a >95% probability of being cost-effective versus BMS.
   a. Conclusions: Following DES price decrease, new generation DES development and taking into account recent meta-analyses results, the DES can now be considered cost-effective regardless of selective indication in France

<u>Expert guidelines</u>

1) NICE 2008 (https://www.nice.org.uk/guidance/ta152**)**
   a. Drug-eluting stents are recommended for use in percutaneous coronary intervention for the treatment of coronary artery disease, within their instructions for use, only if:
      i. the target artery to be treated has less than a 3-mm calibre or the lesion is longer than 15 mm, and
      ii. the price difference between drug-eluting stents and bare-metal stents is no more than £300.
2) European Society of Cardiology/European Society of Cardio-Thoracic Surgery **ESC/ESCTS 2014** guidelines (https://academic.oup.com/ejcts/article/46/4/517/2755259)
   a. Non-ST segment elevation acute coronary syndrome
      i. New-generation DES are indicated for percutaneous treatment of significant coronary lesions in ACS patients (Level of recommendation: 1A)
   b. STEMI
      i. New-generation DES are recommended over BMS in primary PCI. (Level of recommendation: 1A)
3) **2011 ACCF/AHA/SCAI** Guideline for Percutaneous Coronary Intervention (http://www.onlinejacc.org/content/58/24/2550)
   a. DES are useful as an alternative to BMS to reduce the risk of restenosis in cases in which the risk of restenosis is increased and the patient is likely to be able to tolerate and comply with prolonged dual antiplatelet therapy *(Level of Evidence: 1A for elective PCI, Level of Evidence: 1C for UA/NSTEMI*
   b. DES generally preferred over BMS:

i. Left main disease
ii. Small vessels
iii. In-stent restenosis
iv. Bifurcations
v. Diabetes
vi. Long lesions
vii. Multiple lesions
viii. Saphenous vein grafts

a. BMI generally preferred over DES:
   i. Unable to tolerate or comply with dual antiplatelet therapy (DAPT)
   ii. Anticipated surgery requiring discontinuation of DAPT within 12 months
   iii. High risk of bleeding

Expert input

Eric Stecker, OHSU Cardiology

Recommends BMS for very small proportion of cases (large caliber, short lesions in non-diabetics). And some risk of extra stress testing to prove no restenosis that could erode savings. In addition, cardiologists have less familiarity and confidence in BMS than they did when the trials of DES were done, so there will be more unnecessary and costly stress testing done now.

Other coverage

No private insurer restricted drug eluting stents when used in FDA approved clinical situations

HERC staff summary

Second generation drug eluting stents appear to have initially higher cost than bare metal stents, but overall lower costs due to lower rates of repeat revascularization procedures and other complications. Major expert guidelines all recommend DUS in most clinical situations over BMS.

HERC staff recommendation

1) Add HCPCS C9600-C9608 (Drug eluting stent percutaneous coronary interventions) to lines
   a. 45 CORONARY ARTERY ANOMALY
   b. 69 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION, 98 HEART FAILURE
   c. 189 CHRONIC ISCHEMIC HEART DISEASE
   d. 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT

REVIEW ARTICLE

DRUG THERAPY

Drug-Eluting Coronary-Artery Stents

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Percutaneous coronary intervention, which was pioneered by Grüntzig in 1977, has become the most frequently performed therapeutic procedure in medicine.[1] The use of balloon angioplasty, which was limited by abrupt vessel closure owing to dissections and restenosis, prompted the development of stents to maintain lumen integrity.[2] Coronary stents improved procedural safety and efficacy and eliminated the need for surgical standby.[3] However, stent-mediated arterial injury elicited neointimal hyperplasia, leading to restenosis and the need for repeat revascularization in up to one third of patients.[4]

Drug-eluting stents with controlled local release of antiproliferative agents have consistently reduced the risk of repeat revascularization, as compared with bare-metal stents.[5-7] However, a number of reports presented at the European Society of Cardiology Congress in 2006 questioned the long-term safety of drug-eluting stents, leading to a reduction in their use, along with intense review by regulatory agencies and recommendations to extend dual antiplatelet therapy for at least 12 months.[8-10] In 2007, the *Journal* published evidence that stents releasing sirolimus or paclitaxel, as compared with bare-metal stents, were associated with similar risks of death and myocardial infarction but with an increased, albeit small, risk of stent thrombosis beyond 1 year after stent implantation.[8,11-14] Since then, new platforms for drug-eluting stents that are aimed at improving safety and efficacy have been developed. Drug-eluting stents are now implanted in more than 500,000 patients every year in the United States.[15] This review provides an overview of currently available devices, summarizes evidence from randomized trials, and outlines clinical indications for use.

Platforms for Drug-Eluting Stents

Drug-eluting stents have three components: a metallic stent platform, a polymer coating, and an antiproliferative agent (Fig. 1).

Stent Platforms

Available platforms are made of stainless steel, cobalt–chrome, or platinum–chrome. Cobalt–chrome alloys provide improved radial strength and increased radiopacity, as compared with stainless steel, allowing for engineering of thinner struts with greater deliverability. Platforms made with thinner struts may result in less arterial injury and reduce the risk of restenosis,[16] with lower thrombogenicity.[17] Platinum–chrome alloys are used in an effort to further improve radial strength and conformability.

Polymer Coatings

Polymer coatings that are applied to the stent surface serve as drug carriers and permit controlled drug release. Progress in polymer technology has been aimed at decreasing local inflammatory reactions and thrombosis by improving the biocom-

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Cost-Effectiveness of Percutaneous Coronary Intervention with Cobalt-Chromium Everolimus Eluting Stents versus Bare Metal Stents: Results from a Patient Level meta-Analysis of Randomized Trials

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Background: Second-generation drug eluting stents (DES) may reduce costs and improve clinical outcomes compared to first-generation DES with improved cost-effectiveness when compared to bare metal stents (BMS). We aimed to conduct an economic evaluation of a cobalt-chromium everolimus eluting stent (Co-Cr EES) compared with BMS in percutaneous coronary intervention (PCI). Objective: To conduct a cost-effectiveness analysis (CEA) of a cobalt-chromium everolimus eluting stent

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This work is an original manuscript, which has not been published or submitted simultaneously for publication elsewhere. The manuscript does not include any tables or illustrations that were previously published elsewhere or any photographs. This work was supported by Abbott Vascular, who provided funding to develop the model, conduct the analysis and prepare the manuscript. The funding organization had no influence on the study design, conduct of the analyses, interpretation of the study results, or the decision to submit for publication.

Conflict of interest: M.V. reports personal fees from AstraZeneca, Medicine Company, Terumo Medical, St Jude Vascular, Alvimedica, Abbott Vascular and Correvio, grants from AstraZeneca, nonfinancial support from Medicine Company, and other fees for serving as advisory boards from AstraZeneca and St Jude Vascular, outside the submitted work. J.M.T.H. reports grants from Abbott Vascular, and M.S. reports personal fees from Abbott Vascular, outside the submitted work. C.K. reports grants from the Cardiovascular Research Foundation (Basel, Switzerland), Daiichy Sankyo, and other from Eli Lilly, during the conduct of the study. F.E. reports grants from Abbott Vascular, Biotronik, St Jude Medical, and Terumo, outside the submitted work. S.B. reports grants from AstraZeneca, and personal fees from Abbott, outside the submitted work. T.S., J.B.H., and J.T.H. are employees of Abbott Vascular. N.F. and I.M.S. work as consultants for private sector organizations in the healthcare industry. P.W.S., S.G., G.F., A.B., and A.C., have no conflicts of interest to declare.

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(Co-Cr EES) versus BMS in PCI. Methods: A Markov state transition model with a 2-year time horizon was applied from a US Medicare setting with patients undergoing PCI with Co-Cr EES or BMS. Baseline characteristics, treatment effects, and safety measures were taken from a patient level meta-analysis of 5 RCTs ($n = 4,896$). The base-case analysis evaluated stent-related outcomes; a secondary analysis considered the broader set of outcomes reported in the meta-analysis. Results: The base-case and secondary analyses reported an additional 0.018 and 0.013 quality-adjusted life years (QALYs) and cost savings of $236 and $288, respectively with Co-Cr EES versus BMS. Results were robust to sensitivity analyses and were most sensitive to the price of clopidogrel. In the probabilistic sensitivity analysis, Co-Cr EES was associated with a greater than 99% chance of being cost saving or cost effective (at a cost per QALY threshold of $50,000) versus BMS. Conclusions: Using data from a recent patient level meta-analysis and contemporary cost data, this analysis found that PCI with Co-Cr EES is more effective and less costly than PCI with BMS. **© 2016 The Authors. Catheterization and Cardiovascular Interventions Published by Wiley Periodicals, Inc.**

Key words: drug-eluting stent; bare metal stent; percutaneous coronary intervention; cost-effectiveness

INTRODUCTION

As the first major drug-device combination product for cardiovascular disease, drug-eluting stents (DES) represented a clinical breakthrough in treatment of patients with coronary artery disease (CAD) [1]. The technology continues to evolve, with the recent development of second-generation DES platforms such as the cobalt chromium (Co-Cr) everolimus-eluting stent (EES). These platforms are comprised of permanent polymer coatings, less toxic antiproliferative drugs (e.g., everolimus or zotarolimus), and thin strut stent designs compared with first-generation DES.

Robust randomized controlled trials (RCTs) and several meta-analyses of RCTs have shown that Co-Cr EES is significantly safer and more effective than bare metal stents (BMS), with lower rates of stent thrombosis (ST), myocardial infarction (MI), and cardiac mortality [2–8]. A recent patient level meta-analysis of 4,896 patients from five RCTs (including three all comer studies) found that patients receiving Co-Cr EES had significant reductions in cardiac mortality, MI, definite ST, definite or probable ST, and target vessel revascularization (TVR) versus patients receiving BMS [5]. There are also some indications that second-generation DES reduce costs and improve clinical outcomes compared to first-generation DES [9], with improved cost-effectiveness versus BMS [10–12].

The current study leverages the availability of data from the patient level meta-analysis of RCTs to address the cost effectiveness of Co-Cr EES compared to BMS.

METHODS

Type of Analysis and Perspective. The cost-effectiveness analysis (CEA) was conducted for a 2-year time horizon from the US Medicare perspective [13]. A 2-year time horizon was selected to align with the patient level meta-analysis [5] and previous cost-effectiveness studies of DES compared to BMS [10,14–17]. Costs and outcomes at year 2 were discounted at a rate of 3%.

Study Population

The mean age of patients included in the patient level meta-analysis was 67 years and the majority of patients included were male (76%). Type 2 diabetes mellitus was present in approximately 19% of patients. Forty-four percent of all patients received stenting in the setting of primary PCI and more than 87% underwent PCI treatment for an unstable presentation. The methods and results of the meta-analysis have been reported in detail by Valgimigli et al. [5].

Model Overview

A Markov state transition model was developed in Microsoft Excel 2007 using effectiveness and safety data from the patient level meta-analysis (Fig. 1) [5]. Patients started the model in the "alive" health state, and during each model cycle of 1 year, could transition to deceased. During each 1-year model cycle, "event-free" patients could also experience one or more of the following transient events: MI, ST or TVR. Event risks were only available to inform the probability of moving from event-free to a transient event; data was not available to inform movement between the transient events. The data inputs used in the CEA are summarized in Table I.

Transition Probabilities and Event Risks

The risks of mortality, MI, ST, and TVR were informed by the patient level meta-analysis [5]. The

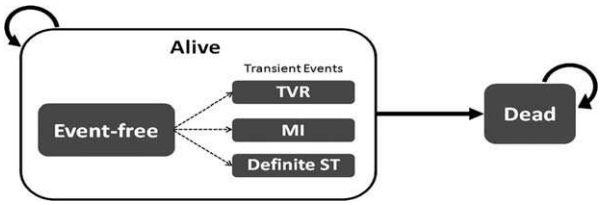


Fig. 1. Overview of the model structure. The model captured both base-case (i.e., TVR, TVR-related MI, ST, and cardiac mortality) and secondary analysis (i.e., TVR, MI, ST, all-cause death) outcomes. MI = myocardial infarction; ST = stent thrombosis; TVR = target vessel revascularization.

authors of the meta-analysis provided the number of patients at risk and the number of events for each treatment group, stratified by year 1 and year 2. The authors also provided cause of mortality (i.e., all-cause or cardiac-related) and type of MI (i.e., TVR-related, any MI).

Resource Use and Unit Costs

The focus of the CEA was costs borne by the US Medicare program, including costs associated with the percutaneous coronary intervention (PCI) procedure (including the stent), TVR, MI, and dual antiplatelet therapy (DAPT). Estimates of resource use and unit costs (2015 US dollars) were obtained from the published literature. Additional technology costs associated with DES versus BMS were included in diagnosis-related group (DRG) payments.

For patients who experienced TVR, re-intervention could be performed by means of coronary artery bypass graft (CABG) or PCI (with stent or without stent). The proportions of patients receiving CABG (10%) or PCI (90%) were taken from a publication reported by Garg et al. [18]. The breakdown of re-intervention with PCI was assumed to be PCI with DES (56%) and PCI without stent (44%) [18].

In the patient level meta-analysis, the duration of DAPT (i.e., clopidogrel in addition to aspirin) ranged from 3 months to 24 months for both DES and BMS [5]. The European Society of Cardiology (ESC) guidelines recommend a DAPT duration of at least 1 month for BMS and 6 months for DES [19]. The ACC guidelines recommended a DAPT duration of 1 month for BMS and 12 months for DES [20]. For the base-case analysis, we assumed a DAPT duration of 6 months for BMS and 12 months for DES. Generic pricing of clopidogrel (75 mg) was based on the wholesale acquisition cost (WAC) published in the US Redbook online pricing database [21]. A 20% mark-up was added to the WAC to be more conservative and to arrive at a total monthly acquisition cost of $23.64 that more closely reflected the average wholesale price (AWP) [22]. An alternative monthly DAPT cost of $91.82 (assuming 50% generic and 50% brand clopidogrel) was evaluated in the sensitivity analyses.

Health Utility

Quality of life impacts were included for CAD, MI, and TVR. A health utility value of 0.85 was applied in the model to patients with CAD and no symptoms [18]. For patients experiencing TVR a health utility decrement of −0.06 was applied for 1 year following the re-intervention, irrespective of revascularization with CABG or PCI [18]. For patients experiencing MI, a health utility of 0.75 was applied for 1 year following the MI [18].

Analysis

The base-case analysis included clinical outcomes from the patient level meta-analysis that were considered to be stent-related: TVR, TVR-related MI, definite ST, and cardiac-related mortality. A secondary analysis was conducted that considered the broader set of clinical outcomes from the meta-analysis: TVR, all MI, definite ST, and all-cause mortality.

One-way sensitivity analyses were conducted in order to test the robustness of the base-case analysis to alternative assumptions and data inputs related to transition probabilities, risks of events, resource use, DAPT therapy costs, and health utility (Table II) [20,23–25]. A probabilistic sensitivity analysis (PSA) was conducted to simultaneously quantify the uncertainty in all key model input parameters.

RESULTS

Base-Case Analysis

Results of the base-case analysis (Table III) demonstrated that Co-Cr EES was more efficacious than BMS. Patients who received PCI with Co-Cr EES experienced fewer cardiac-related deaths, TVR-related MIs, ST, and TVRs, 0.015 additional life years, and 0.018 additional QALYs compared with patients who received PCI with BMS. PCI with Co-Cr EES was also associated with cost savings of $236 per patient. The primary drivers of the cost savings were the reduction in TVR and MI rates, which offset the increased costs of the index procedure and DAPT observed with Co-Cr EES versus BMS.

Results of the secondary analysis (not shown) demonstrated similar results to the base-case analysis. PCI with Co-Cr EES was both more effective (0.009 additional life years and 0.013 additional QALYs per patient) and less costly (-$288 per patient) versus BMS.

openheart

Cost-effectiveness of drug-eluting stents versus bare-metal stents in patients undergoing percutaneous coronary intervention

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ABSTRACT

Objective: To determine the cost-effectiveness of drug-eluting stents (DES) compared with bare-metal stents (BMS) in patients requiring a percutaneous coronary intervention in France, using a recent meta-analysis including second-generation DES.

Methods: A cost-effectiveness analysis was performed in the French National Health Insurance setting. Effectiveness settings were taken from a meta-analysis of 117 762 patient-years with 76 randomised trials. The main effectiveness criterion was major cardiac event-free survival. Effectiveness and costs were modelled over a 5-year horizon using a three-state Markov model. Incremental cost-effectiveness ratios and a cost-effectiveness acceptability curve were calculated for a range of thresholds for willingness to pay per year without major cardiac event gain. Deterministic and probabilistic sensitivity analyses were performed.

Results: Base case results demonstrated that DES are dominant over BMS, with an increase in event-free survival and a cost-reduction of €184, primarily due to a diminution of second revascularisations, and an absence of myocardial infarction and stent thrombosis. These results are robust for uncertainty on one-way deterministic and probabilistic sensitivity analyses. Using a cost-effectiveness threshold of €7000 per major cardiac event-free year gained, DES has a >95% probability of being cost-effective versus BMS.

Conclusions: Following DES price decrease, new-generation DES development and taking into account recent meta-analyses results, the DES can now be considered cost-effective regardless of selective indication in France, according to European recommendations.

KEY QUESTIONS

What is already known about this subject?

- Much debate exists over the risk–benefit and cost-effectiveness ratio of drug-eluting stents (DES) over bare-metal stents (BMS) in terms of safety and efficacy. While DES are widely used in percutaneous coronary interventions, France has one of the lowest rates of use in Europe. Costs of DES devices have come down in recent years and second-generation DES development raises a need for evaluation of cost-effectiveness of DES versus BMS.

What does this study add?

- A cost-effectiveness analysis comparing BMS with DES including second-generation devices showed that in the French-specific setting, DES are associated with a robust cost-reduction mainly due to a reduction in second revascularisations, myocardial infarctions and stent thrombosis. No differences in overall survival were predicted.

How might this impact on clinical practice?

- Consider wider implementation of second-generation DES in percutaneous coronary interventions of this procedure in France.

INTRODUCTION

Coronary artery disease is by far the most common cause of heart disease, resulting from the narrowing of coronary arteries (stenosis) caused by deposition of atherosclerotic plaque. A critical reduction of the blood supply to the heart may result in myocardial infarction or death.[1] Coronary artery bypass grafting was the standard of care before the emergence of bare-metal coronary stents (BMS). Stents are placed via balloon dilation during a percutaneous coronary intervention (PCI). Nonetheless, restenosis occurs in a significant proportion of these patients with BMS (16–44%).[2]

Coronary drug-eluting stents (DES) first became available in 2000. They release antiproliferative and anti-inflammatory substances locally, inhibiting the proliferation of smooth muscle cells, thereby minimising a key aspect contributing to restenosis. In addition, the use of antiplatelet drugs and other

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therapeutic strategies to prevent thrombosis has improved long-term outcomes in these patients. DES are widely employed, with usage varying by country; in the USA, over 70% of PCI performed in 2006 used DES,[3] while in France in 2007 DES were used in 42% of PCIs at a total cost of €106 million.

The relative safety of DES and BMS, notably with respect to stent thrombosis, is still under debate.[4] First-generation DES, sirolimus-eluting stents and paclitaxel-eluting stents have been associated with an increased risk of late stent thrombosis when antiplatelet agents are withheld.[5 6] The introduction of second-generation DES, including everolimus-eluting stents and zotarolimus-eluting stents, has led to claims of improved safety with non-inferior efficacy compared with the first-generation stents, supported by numerous clinical trials.

In 2012, Palmerini *et al*[4] published a large meta-analysis of 49 trials including 50 844 patients comparing the incidence of stent thrombosis with DES versus BMS. They conclude that some DES reduce risk of stent thrombosis, and none have shown a significant increase. The same year, Bangalore *et al*[7] published a meta-analysis comparing the two stent types in terms of stent thrombosis, target vessel revascularisation, death and myocardial infarction with 117 762 patient-years of follow-up from 76 international randomised trials. While they found that the risk of death was not significantly different between the two stent types (long-term median rate from 11.5 per 1000 patient-years of follow-up with Zotarolimus-R to 16.6 with BMS[7]), there was nonetheless a lower risk on short-term outcomes (ORs from 0.55 to 0.67 at 1-year, median rate was 2.85% with BMS) and on long-term outcomes (risk ratio from 0.63 to 0.82, median rate 26.51 per 1000 patients-year with BMS) except for the paclitaxel-eluting stent. These updates of safety and efficacy of DES versus BMS are discussed in depth in the 2014 European Society of Cardiology (ESC)/the European Association for Cardio-Thoracic Surgery (EACTS) guidelines on myocardial revascularisation.[8]

The reduction in cost from the first somewhat expensive DES (€2600) to the newest generation DES (~€950), combined with improvements in safety, long-term coronary effects and medical care with antiplatelet treatments, have modified the risk–benefit ratio and the cost-effectiveness, as discussed by Barone-Rochette *et al*.[9] The 2014 European guidelines recommend the use of DES over BMS in all cases.[8] In France, the last evaluation of DES was performed in 2009 by the Healthcare Strategies Assessment Department.[10] In the light of the publication of these two meta-analyses in 2012 along with the 2014 revised European recommendations, an update of cost-effectiveness evaluation of the different stent types in France, including second generation DES, was performed. This study evaluates the cost-effectiveness of DES compared with BMS in patients undergoing PCI using the recent meta-analyses including second-generation DES.

METHODS

Model structure

On the basis of the recent literature, and notably Bangalore *et al*'s[7] meta-analysis, the model was Markov's model with three health states: major cardiac event-free state (state 0), post major cardiac event state (state 1) and death (state 2), as illustrated in figure 1. The three major events that lead to transition from state 0 to state 1 are: myocardial infarction, stent thrombosis and revascularisation. Only the first occurrence of any of these events was included in the model. We assumed that patients experiencing an event were either stable or dead at the following cycle; patients may also die directly from any state, without the listed events. This model is non-homogeneous and therefore probabilities of transition depend on the duration from the entry state in the model: first year and after 1 year.

The cycle length used was 6 months. Based on published efficacy studies,[7] the most reliable time horizon is 5 years, because follow-up is between 2 and 4 years and

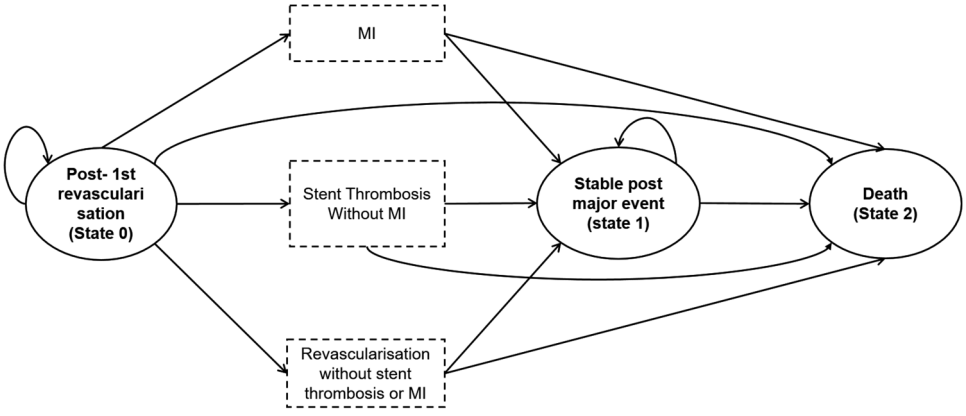


Figure 1 Markov model scheme. Patients start (state 0) with uncomplicated PCI revascularisation; then cycle between health states until death occurs or the 5-year period ends. Dotted boxes are events that cause a change of state. Each cycle is 6 months. The health states are equivalent for BMS and DES; however, probabilities and initial costs vary with the strategy. BMS, bare-metal stents; DES, drug-eluting stents; MI, myocardial infarction; PCI, percutaneous coronary intervention.

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therefore extrapolation over 5 years would introduce uncertainty. Half-cycle correction was applied as recommended by International Society for Pharmacoeconomics and Outcomes Research (ISPOR).[11] Outcomes were estimated for the two cohorts undergoing PCI with either BMS or DES. The different kinds of DES were pooled since no difference was expected between kinds of DES. An annual discount rate of 4% was applied to costs and outcomes, according to recommendations of the Department of Economics and Public Health Assessment (French health technology assessment body).[12]

The cost-effectiveness of DES is expressed in terms of the incremental cost per year gained without a major cardiac event (myocardial infarction, stent thrombosis or revascularisation), in the context of the French National Health Insurance. A cost-utility approach was excluded because of lack of utility values in the French context for this pathology. The incremental cost per year gained was not considered because no difference in mortality was expected between the two strategies; other authors have assessed the efficiency of cardiac interventions with a cost per major adverse cardiovascular and cerebrovascular events (MACCE) averted, thus establishing a benchmark for our analyses.[13–15]

The base case patient cohort had a mean age of 60 years, and 60% of patients were men, concordant with Bangalore *et al*'s publication.[7] The number of stents for PCI is assumed to be 1.5 per procedure, assuming that it does not depend on the choice of the stent, but only on the characteristics of the patient and lesions. The French national hospital database (PMSI) from 2007 reported a mean of 1.1 stents per DES PCI and 1.5 per BMS PCI.[16] Our assumption is then conservative.

The model was developed with Microsoft Excel 2013 and Microsoft Visual Basic V.7.1 (Microsoft Corporation, Redmond, Washington, USA).

Transition probabilities

The majority of event probabilities were extracted from Bangalore *et al*,[7] and are summarised in table 1 according to the short term (1-year) and long term (after 1-year). Bangalore *et al* estimated rates for BMS and for each DES separately. To model the whole category of DES, the means of rates were used (eg, the rate of 'definite or probable' thrombosis in the short term (up to 1-year) for patients with BMS was estimated as 0.12%, varying from 0.04% for everolimus to 0.12% for zotarolimus, which were summarised by the mean 0.084%). Results from Palmerini *et al*[4] were also used for definite or probable stent thrombosis in sensitivity analyses; OR for DES versus BMS varied from 0.34 for cobalt-chromium everolimus DES to 1.13 for phosphorylcholine polymer-based zotarolimus DES, summarised by a mean 0.61. This mean OR applied to a base rate of 0.12% from Bangalore leads to a 1-year rate in the DES group of 0.073%. The two sources are then consistent.

No specific mortality probabilities during each cardiac event and from each health state were available for this specific population of patients after a first PCI. Thus, only global mortality for all causes was considered. Mortality probability from the post major cardiac event state was

Table 1 Summary of events and transition probabilities

From	To	Cohort	Cycles	6-month probabilities			Source
				Base case	Minimum	Maximum	
Major cardiac event-free state	Myocardial infarction	BMS	First year	2.14%	1.83%	2.48%	(7)
			Following years	1.32%	1.16%	1.48%	(7)
		DES	First year	1.40%	0.82%	2.19%	(7)
			Following years	1.02%	0.61%	1.57%	(7)
Major cardiac event-free state	Stent thrombosis	BMS	First year	0.06%	0.00%	0.60%	(7)
			Following years	0.26%	0.11%	5.20%	(7)
		DES	First year	0.042%	0.00%	0.70%	(7)
			Following years	0.26%	0.11%	5.50%	(7)
Major cardiac event-free state	Second revascularisation	BMS	First year	8.22%	7.17%	9.15%	(7)
			Following years	4.37%	4.06%	4.35%	(7)
		DES	First year	2.88%	1.33%	5.31%	(7)
			Following years	2.15%	1.22%	3.38%	(7)
Myocardial infarction	Death	–	–	3.20%	2.90%	3.50%	(17)
Stent thrombosis	Death	–	–	1.00%	0.50%	20.00%	Calibration
Second revascularisation	Death	–	–	1.00%	0.50%	20.00%	Calibration
Stabilised post major cardiac event state	Death	–	–	1.01%	0.50%	10.00%	(17)
Global death		BMS	First year	0.12%	0.00%	0.78%	(7)
			Following years	0.83%	0.65%	1.07%	(7)
		DES	First year	0.11%	0.00%	1.02%	(7)
			Following years	0.71%	0.25%	1.10%	(7)

BMS, bare-metal stents; DES, drug-eluting stents.

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Table 2 Summary of costs

	Inpatient	Outpatient	Base case	Minimum	Maximum	SD
Initial revascularisation cost (€)						
BMS medical care	2957.42	154.58	3112	1841.93	7042.57	1505.69
BMS device	550		550	440	550	
DES medical care	2957.42	218.75	3176.17	1893.27	7119.57	1505.69
DES device	925		925	740	925	
Following cycles standard care cost per cycle in major cardiac event-free state or post major cardiac event state		132.73	132.73	106.18	159.27	26.55
Cost per event (€)						
Myocardial infarction	4190.23	132.73	4322.96	681.23	12956.31	3452.94
Stent thrombosis	2547.68	148.97	2696.65	398.96	11485.83	3273.25
Second revascularisation	4289.53	141.23	4430.76	688.04	5568.88	4175.21
Death	822.54		822.54	658.03	987.05	164.51

Cycle length is 6 months.
BMS, bare-metal stents; DES, drug-eluting stents.

based on a randomised trial published by Kastrati *et al*[17] evaluating recurrences in patients with coronary in-stent restenosis, assuming a similar risk for myocardial infarction, stent thrombosis and new revascularisation. Death probability during the 6 months following a myocardial infarction was estimated from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR) registry, as in the model proposed by Wisløff *et al*.[18]

We assume that PCI for patients free from any of the three listed major cardiac events did not lead to increased mortality risk compared with the French general population at the same age and same sex proportion. Other mortality probabilities were estimated empirically by calibration to be coherent with global mortality estimated in Bangalore *et al*'s meta-analysis. Since cohorts grow older during a cycle, mortality probabilities are assessed to never be lower than in the general population. Base mortality probabilities were estimated using the French National Institute of Statistics and Economic Studies (INSEE). In the absence of the Kaplan-Meier estimation and to simplify, exponential function was used to convert the annual rate to 6 month probabilities and to extrapolate until time horizon.

Costs

Costs were derived from the perspective of the French National Health Insurance, as evaluated in 2012, and only direct medical costs were used. All hospital costs were taken from the PMSI, and diagnosis-related groups were used to identify hospital stays for DES and BMS PCIs, taking into account stay duration and additional costs for intensive care. Stent device prices were added to the cost of the initial hospital stay for PCI, including the number of implanted stents.

Standard care after the first revascularisation, mainly involving patient monitoring, included drug treatment costs and the costs of radiology and laboratory tests, according to the recommendations for antiplatelet treatment of coronary disease from the French National Insurance.[19] Follow-up was estimated from the Haute Autorité de Santé (HAS) guideline for coronary heart disease. Treatment costs were distinguished for myocardial infarction, bypass surgery or second PCI. Costs of the events related to hospitalisation were taken from the PMSI extraction in 2012. Cost of death was based on a specific diagnosis-related group. Resource quantities and unit costs are summarised in table 2.

Sensitivity analyses

One-way sensitivity analyses on parameter values and structural assumptions were undertaken to assess the robustness of results to changes in individual model parameters while the remaining assumptions were held constant.[20] In terms of demographics, the initial age varied from 40 to 70 years, sex ratios varied from 45% to 75%, and number of stents from 1.1 to 2.7, according to range values in previous models. The discount rate varied to 0%, 2.5% and 6.0%.

Assumption of a constant mortality rate after PCI for patients free from cardiac events was evaluated by considering a risk ratio of 2 for this population, compared with the general population. Each transition probability varied between the credibility limits. For the DES cohort, to consider the uncertainty of pooled stents, the most extreme lowest and upper limits of all credibility limits were used. This approach, considering the broadest range of values, is thus a 'worst case' scenario. For parameters chosen by calibration, extreme tested values were 0.5 and 20%. Costs variations are described in table 2 and were derived from the 95% CI from the database extraction. For calibration analysis, results were evaluated over a lifetime horizon, to validate what may happen after 5 years, and the expected life expectancy was used.

Probabilistic sensitivity analysis (PSA) was used to assess overall parameter uncertainty in the model. Point estimates for each parameter were replaced with values

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Table 3 Base case deterministic outcomes for DES versus BMS

	BMS	DES	Delta
Time (years) in health state			
Major cardiac event-free	3.382	4.077	0.695
Stabilised post major cardiac event	1.462	0.790	−0.672
LY	4.844	4.867	0.022
5-year proportion of patients with transition*			
MI	10.8%	9.2%	−1.6%
ST (w/o MI)	1.9%	1.7%	−0.2%
Revascularisation (w/o MI or ST)	37.1%	19.0%	−18.1%
Cumulative cost (€)**	7 153.71 €	6 969.86 €	−183.85 €
Major cardiac event-free survival years (discount)**	2.908	3.448	0.541
Cost per major cardiac event-free survival year gained (discount)**			−340.13 €

*Only the first event occurrence is considered.
**Over 5 years.
BMS, bare-metal stent; DES, drug-eluting stent; LY, Life-year; MI, myocardial infarction; ST, stent thrombosis; w/o, without.

sampled from statistical distributions and the incremental cost-effectiveness ratio (ICER) was recalculated using the new resampled values.[20] Probabilities followed β distribution and costs γ distribution (see online supplementary appendix 1 for more details). This process was repeated 2000 times to estimate uncertainty and to predict the likelihood that DES would be cost-effective at different cost-effectiveness thresholds (the value the decision-maker is willing to pay for each additional cardiac event-free year).

The uncertainty related to the structure of the model is not explored, particularly on the choice to model only the first major cardiac event occurrence, because of lack of data, and because the main outcome is not influenced by what happens after this first event.

RESULTS

Base case

Base case results are presented in table 3, including the proportion of patients with each event. Over 5 years, after a discount, DES was expected to improve major cardiac event-free survival duration by 0.541 years (more than 6 months) compared with BMS. The model predicted that, over 5 years, the cost decreases by €184. This saving is mainly due to the avoided second revascularisation (19.0% over 5 years in the DES cohort compared with 37.1% in the BMS cohort). In the base case, DES dominate over BMS.

Deterministic sensitivity analyses

A tornado diagram of the one-way deterministic analyses shows the effect on the estimated ICER if one model assumption is altered while other assumptions remain at base case values (figure 2). Only parameters that lead to a variation >€200 on ICER are shown. In particular, if the number of stents varied from 1.1 to 2.7, ICER varied from −€605 to €454. The two most influential parameters are the cost for initial PCI for both strategies. The uncertainty comes from the PMSI database extraction variability. The worst case is an initial PCI cost (for BMS) fixed at €7120 instead of €3176, leading to an overall incremental cost of €3760, and an ICER of €6955. It can thus be concluded that results are robust to uncertainty.

On the lifetime horizon, for calibration, life expectancy was 23.1 years in the BMS group and 23.5 years in the DES group. There was no difference in mortality with BMS versus DES, and our model shows no

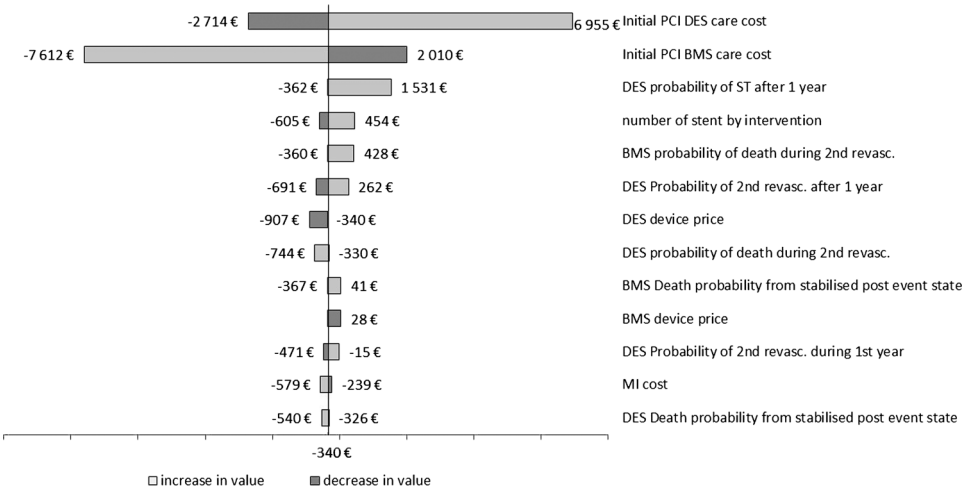


Figure 2 Tornado diagram of one-way deterministic sensitivity analysis. Numbers are the estimated ICER when changing parameter value to a maximal value (light grey) or a minimal value (dark grey). Only parameters giving variation above €200 are shown. BMS, bare-metal stent; DES, drug-eluting stent; ICER, incremental cost-effectiveness ratio; MI, myocardial infarction; PCI, percutaneous coronary intervention; ST, stent thrombosis.

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differences in overall survival between the two strategies (30.6% vs 29.3% at 20 years). DES was expected to improve major cardiac event-free survival by 2.6 years more than BMS, with a decreased cost of €1. DES dominated BMS in all settings; however, these results may not be reliable in terms of long-term extrapolation.

Probabilistic sensitivity analyses

The spread of simulated points is shown in figure 3A and the acceptability curve in figure 3B. Fifty-four per cent of simulations show that DES are dominant, and 46% that DES are more expensive and more effective. Probabilistic sensitivity analysis indicates that using a cost-effectiveness threshold of €7000 per major cardiac event-free year gained, DES has a >95% probability of being cost-effective versus BMS, and with a threshold of €3000, this probability is more than 80%. We conclude that the model is robust to uncertainty.

DISCUSSION

Controversy exists over the cost-effectiveness of DES compared with BMS for patients undergoing PCI. In two systematic reviews published in 2007, 10 studies were discussed by Hill *et al*[21] and 13 studies by Kuukasjärvi *et al*.[22] The diversity of conclusions may be explained by the multiplicity of designs for such evaluations, each design associated with its own biases: ancillary studies of randomised trials, direct comparison in a single-centre; model-based evaluations, and data from patient registries.[9] Nonetheless, most of them conclude that DES can be cost-effective for high-risk subgroups. Another factor to take into account is that most of these studies used results from the first-generation DES.[9 23] In 2011, Müller-Riemenschneider *et al*[24] asserted the need for rigorous economic evaluations using second-generation DES. Until now, models used do not take into account the stent thrombosis event.[18]

Our current analysis, which includes second-generation DES, reports promising results which are consistent with a recent study published by Wisløff *et al*,[18] using randomised controlled trials, and Swedish registry analyses in secondary analysis.

In addition, Bangalore *et al*'s meta-analysis is the largest and the most recent data source that we could use.

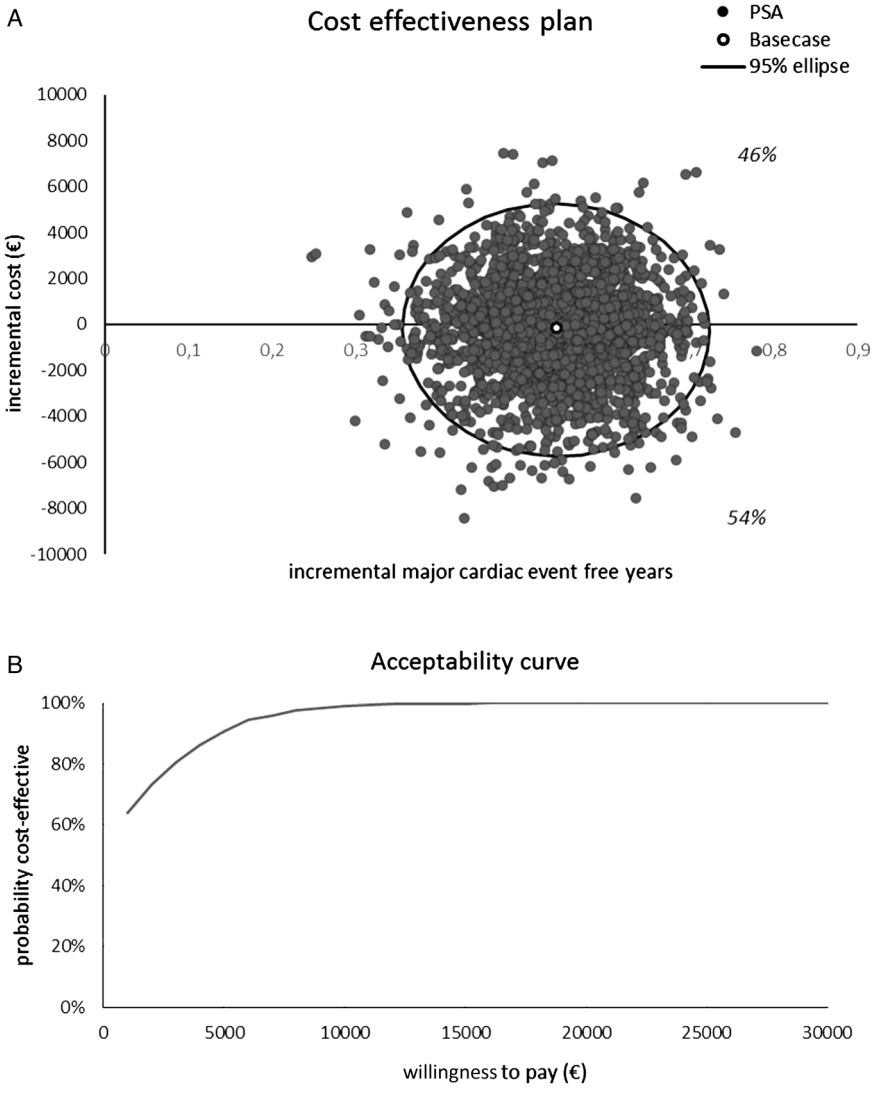


Figure 3 Sensitivity analysis results. (A) Cost-effectiveness plan and (B) acceptability curve. PSA, Probabilistic sensitivity analysis.

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DES was better than BMS in terms of cost-reduction (€184 saving with the base case), attributed largely to a reduction in second revascularisations, and the absence of myocardial infarctions and stent thrombosis. Results were consistent under sensitivity analyses.

Limitations

Our Markov model is based on results from randomised clinical trials. Registry data may be considered as more appropriate to estimate a real-life effect. This is particularly important given that in randomised clinical trials, second revascularisation is frequently identified from complete investigations, and can be identified in asymptomatic patients (so-called 'protocol-driven' reintervention), in comparison with real life, where second revascularisation is usually identified on the basis of clinical symptoms.[1] To investigate this uncertainty, we added an exploratory analysis, using probabilities from the Swedish SCAAR registry, as proposed by Wisløff et al[18] and Palmerini *et al*[4] results for stent thrombosis. The results were very encouraging, with an ICER at €7823, and using a cost-effectiveness threshold of €27 000 per major cardiac event year gained, DES has a >75% probability of being cost-effective versus BMS. The main difference with our initial method was the method for estimating necessity of revascularisation in randomised clinical trials with a rigorous follow-up with frequent imaging measurements, and less strict follow-up in real life (predicted proportions of 14.8% of second revascularisation at 5 years with BMS and 13.4% with DES).

With respect to uncertainty of probabilities chosen by calibration, for death after a second revascularisation, the assumed 1% is close to the non-rigorous but informative estimation of 0.8% from the PMSI database extraction. Sensitivity analyses showed that even extreme values had a small impact on results. A cost-utility analysis may be of interest; however, utilities associated with each health state, with a French specificity, should be investigated first.

France in the European context

In France, since the publication by the HAS in 2009 of selected recommendations, for economic reasons DES are currently reserved first for patients with high risk of stenosis (diabetes, long lesion, small vessel). However, in 2014, the ESC/EACTS guidelines on myocardial revascularisation published indications for new-generation DES: increased efficacy and safety of new-generation DES have enabled their unrestricted use in patients with coronary artery disease requiring PCI, including patients with diabetes, multivessel and left main coronary artery disease, acute myocardial infarction, saphenous vein graft and restenotic lesions, and chronic total occlusions.[8] New-generation DES should therefore be considered the default option in all clinical settings and lesion subsets.

In France, according to the healthcare products pricing committee 2013 activity report, more than 196 000 stents were implanted in 2013, and 72.5% were DES, the lowest proportion in Europe, with 89% in the UK/Ireland, 78% in Italy, 77% in Germany and 74% in Spain (Eucomed data).

Conclusion

In the light of the decreasing costs of the DES device, the development of new-generation devices and outcomes of recent meta-analyses, the DES can now be considered cost-effective irrespective of any restrictions for selective indications according to the 2014 European recommendations. This supports the need for discussion of the use of DES in France.

Contributors IDZ, SM, KL and FW were involved in the study conception and design. LB, SM and SB were involved in model construction and interpretation of results and drafted the article. IDZ and ET were involved in data interpretation and results interpretation. All the authors approved the final manuscript.

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Competing interests IDZ reports personal fees from Medtronic, during the conduct of the study; personal fees from BMS, outside the submitted work. ET reports personal fees from Medtronic, personal fees from Saint Jude medical, outside the submitted work. Capionis and Strategique Santé were contracted to perform the analysis, supporting LB, SM and SB through salary or consultancy payments. FW is a Medtronic employee and member of the SNITEM group. KL is an Abbott employee and member of the SNITEM group.

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2018 HCPCS "C" Code Review
Transnasal Balloon Dilation of the Eustachian Tube

Question: Should transnasal balloon dilation of the Eustachian tube be paired with various ear diagnoses on the Prioritized List?

Question source: Primary Health CCO

Issue: A new HCPCS code for transnasal balloon dilation of the Eustachian tube (C9745) was introduced with the 2018 new codes, but not reviewed as part of the HERC code review in fall 2017. In the past, HERC staff was under the impression that "C" codes did not require review; however, it has come to our attention that these codes do require review. Primary Health CCO received a request for pairing this procedure with Eustachian tube dysfunction (ICD-10 H69.81), conductive hearing loss (ICD-10 H90.11), and tinnitus (ICD-10 H93.11) and requested HERC review of the procedure.

Eustachian tubes are small tubes that run between the middle ear and the pharynx. They are responsible for equalizing ear pressure and draining fluid from the middle ear. Blocked eustachian tubes can cause pain, hearing difficulties, and a feeling of fullness in the ears. Such a phenomenon is referred to as Eustachian tube dysfunction (ETD). Conventional medical treatment includes nasal steroids, decongestants, or antihistamines. Balloon dilation involves the inflation of a balloon in the cartilaginous part of the Eustachian tube to cause local dilation and was first described in 2010.

Current Prioritized List status

1) ICD-10 H69.8 (Eustachian tube dysfunction) is on line 652 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

Evidence

1) **Huisman 2018**, systematic review of Eustachian tube dilation: https://onlinelibrary.wiley.com/doi/pdf/10.1002/lary.26800
    a. N=15 studies, all case series
        i. Total patients: 1,155
    b. All articles showed short-term improvement of original symptoms; some showed further improvement over time. Follow-up ranged from just after therapy to 50 months. Relatively mild and self-limiting complications were described in 36 patients.
    c. Conclusion: All current studies suggest that balloon dilation of the Eustachian tube can be a helpful treatment in patients with Eustachian tube dysfunction. However, placebo controlled trials are still warranted.
2) **Hwang 2016**, systematic review of eustachian tube dilation
    a. N=9 studies (474 patients)
    b. Ability to perform a Valsalva manoeuvre improved from 20 to 177 out of 245 ears following Eustachian tube balloon dilation and, where data were reported in terms of patient numbers, from 15 to 189 out of 210 patients. Tympanograms were classified as type A in 7 out of 141 ears pre-operatively and in 86 out of 141 ears post-operatively.
    c. Conclusion: Prospective case series can confirm the safety of Eustachian tube balloon dilation. As a potential solution for chronic Eustachian tube dysfunction, further investigations are warranted to establish a higher level of evidence of efficacy.

2018 HCPCS "C" Code Review
Transnasal Balloon Dilation of the Eustachian Tube

HERC staff summary:
Eustachian tube dilation appears to be a promising but unproven treatment for Eustachian tube dysfunction.

HERC staff recommendation:

1) Add Eustachian tube dilation (HCPCS C9745) to GN173/line 660

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

The following Interventions are prioritized on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
C9745	Nasal endoscopy, surgical; balloon dilation of Eustachian tube	Insufficient evidence of effectiveness	May, 2018

2) Alternative: Place Eustachian tube dilation (HCPCS C9745) on line 652 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY to pair with Eustachian tube dysfunction

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Systematic Review

Treatment of Eustachian Tube Dysfunction With Balloon Dilation: A Systematic Review

Jolien Marieke Lieselot Huisman, MD; Froukje Jantina Verdam, MD, PhD; Inge Stegeman, PhD; Jacob Alexander de Ru, MD, PhD

Objective: Balloon dilation is a new entity in the therapeutic approach of Eustachian tube dysfunction. The aim of this systematic review is to evaluate the success of balloon dilation of the tuba auditiva in reducing symptoms in adult patients with Eustachian tube dysfunction.

Data Sources: Embase, PubMed, and Cochrane Library.

Review Methods: The systematic literature search was conducted independently by two authors based on title and abstracts, and resulted in 36 articles. These articles were screened as full text, 15 of them were eligible for critical appraisal. Data were extracted from selected studies and presented in this article. A meta-analysis was conducted for four subgroups. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement was used as a writing guideline for this systematic review.

Results: All 15 included studies were case series. A total of 1,155 patients were treated with balloon dilation of the tuba auditiva. Outcome parameters were relief of symptoms, otoscopy, Valsalva maneuver or Toynbee test, audiometry, tympanometry, Eustachian tube dysfunction classification, and Eustachian tube score. All articles showed short-term improvement of original symptoms; some showed further improvement over time. Follow-up ranged from just after therapy to 50 months. Relatively mild and self-limiting complications were described in 36 patients.

Conclusion: All current studies suggest that balloon dilation of the Eustachian tube can be a helpful treatment in patients with Eustachian tube dysfunction. However, placebo controlled trials are still warranted.

Key Words: Eustachian tube dysfunction, balloon dilation of the tuba auditiva, adults, systematic review.

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INTRODUCTION

Eustachian tube dysfunction (ETD) has a major impact on the general population, with a prevalence of 0.9%.[1,2] The function of the Eustachian tube is to equalize pressure, clear mucociliary secretions, and protect the middle ear.[3] Dysfunction of the Eustachian tube can be caused by a variety of diseases that interfere with the mucosal function or cartilaginous structures, resulting in a diminished possibility to open the Eustachian tube. ETD's exact pathophysiology has not yet been elucidated, and one simple standardized test to objectify ETD is lacking.[4] Negative pressure in the middle ear seems to be the key factor and may coincide with contributing factors such as microbial overload or obstruction of the nasopharynx, for example, in case of adenoid hypertrophy or nasopharyngeal cancer.[5–7] The negative pressure in the middle ear may lead to tympanic membrane retraction and fluid accumulation in the middle ear.[3,5] ETD causes symptoms, especially during barometric changes, such as aural fullness, otalgia, tinnitus, and/or temporary hearing loss.[2,4,5] Similar symptoms also are observed in chronic otitis media, cholesteatoma, (allergic) rhinitis, chronic rhinosinusitis, and laryngopharyngeal reflux.[2,8] Conventional medical treatment aimed at improving mucosal conditions of the nasal cavity and Eustachian tube, includes nasal steroids, decongestants, or antihistamines. Unfortunately, it remains challenging to predict the effectiveness of these treatments, partly due to the difficulty to objectify ETD.[2,9] Well-known invasive symptomatic treatments are paracentesis and ventilation tubes, in order to equalize pressure via the tympanic membrane.[2,9]

Until now, no gold standard treatment for ETD has emerged.[4] Therefore, a safe, easily performable, and effective treatment option would be welcomed in the otolaryngological armamentarium. The new Eustachian tube

Additional supporting information may be found in the online version of this article.

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balloon dilation (ETBD) technique, first described in patients in 2010, comprises the inflation of a balloon in the cartilaginous part of the Eustachian tube to cause local dilation.[10] Some consider ETBD to be a new promising entity in therapeutic options for patients with complaints of tuba dysfunction. However, ETBD also has been referred to as a "gizmo" and an unproven procedure.[11] Therefore, we systematically reviewed the current literature on balloon dilation therapy, adverse events, outcome parameters, and results in adults with Eustachian tube dysfunction and herein present our critical appraisal.

MATERIALS AND METHODS

Search and Selection

A systematic literature search in PubMed, Embase, and the Cochrane library was conducted on May 1, 2016. Search terms used were "Eustachian tube," "balloon," and "dilation," as well as relevant synonyms (see Appendix 1, available online). No terms were included in the search for patient characteristics to avoid publication bias. No search terms were included for outcome because there is no reference standard. Titles, abstracts, and full texts were screened independently by two authors (J.M.L.H. and F.J.V.) on predetermined inclusion and exclusion criteria. Inclusion criteria were balloon dilation of Eustachian tube and adults with tuba dysfunction. Exclusion criteria were studies in other than human, cadaver studies, non-English and children studies, editorial articles, conference abstracts, case reports, comments or opinions, (systematic) reviews, when no balloon dilation was performed, and if balloon therapy was performed as part of more profound middle ear surgery. Cross-referencing was performed through Scopus after full text screening. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement was used as the writing guideline for this systematic review.[12]

Study Assessment

Because ETD has no clear definition, not all investigators use the same criteria to diagnose ETD. We classified the relevance of articles based on three criteria: 1) patient characteristics, 2) therapy, and 3) ETD measurements before and after therapy. Quality outcome parameters were objective and/or subjective evaluation of complaints, additional diseases (such as cholesteatoma), and other therapy besides ETBD. Objective measurements were tympanometry, Valsalva maneuver, Toynbee test, otoscopy, tuba manometry, histopathology, mucosal inflammation, the Eustachian Tube score (two types of scoring systems), and the Eustachian tube classification (see Appendix 2). Studies used retrospective data from patient files, and two studies used questionnaires to evaluate symptoms. The two questionnaires were the 7-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7), and the Glasgow Benefit Inventory (GBI).

Studies were considered of high relevance if they complied with all three criteria, moderate relevance when two or more criteria were met, and low if fewer than two criteria were met (see Table I). Risk of bias was measured by seven criteria: study population, standardization of outcome, blinding, missing data, selection bias, confounders, and follow-up. Missing data were subdivided into less than 10%, between 10 % to 20%, more than 20%, or not reported. Finally, follow-up was scored satisfactory if measurements were performed more than 6 months after treatment. If studies complied with six or more criteria, they were classified as having low risk of bias, with four or five as moderate risk of bias, and less than four as high risk of bias.

Data Extraction and Statistical Analysis

Study characteristics and outcome data were extracted from selected articles independently by two authors (J.M.L.H. and F.J.V.). No selection was made on type of outcome.

To perform the meta-analysis, we calculated the relative risk with a 95% confidence interval (CI) and random effects modelling using RevMan 5.3.[13] Articles that described the results pre- and post-ETBD were included for meta-analysis. We assessed the heterogeneity among the studies by calculating the I^2 statistic.

RESULTS

Search and Study Selection

As illustrated in Figure 1, 103 articles were retrieved from the PubMed, Embase, and Cochrane Library search. Removal of duplicates and screening on title and abstract resulted in 36 articles; these were screened in full text, and 15 remained for critical appraisal. Cross-referencing through Scopus did not result in additional articles.

Assessing Quality of Studies

The critical appraisal of the 15 articles on relevance and risk of bias is shown in Table I. All studies were case series evaluating the effect of ETBD on patients with ETD without a control group. In several studies, patients received additional conventional treatment apart from ETBD.[6,10,14–19] Three articles[20–22] were considered to be of high relevance; the remaining studies were of moderate relevance, for example, due to additional treatment next to ETBD (such as nasal corticosteroid spray or functional endoscopic sinus surgery) or patients with additional illnesses (such as chronic otitis media with cholesteatoma). One study blinded the caretakers after treatment to prevent influence on the test results[23]; one study[6] treated both children and adults; and all studies had a moderate-to-high risk of bias.

Data Extraction and Statistical Analysis

A descriptive analysis is provided. The conducted meta-analysis was made per subgroup. Inclusion criteria varied between studies, and not all studies described their population baseline characteristics. In addition, heterogeneity existed between follow-up times and the types of provided data at the outpatient clinic visits. Pooling of data was therefore difficult, and not for all types of outcome a meta-analysis could be provided. The outcome "reported symptoms" presented either no data before ETBD, or the inclusion of the symptoms differed too much between studies and therefore this parameter had to be excluded from analyses. The outcomes "audiometry," "tubamanometry," "mucosal inflammation," "Eustachian tube score 2," and "ETD classification" also had to be excluded because no data before ETBD were reported or because one or two studies remained to conduct the meta-analysis. The remaining four subtypes that could be analyzed over time include the Valsalva test, otoscopy, tympanometry, and the Eustachian tube score. Three subgroups used dichotomous data (relative

TABLE I.
Critical Appraisal.

Study (year)	Study Design	Sample Size* (years)	Mean Age in Years* (range)	Relevance				Validity							
				Patients	Therapy	Outcome	Verdict	Study Population	Standardization of Outcome	Blinding	Missing Data	Follow-up	Selection Bias	Confounders	Risk of Bias
Bast (2014)	RCS	30 (?)	49.7 (24–73)	●	●	◐	M	○	◐	○	?	●	●	○	H
Catalano (2012)	RCS	70 (100)	45 (18–73)	●	◐	●	M	○	◐	○	●	●	●	●	M
Dai (2016)	RCS	8 (12)	53 (45–62)	◐	●	●	M	●	◐	○	◐	●	●	○	M
Dalchow (2016)	PCS	217 (324)	45.6 (6–88)	●	◐	●	M	○	◐	○	●	●	●	●	M
Gürtler (2015)	RCS	21 (?)	37.5 (19–67)	●	●	●	M	●	◐	○	●	●	○	○	H
Jurkiewicz (2013)	RCS	4 (7)	45.8 (23–61)	●	●	●	H	●	◐	○	●	○	○	●	H
Kivekas (2015)	RCS	13 (26)	46 (18–74)	●	◐	●	M	●	◐	○	●	○	○	○	H
McCoul (2012)	PCS	22 (35)	55.1 (46.4–63.8)	●	●	●	H	●	●	○	●	●	○	◐	M
Ockermann (2010)	PCS	8 (13)	44.1 (21–81)	◐	◐	●	M	●	◐	○	●	○	○	○	H
Poe (2011)	PCS	11 (11)	51.8 (33–76)	◐	◐	●	M	●	◐	○	●	●	●	◐	M
Schröder (2015)	RCS	622 (1076)	? (7–84)	●	◐	●	M	●	◐	○	◐	●	●	◐	M
Silvola (2014)	PCS	37 (42)	48 (15–38)	◐	◐	●	M	●	◐	○	●	●	●	●	M
Wanscher (2014)	PCS	34 (50)	45 (20–74)	◐	◐	●	M	●	◐	○	●	○	○	◐	H
Williams (2016)	RCS	18 (25)	40.6 (18–68)	◐	●	●	M	●	◐	◐	●	●	○	◐	M
Xiong (2016)	RCS	40 (58)	42 (21–70)	●	●	●	H	●	◐	○	●	●	○	◐	M

Patients	● Adults with tuba dysfunction |◐ Pathology that can be caused by tuba dysfunction |○ Symptoms not related to tuba dysfunction Verdict = level of relevance
Therapy	● Balloon tuba dilation without combination treatment | ◐ Combination treatment | ○ No balloon tuba dilation (M)oderate or (H)igh relevance
Outcome	● Clinically relevant objective measures | ◐ Subjective measures | ○ No clinically relevant measures
Study population	● Patient characteristics well described | ○ Patient characteristics not reported or incompletely described Risk of bias = level of validity
Standardization of outcome	● Validated test | ◐ Validated test not specific for condition | ○ No validated test (M)oderate or (H)igh validity
Blinding	● Blinding | ◐ Partial blinding | ○ No blinding
Missing data	● <10% of missing data | ◐ 10–20% missing data | ○ >20% missing data | ? not reported
Follow-up	● ≥ 6 months | ○ < 6 months
Selection bias	● No selection bias |○ Susceptible to bias
Confounders	● There are no confounders, or they are corrected in the analysis | ◐ Confounders are only mentioned | ○ Confounders are not mentioned

*Sample size: number of patients (number of ears treated, if mentioned). Mean age: in years (range of age).
PCS = prospective case series; RCS = retrospective case series.

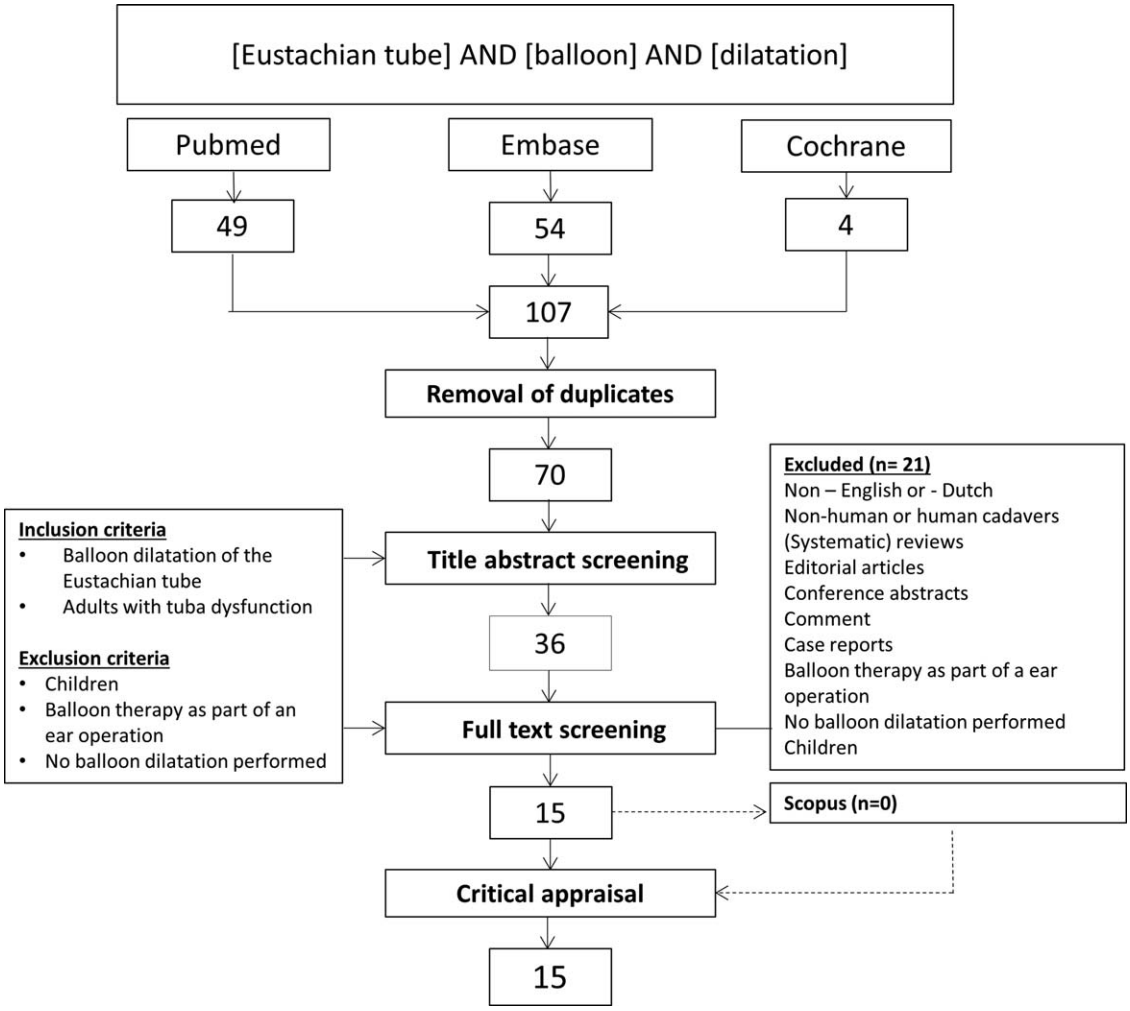


Fig. 1. Flow chart.

risk [RR]) and one continuous data (mean score and standard deviation [SD]). Two studies in which these subgroups were mentioned had to be excluded due to the absence of data before the ETBD procedure.[18,24]

Study Characteristics

The study characteristics are presented in Table II. In this table, several aspects are highlighted: number of patients, mean age, tests, follow-up, comorbidities, other therapy, and anesthesia. The 15 included studies concern 1,155 patients who suffered from ETD, although it was not always further specified how ETD was diagnosed. Patients often had coexisting disease or comorbidity such as cholesteatoma, sinusitis, or mucosal hypertrophy of the turbinates, and some patients previously underwent radiotherapy. Mostly, subjects were included if they did not respond to conventional treatment such as nasal steroids and antihistamines. Some underwent tympanoplasty or ventilation tubes. Exclusion criteria varied; patients with anatomical variations such as severe nasal septal deviation or patients who did not show an intact bony wall of the internal carotid canal by means of computed tomography (CT). In order to assess potential dehiscence of the bony wall of the internal carotid artery or anomalies of the tuba auditiva, a preoperative (high-resolution) CT scan of the temporal bone was performed in nine studies[6,14,17,18,21,22,25–27] and a digital volume tomography in one.[15] The remaining five studies refrained from imaging.[14,16,19,23,24]

Every patient underwent clinical examination, tympanometry, audiometry, and sometimes tubamanometry. All studies used either Spiggle & Theis (Overath, Germany),[6,10,15,19,20,22–26] or Acclarent (Acclarent, Inc.; Irvine, CA)[14,16–18,21] for balloon dilation. Spiggle & Theis uses a balloon of 20 mm in length and 3 mm in width, which is inflated to 10 bars for 2 minutes, whereas Acclarent (Acclarent, Inc.) is 16 mm in length and 5 to 7 mm in width and inflated to 12 bars for 1 to 2 minutes. Patients received general anesthesia in 10 studies. In three studies, both general (n = 82) and local (n = 30) anesthesia was used.[14,19,24] Two studies did not report their way of providing anesthesia.[10,17]

Outcome

In the 15 appraised studies, a total of 1,155 patients received at least 1,830 and up to 1,881 ETBD

TABLE II.
Study Characteristics.

Study (year)	Number of Patients (men:women)	Mean Age in Years (range)	Tests	Follow-up (months)	Comorbidities	Other Therapy	Anaesthesia: Number of Operators*
Bast (2014)	30 (11:19)	49.7 (24–73)	GBI questionnaire	6–18	NR	NR	0: 1
Catalano (2012)	70 (26:44)	45 (18–73)	Subjective symptoms and tympanometry	3 and 34	NR	39 sinonasal procedures, 5 otologic procedures	0 and 1: NR
Dai (2016)	8 (NR)	53 (45–62)	Subjective symptoms, tympanic membrane, audiometry, tympanometry	3, 6, and 12	NR	NR	0: NR
Dalchow (2016)	217 (119:98)	45.6 (6–88)	ETS 2	1, 3, 6, 9, and 12	NR	Cefuroxime and prednisolone, 124 tympanoplasty	0: NR
Gürtler (2015)	21 (14:7)	37.5 (19–67)	Subjective symptoms, audiometry, otoscopy, tympanometry, tubamanometry, ETS	1 week, 3 and 26	6 cholesteatoma, 1 carcinoma nose (not specified where)	6 cholesteatoma operations, 1 irradiated carcinoma of the nose	0: NR
Jurkiewicz (2013)	4 (3:1)	45.8 (23–61)	Valsalva, air–bone gab audiometry, tympanometry	1 and 6 weeks	1 rhinitis, 2 mucoserous otitis	Rhinitis treatment	0: NR
Kivekas (2015)	13 (10:3)	46 (18–74)	Otoscopy (tympanic membrane retraction), tympanometry, histopathology	5–12 weeks	NR	2 tympanoplasty, nasal steroids and antihistamines continued if patients were on it chronically	0: NR
McCoul (2012)	22 (NR)	55.1 years (46.4–63.8)	ETDQ-7, tympanometry	3, 6, 12 weeks, and 6	NR	7 tympanoplasty	0: NR
Ockermann (2010)	8 (NR)	44.1 (21–81)	Valsalva, tubamanometry, ETS	1, 2, and 8 weeks	NR	2 tympanostomy tubes (in 3 patients removed)	0: NR
Poe (2011)	11 (5:6)	51.8 (33–76)	Valsalva, tympanic membrane, tympanometry, mucosal biopsy	directly after, and 7–14	11 tympanoplasty or perforation, 6 CRS	Nasal steroids	0: NR
Schroder (2015)	622 (ratio ± 1:1)	? (7–84)	Subjective symptoms, ETS	2, 12, 24, and 36	NR	Nasal steroids, tympanostomy	0: NR
Silvola (2014)	37 (ratio ± 1:1)	48 years (15–38) -> probably a typo	Valsalva, otoscopy, tympanometry, mucosal biopsy	mean 2.5 years (1.5–4.2)	16 CRS, 12 perforated tympanic membranes/ tubes	Decongestant, nasal steroids, antibiotics	0: NR
Wanscher (2014)	34 (18:16)	45 (20–74)	Subjective symptoms, Valsalva/Toynbee, audiometry, tympanometry, ETD classification	2	6 tubes	5 ventilation tubes	0 and 1 (3): 2
Williams (2016)	18 (NR)	40.6 (18–68)	Tympanometry	2–3, 6–9, and 12–15	NR	6 ventilation tubes, 4 patients previously mastoid surgery or tympanoplasty	0: at 2 different centers
Xiong (2016)	40 (21:19)	42 (21–70)	Subjective symptoms, Valsalva, otoscopy, tympanometry, tubamanometry, ETS	1 week, 3 and 12	NR	NR	0: NR

*0 = general anesthesia
1 = local anesthesia.
CRS = chronic rhinosinusitis with/without nasal polyps; ETBD = Eustachian tube balloon dilation; ETD = Eustachian tube dysfunction; ETDQ-7 = Eustachian tube dysfunction questionnaire; ETS = Eustachian tube score; GBI = Glasgow Benefit Inventory; NR = not reported.

TABLE III.
Outcome: Reported Symptoms, Valsalva Test, and Complications.

Study (year)	Reported Symptoms Follow-up (months): symptom relief in % or scores, *P* value	Valsalva Follow-up (months): ability to perform in % or scores, *P* value	Complications number, classification (type and treatment)*
Bast (2014)	6–18: scores NR, $P = 0.001$	NR	NR
Catalano (2012)	3: 71%.	NR	1, mild (1A)
	34: 88% (n = 8)		
Dai (2016)	3: 83%	NR	0
	6: 86% (7 ears)		
	12: 100% (3 ears)		
Dalchow (2016)	NR	NR	0
Gürtler (2015)	1/4: 71%	NR	11, mild (1x 2A, 10x 3A)
	3: 76%		
Jurkiewicz (2013)	NR	1/4: 29% improvement	0
		1 1/2: 71% improvement	
Kivekas (2015)	NR	NR	11, mild (4A)
McCoul (2012)	Before: mean 4.5 (SD 1.2), $P < 0.001$	NR	1, severe (2B)
	3/4: mean 2.7 (SD 1.5), $P < 0.001$		
	1/2: mean 2.6 (SD 1.1), $P < 0.001$		
	3: mean 2.8 (SD 1.7), $P < 0.001$		
	6: mean 2.8 (SD 1.3), $P < 0.001$		
Ockermann (2010)	NR	Before: 23%	0
		2: 92%	
Poe (2011)	NR	Directly after: 100%	5, mild (2A)†
		7–14: 63–100%, $P < 0.001$	
Schroder (2015)	24: 74% (n = 30)	NR	3, mild (1A, 2A, 5A)
Silvola (2014)	NR	Mean 30: from 0% to 80%, $P < 0.001$	0
Wanscher (2014)	2: 55% (only concerning aural fullness) and 48% (only concerning otalgia), $P < 0.05$	2: 66%, $P < 0.05$	4, mild (6?)
		Toynbee: 2: from 7% to 77%	
Williams (2016)	NR	NR	0
Xiong (2016)	1/4: 88%	Before: 0%	0
	3: 95%	1/4: 62%	
	12: 98%	3: 83%	
		12: 98%	

*mild = symptoms resolved spontaneously; severe = symptoms did not resolve spontaneously without treatment; 1 = preauricular emphysema; 2 = self-limiting bleeding at site of balloon dilation; 3 = mild rhinitis; 4 = diffuse (sub)mucosal crush injury; 5 = increased tinnitus; 6 = otitis media acuta; A = resolved spontaneously; B = resolved with myringotomy; ? = not reported.

†1 patient had temporary C6-7 contralateral radiculopathy due to neck extension.

Ears = number of ETBD procedures; ETBD = Eustachian tube balloon dilation; NR = not reported; SD = standard deviation; TM = tympanic membrane.

procedures (for 51 patients, it was not clear whether the procedure was done unilaterally or bilaterally). The sample sizes ranged from seven ETBD procedures in four patients to 1,076 ETBD procedures in 622 patients, and average follow-up was 6.9 months (range 0 to 50 months). In Tables III to V, all outcome parameters are subdivided per type of measurement of ETD. Almost all parameters showed an improvement, mostly qualified as significant, which remained during the follow-up time or even ameliorated further over time.[9,10,14–17,19–26,28] Two studies reported diminished results over time. More specifically, Poe showed an improved Valsalva maneuver at all follow-up times, but there was a decline in percentage from 100% positive Valsalva maneuver directly after ETBD to 63% after a period of 7 to 14 months.[18] Schröder measured a decline of improvement in mean Eustachian tube score; only at 3 years of follow-up.[6] Revisions due to failure of the first ETBD procedure were reported in three out of the 15 studies; out of at least 1,830 procedures performed, 122 needed a revision.[6,14,21] However, specific outcomes for these patients were not separately described.

Mucosal Inflammation

Three studies reported mucosal inflammation in the tuba auditiva as one of their outcome parameters.[16–18]

TABLE IV.
Outcome: Otoscopy, Audiometry, Tympanometry, and Tubamanometry.

Study (year)	Otoscopy F: normal TM in % or scores, *P* value	Audiometry F: reduction of anion gab in % or scores, *P* value	Tympanometry F: improvement of graph type in % or scores, *P* value	Tubamanometry F: improvement of ventilation in % or scores, *P* value
Bast (2014)	NR	NR	NR	NR
Catalano (2012)	NR	NR	3: 90% (28 ears)	NR
Dai (2016)	3: 83%, $P < 0.05$ 6: 100% (7 ears), $P < 0.05$ 12: 100% (3 ears), $P < 0.05$	3: 83% 6: 86% 12: 100% (3 ears)	3: 83% 6: 86%. 12: 100% (3 ears)	NR
Dalchow (2016)	NR	NR	NR	NR
Gürtler (2015)	1/4–3: 18%	1/4–3: 5 dB, $P < 0.01$	1/4–3: 55%	1/4–3: 30 mbar: from 15.81 to 1.20, $P < 0.01$ 40 mbar: 4.10 to 0.98, $P < 0.001$ 50 mbar: 1.66 to 0.83, $P < 0.001$
Jurkiewicz (2013)	NR	1/4: 43% 1 1/2: 86%	1/4: 0% 1 1/2: 86% PST 1/4: 0% 1 1/2: 86%	NR
Kivekas (2015)	1 1/4–3: from 22% to 72%	NR	1 1/4–3: from 25% with normal graph to 58%	NR
McCoul (2012)	1 1/2: from 5.7% to 100%, $P < 0.001$	NR	1 1/2: from 0% to 97% normal graph, $P < 0.001$	NR
Ockermann (2010)	NR	NR	NR	1/4: 30 mbar: from 37.5% tubes opening to 87.5% 40 mbar: from 25% tubes opening to 87.5% 50 mbar: from 12.5% tubes opening to 87.5%
Poe (2011)	7–14: from 0% to 45%	NR	7–14: 36%	NR
Schroder (2015)	NR	NR	NR	NR
Silvola (2014)	Mean 30: from 0% to 90%, $P < 0.001$	NR	Mean 30: from 2% type A curve to 56%, $P < 0.001$	NR
Wanscher (2014)	NR	2: 10 dB, $P < 0.05$	2: from 0% type A curve to 28%. Positive change in 58% (38 ears)	NR
Williams (2016)	NR	NR	Before: −295 DaPa (SD 77.38) 2–3: −164 (SD 105.09) 6–9, 14% −255 (SD 90.08) 12–15: −213 (SD 124.64) In total 68% improvement, $P < 0.05$	NR
Xiong (2016)	Normal pre- and postoperatively	NR	Before: 74% type A curve 1/4: 83% 3: 86%, 12: 98%	1/4, 3, 12: 30 mbar: from 36% tubes opening to 67%, 71%, and 79% respectively, $p<0.05$ 40 mbar: from 43% tubes opening to 71%, 78%, and 86%, $P <0.05$ 50 mbar: from 50% tubes opening to 74%, 84%, and 90%, $P <0.05$

Ears = number of ETBD procedures; ETBD = Eustachian tube balloon dilation; NR = not reported; PST = pressure swallow test; SD = standard deviation; TM = tympanic membrane.

TABLE V.
Outcome: Eustachian Tube Score, Eustachian Tube Score 2, and ETD Classification.

Study (year)	Eustachian Tube Score Follow-up (months): improvement in % or scores, *P* value.	Eustachian Tube Score 2 Follow-up (months): improvement in % or scores, *P* value	ETD Classification
Bast (2014)	NR	NR	NR
Catalano (2012)	NR	NR	NR
Dai (2016)	NR	NR	NR
Dalchow (2016)	NR	Before: mean 2.23 (SD 1.15)	NR
		1: mean 2.07 (SD 1.14)), NS	
		3: mean 2.31 (SD 1.23)), NS	
		6, mean 2.32 (SD 1.26)), NS	
		9: mean 2.33 (SD 1.29)), NS	
		12: mean 2.68 (SD 1.01)), $P < 0.05$	
Gürtler (2015)	1/4–3: mean score from 3 raised to 7, $P = 0.0001$	NR	NR
	26: mean score similar to 3 months		
Jurkiewicz (2013)	NR	NR	NR
Kivekas (2015)	NR	NR	NR
McCoul (2012)	NR	NR	NR
Ockermann (2010)	Before: 1.077 (SD 0.605)	NR	NR
	1/4: 4.154 (SD 63.023), $P < 0.05$		
	1/2: 5.846 (SD 62.609), $P < 0.05$		
	2: 7.539 (SD 61.391), $P < 0.05$		
Poe (2011)	NR	NR	NR
Schroder (2015)	Before: mean 3.15 (SD 2.54).	NR	NR
	2: mean 5.37 (SD 2.71) (n = 506), $P < 0.001$		
	12: mean 5.75 (SD 2.76) (n = 188), $P < 0.001$		
	24: mean 6.26 (SD 3.07) (n = 34), $P < 0.001$		
	36: mean 5.27 (SD 3.82) for n = 11, $P < 0.032$		
Silvola (2014)	NR	NR	NR
Wanscher (2014)	NR	NR	75% moved to a lower class.
Williams (2016)	NR	NR	NR
Xiong (2016)	Before: mean 3.3 (SD 1.4)	NR	NR
	1/4: mean 6.2 (SD 1.6)		
	3: mean 7.1 (SD 0.8)		
	12: mean 7.9 (SD1.2)		

Ears = number of ETBD procedures; ETBD = Eustachian tube balloon dilation; ETS = Eustachian tube score: history and tubamanometry (ETS 2: tubamonometry and tympanometry, ETD classification: Valsalva performance with help); NR = not reported; SD = standard deviation.

Kivekas et al. obtained biopsies of the Eustachian tube mucosa; postoperative biopsies demonstrated a thinner layer of fibrous tissue and restoration of epithelium at 5 to 12 weeks follow-up.[16] Two studies rated mucosal inflammation by means of nasendoscopy, which was assessed by various physicians.[17,18] Scores ranged from 1 to 4, where 1 was an open Eustachian tube, and 4 severe edema and inability to dilate the lumen. The mean preoperative score was either 2.91 (SD 0.83)[17,18] or 2.8 (SD 1.2),[12] and ameliorated postoperatively to 1.73 (SD 0.79) at a follow-up of 7 to 14 months and 1.4 (SD 0.8) after 30 months, respectively.[17] Both showed a significant ($P < 0.01$) decline of mucosal inflammation.

Adverse Events

Complications were mild, few, and self-limiting; of all the procedures in the 1,830 to 1,881 procedures, 36 minor adverse events were encountered (2%) (see Table III). Most often, a diffuse crush injury or local bleeding of the mucosa at the site of the Eustachian tube was reported (n = 20). One study described a severe side effect; a hematotympanum and

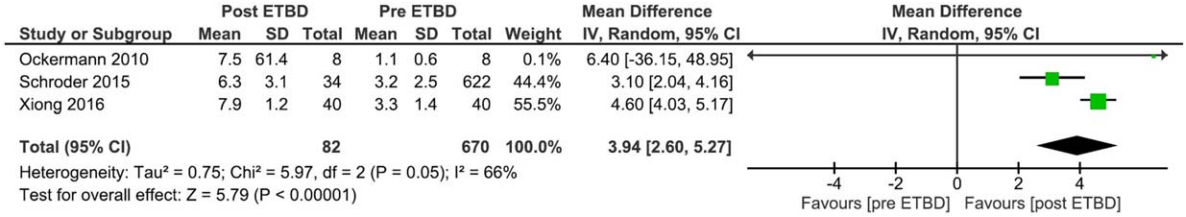


Fig. 2. Forest plot of the Eustachian tube score. A higher score correlates with fewer symptoms. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

myringotomy was necessary to relieve symptoms.[21] Four patients suffered from temporary otitis media acuta after ETBD,[19] and three patients had preauricular emphysema that spontaneously resolved over a few days.[6,14] Rhinitis complaints were reported in five patients during 1 to 5 days after ETBD.[26] One patient had a temporary increase in tinnitus complaints.[6]

Meta-Analysis

For four subgroups, a meta-analysis could be conducted: Valsalva, otoscopy, tympanometry, and Eustachian tube score (see Figs. 2–5). The subgroup Valsalva included five studies with 153 procedures in total and showed a decline of inability to perform the Valsalva maneuver after ETBD (RR: 0.13, 95% CI: 0.04–0.38, P = 0.0002, I^2 = 78%).[10,17,19,20,22]

Otoscopy showed either a normal tympanic membrane or not. An abnormal tympanic membrane usually implied either a retracted membrane, tubes or perforation. Six included studies with 166 procedures all showed a decline of otoscopic abnormal tympanic membranes after ETBD (RR: 0.38, 95% CI 0.07–2.05, P = 0.26, I^2 = 99%).[16–18,21,22,26]

In nine included studies accounting for 255 procedures tympanometry was described, showing a decline in the inability to dilute the Eustachian tubes (RR: 0.47, 95% CI 0.32–0.70, P = 0.0002, I^2 = 84%).[16–23,26]

Last but not least, the Eustachian tube score showed a mean improvement of 3.94 (95% CI:2.60–5.27, P < 0.00001, I^2 = 66%,) across three included studies, with up to 670 procedures.[6,10,22]

DISCUSSION

We conducted a systematic review aimed to evaluate balloon dilation as a treatment of ETD in adults and reviewed 15 articles, including 1,155 patients, undergoing 1,830 to 1,881 procedures. Although we may assume that all patients underwent ETBD procedure bilaterally, this was not specifically mentioned in 51 patients. Evaluation of the effect of ETDB was performed by a combination of prospective and retrospective collection of patient data (ETDQ-7 and GBI questionnaires), the Eustachian tube score, the Valsalva maneuver/Toynbee test, otoscopy, tympanometry, audiometry, ETD classification, and/or histopathology and mucosal inflammation by means of biopsies and nasendoscopy. All types of evaluation of ETD showed an improvement in short-term follow-up. In general, treatment provided symptom relief, which either remained stable over time or improved even further during an average follow-up time of 6.9 months (range 0–50 months). Furthermore, the number of complications was classified as relatively low and self-limiting. Revisions had to be performed in a total of 122 out of the 1,830 to 1,881 procedures. Overall, every published case study concludes ETBD to be a useful treatment of ETD, although further controlled studies are warranted. Supporting this claim is the meta-analysis provided in this review. The meta-analysis was restricted to four subgroups: the Valsalva maneuver, otoscopy, tympanometry, and the Eustachian tube score. All showed a decline of symptoms in favor of treatment. The heterogeneity ranged between 66% to 99% with a RR ranging from 0.13 to 0.47, showing a significant decline of symptoms.

All studies reported short-term symptom relief, although two studies reported a relative decline of this improvement over time (at 7–14 and 36 months).[6,18] Because follow-up ranged between 0 and 50 months postoperatively, no definite conclusion can be drawn on the long-term effectiveness of ETBD.

Overall risk of bias of the included studies was high because all studies were case series, without a control

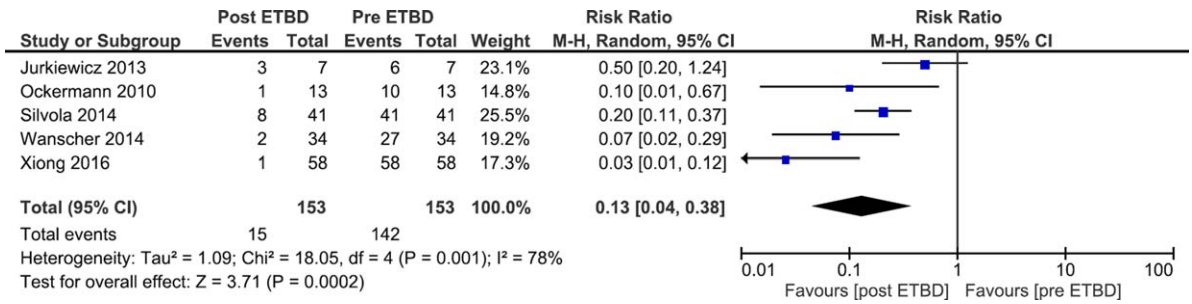


Fig. 3. Forest plot of the Valsalva maneuver. The lower the score, the more patients can perform a successful Valsalva maneuver. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

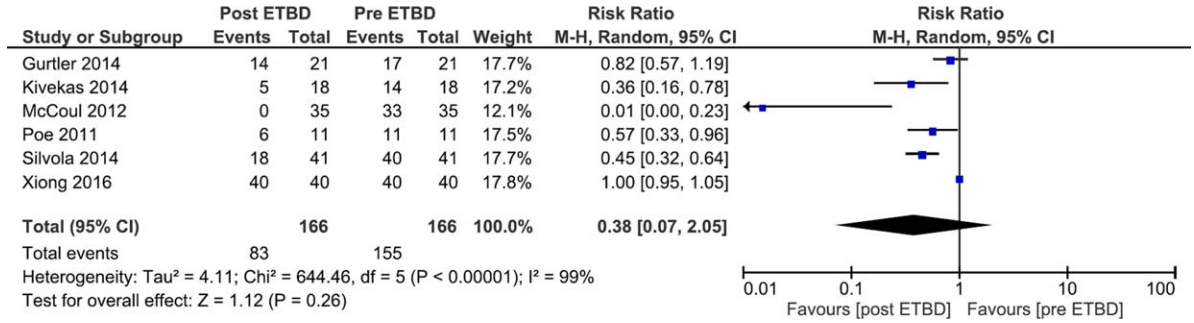


Fig. 4. Forest plot of otoscopy. The lower the score, the smaller the number of patients with an otoscopic tympanic membrane classified as abnormal. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

group or blinding, and susceptible to selection bias. Moreover, data needed for adequate comparison between studies and patient populations were not alike in all studies. Importantly, only relatively mild and few complications were reported, but not all studies mentioned side effects or complications in the first place. In addition, patient groups were not homogenous: some patients were preoperatively treated with decongestive nose spray; others received a ventilation tube; and some patients received other therapy (nasal steroids, decongestants, antibiotics, and tympanoplasty) during or after ETBD. In data analysis, there was no correction for confounders such as additional treatment and comorbidities.

Our meta-analysis was hampered by a high heterogeneity. As stated above, the inclusion criteria were not homogenous among studies, the manner of reporting differed, and the presence of simultaneous other therapies are all factors that might influence the reported outcome. Furthermore, the follow-up times differed between studies, which we could not correct for in the analysis.

With respect to radiological assessment, 10 studies performed imaging before EBTD in order to detect dehiscence of the carotid artery in the temporal bone. It may seem obvious that exclusion of these patients can prevent potential severe side effects, but no data were provided on how many patients were excluded for this reason. Abdel-Aziz et al.[29] previously questioned whether CT imaging is necessary and conclude that imaging does not predict intra- or postoperative difficulties in balloon dilation, and that fear of injury to the internal carotid artery might be disproportionate.[29] This is concomitant with a radiological study in which one thousand CT scans from the archives of the Military Hospital Ulm (Ulm, Germany) were evaluated and no dehiscence of the bony wall of the carotid was found.[30]

For future research on evaluating this promising ETBD therapy, three points need to be addressed. Primarily, it would be challenging to measure the effectiveness of balloon dilation more objectively.[9] The relationship between symptoms and the extent of measurable tuba dysfunction is not always linear. Several authors designed tools in order to assess ETD; one study used a self-designed externally validated Eustachian tube dysfunction questionnaire (ETDQ-7),[21] reaching both a high sensitivity (91%–100%) and specificity (95%–100%).[31–33] However, until now no other studies have used this test. Tubamanometry can be very useful, although it is not specific enough to diagnose ETD.[34] The combination of tubamanometry and symptoms by means of the Eustachian tube score may provide a more objective modality to assess ETBD severity. In a systematic review from 2014, the Eustachian tube score was reported to reach a sensitivity of 72% to 91% and a specificity of 53% to 86%.[9] Adding tympanometry to the Eustachian tube score raises both sensitivity and specificity to 96%.

Secondly, some argue that comparison of ETBD to other treatment should be performed before clinical

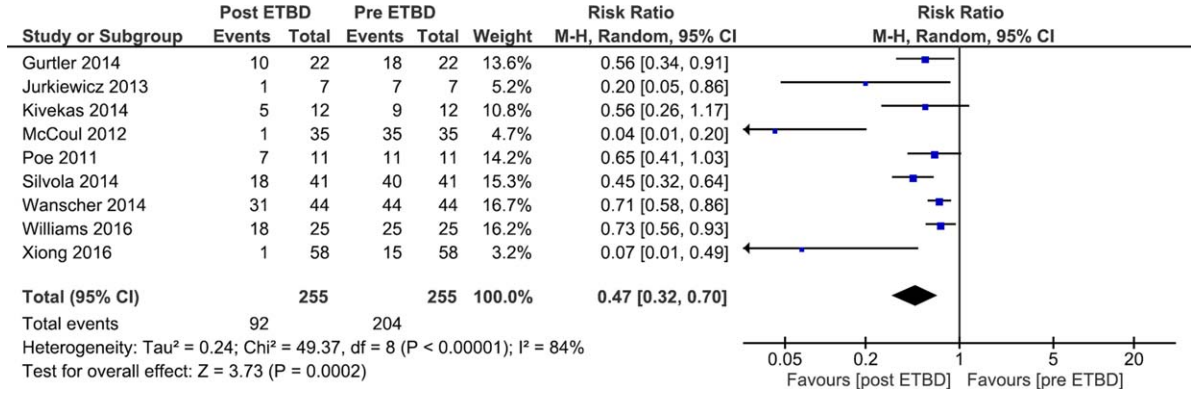


Fig. 5. Forest plot of tympanometry. The lower the score, the smaller the number of patients with a tympanogram type B or C. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

broad-scale implementation. Although this study design is the gold standard to demonstrate the effectiveness of a treatment, some treatments can have such a clear response that background noise has a subordinate effect.[35] As a result, randomized controlled trails not always are necessary. The least we can conclude is that treatment of ETD with balloon dilation seems favorable to reduce symptoms of ETD.

Thirdly, it is pivotal to select the appropriate study population. Not all patients with ETD complaints are hampered in the same manner. For some patients, ETD may be a leisurely problem, and for other patients such as pilots and divers who are exposed to relatively large changes in barometric pressure, it can severely affect their job capabilities.[2] It is recommended to provide a clear definition and standard measurements for ETBD in order to compare studies and outcome parameters, and a potential overlap with coinciding pathologies or comorbidities such as otitis media with effusion and atelectasis should be clearly described.

CONCLUSION

The Eustachian tube balloon dilation technique comprises the inflation of a balloon in the cartilaginous part of the Eustachian tube to cause local dilation. This procedure results in reduction of symptoms and diminished ETD severity scores in all the included studies. We recommend future research in randomized, homogenous populations, using a solid combination of the available diagnostic instruments and symptom scores to evaluate pre- and postoperative severity of tuba dysfunction.

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REVIEW ARTICLE

Balloon dilation for eustachian tube dysfunction: systematic review

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Abstract

Background: Eustachian tube dysfunction is a disorder for which there are limited medical and surgical treatments. Recently, eustachian tube balloon dilation has been proposed as a potential solution.

Method: A systematic literature review was performed. Abstracts were selected for relevance, and pooled data analysis and qualitative analysis was conducted.

Results: Nine prospective studies, describing 713 eustachian tube balloon dilations in 474 patients (aged 18–86 years), were identified. Follow-up duration ranged from 1.5 to 18 months. Ability to perform a Valsalva manoeuvre improved from 20 to 177 out of 245 ears following eustachian tube balloon dilation and, where data were reported in terms of patient numbers, from 15 to 189 out of 210 patients. Tympanograms were classified as type A in 7 out of 141 ears pre-operatively and in 86 out of 141 ears post-operatively.

Conclusion: Prospective case series can confirm the safety of eustachian tube balloon dilation. As a potential solution for chronic eustachian tube dysfunction, further investigations are warranted to establish a higher level of evidence of efficacy.

Key words: Auditory Tube; Balloon; Dilation; Eustachian Tube

Introduction

Eustachian tube dysfunction is a physiological disorder of the eustachian tube that results in inadequate middle-ear ventilation, causing aural fullness and tinnitus. In addition, complications such as serous otitis media, tympanic membrane retraction and cholesteatoma can occur.[1] Eustachian tube dysfunction affects around 1 per cent of adults.[2,3]

Current treatment modalities for eustachian tube dysfunction, which include pharmacological agents, mechanical devices and nasal surgery, can be ineffective.[1,2] Treatment may entail multiple insertions of ventilation tubes in patients with chronic eustachian tube dysfunction, leading to complications such as tympanosclerosis, chronic perforation and cholesteatoma.[4]

Recently, eustachian tube balloon dilation has been researched in prospective cohort studies and is currently used 'off-label' as a potential treatment for chronic eustachian tube dysfunction.[5,6] It aims to improve eustachian tube compliance and middle-ear ventilation. Its proposed mechanisms include mechanical dilation of the cartilaginous eustachian tube and initiation of histopathological changes to the mucosa that can alter the inflammatory process.[7]

However, eustachian tube balloon dilation is a new procedure, and the operative technique needs to be verified for its efficacy and complications. This paper systematically reviews the available evidence on eustachian tube balloon dilation for treating chronic eustachian tube dysfunction.

Materials and methods

Criteria for study eligibility

Studies were eligible for inclusion in data analysis if they were prospective (cohort or randomised), aimed to assess the effectiveness of eustachian tube balloon dilation in adults, and included outcomes of ability to perform Valsalva or Toynbee's manoeuvre and/or tympanometry results. Retrospective studies, studies that did not include one of the two aforementioned outcomes, cadaveric studies and technical studies were excluded from data analysis but included in the discussion. Published conference abstracts and case reports were excluded from this review.

Literature search and study selection

Two authors (SH and JW) independently searched Medline, PubMed and Embase databases for relevant

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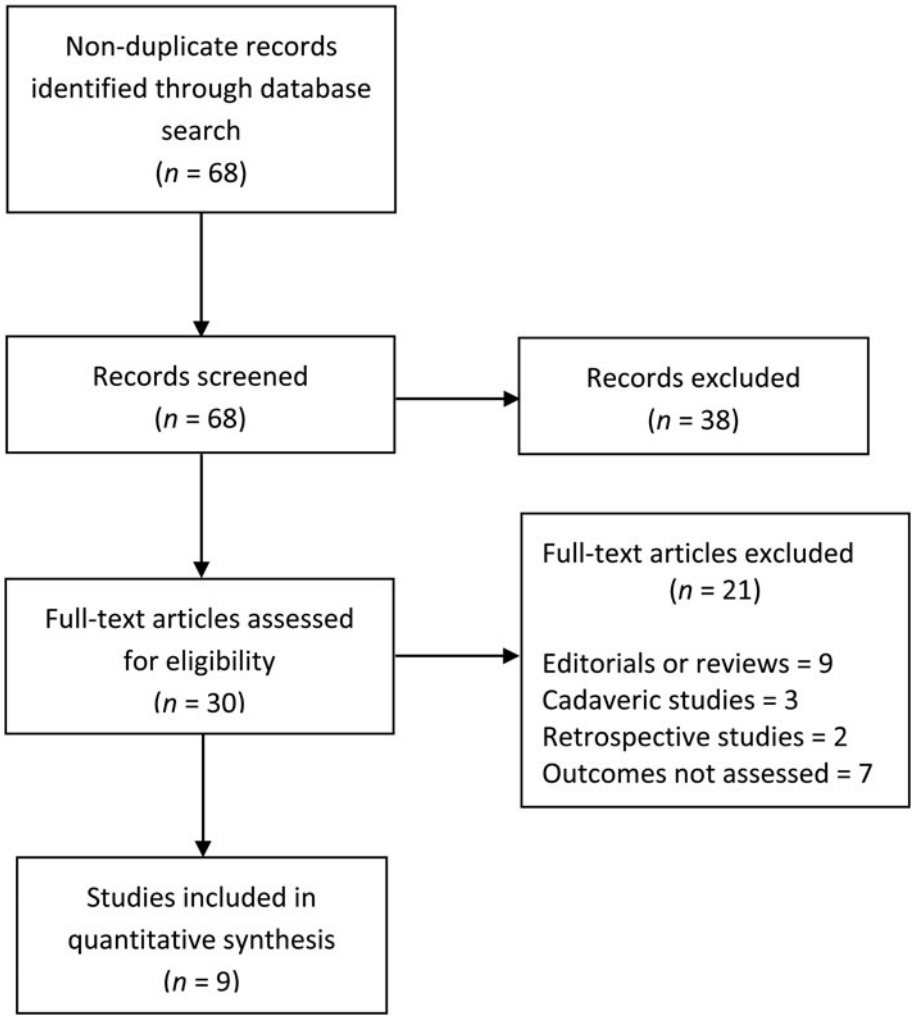


FIG. 1
Preferred Reporting Items for Systematic Reviews and Meta-Analyses ('PRISMA') flow diagram of search method.

papers published from 1950 to October 2015. No restrictions were made on language. The keywords 'eustachian tube', 'auditory tube', 'dilation', 'dilatation' and 'balloon' were used. This search was supplemented by using the 'related article' function. The search was repeated on Google Scholar to locate additional abstracts. A manual search of references of eligible manuscripts was also performed.

Studies that were eligible for inclusion in the systematic review were assessed independently and any disagreements were resolved by discussion between the two aforementioned authors. Figure 1 demonstrates the Preferred Reporting Items for Systematic Reviews and Meta-Analyses ('PRISMA') flow diagram.

Data extraction and statistical analysis

Data extraction was performed independently by two authors (SH and JW). Pooled data analysis was performed.

Results

Nine prospective studies,[4,6,8–14] describing 713 eustachian tube balloon dilations in 474 patients (aged 18–86 years), were identified. Follow-up duration ranged from 1.5 to 18 months. The included studies are summarised in Tables I and II.

Indications

The indication for eustachian tube balloon dilation in all studies was chronic eustachian tube dysfunction. The method of diagnosis varied between the studies, but all included clinical history and otoscopy, with six studies using tympanometry and two studies using tubomanometry.

Techniques

Two main balloon dilation techniques were described in the literature, with five studies[6,8,11,13,14] reporting the use of the Bielefeld technique (developed in Germany) and four studies[4,9,10,12] using the Acclarent balloon technique (developed in North America). Both techniques were performed under general anaesthetic, with pre-operative topical decongestant applied to nasal mucosa and the eustachian tube orifice.

In the Bielefeld technique, a Storz micro-endoscope is used to visualise the insertion of a purpose-built

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TABLE I
PAPERS EVALUATING EUSTACHIAN TUBE BALLOON DILATION

Authors	Year	Pt age (mean (range); years)	Number of cases	Technique	Mean follow-up time (months)
Ockermann *et al.*[6]	2010	44.1 (21–81)	13 ETBDs in 8 pts	Bielefeld catheter	2
Poe *et al.*[10]	2011	51.8 (33–76)	11 ETBDs in 11 pts	Acclarent catheter	7 (median)
Catalano *et al.*[4]	2012	45 (18–73)	100 ETBDs in 70 pts	Acclarent catheter	7
McCoul & Anand[9]	2012	55.1 (NR)	35 ETBDs in 22 pts	Acclarent catheter	10 (median)
Jurkiewicz *et al.*[8]	2013	45.8 (23–61)	7 ETBDs in 4 pts	Bielefeld catheter	1.5
Schroder *et al.*[11]	2013	54 (18–86)	135 ETBDs in 78 pts	Bielefeld catheter	12
Tisch *et al.*[13]	2013	46 (18–74)	320 ETBDs in 210 pts	Bielefeld catheter	3
Wanscher & Svane-Knudsen[14]	2014	45 (20–74)	50 ETBDs in 34 pts	Bielefeld catheter	2
Silvola *et al.*[12]	2014	48 (15–38)	41 ETBDs in 37 pts	Acclarent catheter	18

Pt = patient; ETBD = eustachian tube balloon dilation; NR = not reported

TABLE II
RESULTS OF EUSTACHIAN TUBE BALLOON DILATION

Authors	Ability to perform Valsalva (*n*)		Type A tympanometry (*n*)	
	Pre-op	Post-op	Pre-op	Post-op
Ockermann *et al.*[6]	0/13	12/13	N/A	N/A
Poe *et al.*[10]	0/11	11/11	0/11	4/11
Catalano *et al.*[4]	N/A	N/A	0/28	25/28
McCoul & Anand[9]	N/A	N/A	0/35	34/35
Jurkiewicz *et al.*[8]	1/7	6/7	0/7	6/7
Schroder *et al.*[11]	16/135	86/135	N/A	N/A
Tisch *et al.*[13]	15/210*	189/210*	N/A	N/A
Wanscher & Svane-Knudsen[14]	3/38	29/38	0/44	12/44
Silvola *et al.*[12]	0/41	33/41	1/17	23/29

*Results reported as numbers of patients not individual eustachian tubes. Pre-op = pre-operative; post-op = post-operative; N/A = not applicable

Bielefeld balloon catheter into the eustachian tube. The balloon is inflated to a pressure of 10 bars for 2 minutes, with the aim of inflating the balloon to a size of 3×20 mm.

In the Acclarent balloon technique, a 30- or a 45-degree, 4 mm Hopkins rod is used to visualise the insertion of an angled 70-degree catheter into the eustachian tube. Balloon sizes, pressures and duration of inflation vary between the papers that use this technique. These include a 5×16 mm balloon inflated to 8 atm for 30 seconds,[4] a 5×24 mm or 7×24 mm balloon (adjusted for individual patients) inflated to 10 atm for 2 minutes,[9] or a 7×16 mm balloon inflated to 12 atm for 1 minute.[10,12]

Valsalva

The ability to perform a Valsalva or Toynbee's manoeuvre pre- and post-eustachian tube balloon dilation was reported in seven studies. This improved from 20 (8 per cent) to 177 (72 per cent) out of 245 ears following eustachian tube balloon dilation,[6,8,10–12,14] and, where data were reported in terms of patient numbers, from 15 (7 per cent) to 189 (90 per cent) out of 210 patients.[13]

Tympanometry

Tympanometry results were reported in six studies.[8–12,14] Tympanograms were classified as type A in 7 out of 141 ears (5 per cent) pre-operatively, and this improved to 86 out of 141 ears (61 per cent) post-operatively. Twelve of these classifications (9 per cent) were because of grommets being removed and/or tympanic membrane perforations healing.

Tubomanometry

Tubomanometry was performed pre-operatively in two studies,[6,11] but no post-operative data were provided. Tubomanometry was mainly used as an adjunct to aid in the diagnosis of eustachian tube dysfunction.

Quality of life

One study[9] used the 7-item Eustachian Tube Dysfunction Questionnaire and the 22-item Sino-Nasal Outcome Test (SNOT-22) to evaluate improvement in symptoms and quality of life pre- and post-eustachian tube balloon dilation.

There were statistically significant improvements in both measures: the 7-item Eustachian Tube Dysfunction Questionnaire pre-operative mean score of 4.5 decreased to 2.8 at 6 months ($p < 0.001$), and the SNOT-22 pre-operative mean score decreased from 51.4 to 30 at 6 months ($p = 0.001$).

Complications

All studies documented complications. Four studies[6,8,9,12] reported no eustachian tube balloon dilation related complications and one study[11] reported only minor epistaxis. More serious complications included two cases of self-resolving subcutaneous emphysema in two separate studies.[4,13]

Complications associated with a learning curve were described by Wanscher and Svane-Knudsen,[14] who reported 3 cases of acute otitis media in the first 20 eustachian tube balloon dilations, which decreased to 1 out of 30 after 5 days of post-operative prophylactic oral antibiotics.

Poe *et al.*[10] reported 5 cases of minor mucosal lacerations in 11 eustachian tube balloon dilations

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and 1 case of C6–C7 contralateral radiculopathy, the latter of which was thought to be caused by operative positioning.

There were no reported cases of carotid artery injury or patulous eustachian tube in any of the papers reviewed.

Discussion

The eustachian tube in adults is approximately 37.5 mm long, and consists of bony and cartilaginous portions, extending from the middle-ear cleft to the nasopharynx.[15] It has several physiological functions, which include pressure equalisation, drainage of the middle ear and protection from the nasopharyngeal environment.[15]

Poor or inadequate eustachian tube function causes eustachian tube dysfunction, which is a physiological disorder that may be temporary and spontaneously resolving.[1] Chronic eustachian tube dysfunction occurs when the dysfunction lasts for over three months; it is a poorly defined clinical entity, with variable diagnostic criteria based on clinical history, otoscopy and tympanogram results.[2] It can be a difficult pathology to manage, with debilitating symptoms affecting quality of life; current conventional treatments may not be effective.

A recent health technology assessment found that there was minimal evidence of effectiveness for current medical and surgical interventions, including nasal decongestants, topical and systematic corticosteroids, antihistamines, mechanical devices, and nasal surgery.[2] It identified only one study with a low risk of bias, a randomised, controlled trial, which found no improvement in eustachian tube dysfunction symptoms after six weeks of nasal steroids.[16]

In cases of chronic eustachian tube dysfunction refractory to conventional treatment, multiple insertions of ventilation tubes may be required. This can cause persistent perforation requiring dry ear precautions and/or myringoplasty. As a potential solution for this, eustachian tube balloon dilation (proposed as a treatment for chronic eustachian tube dysfunction) aims to ventilate and drain the middle ear by improving the physiological function of the eustachian tube.[6,10]

The initial papers by Ockermann *et al*. in 2010[5,6] and Poe *et al*. in 2011[10,17] focused on establishing the safety of eustachian tube balloon dilation by performing both cadaveric and clinical studies. The cadaveric studies revealed no evidence of fractures to the cartilaginous or bony lumen, and no damage to the internal carotid artery. Only minor mucosal lacerations at the eustachian tube orifice were noted.[5,17]

Since then, numerous prospective cohort studies have examined the role of eustachian tube balloon dilation. Pooled data analysis in this review revealed that the ability to perform a Valsalva improved from 8 per cent pre-eustachian tube balloon dilation to 72 per cent post-eustachian tube balloon dilation, while the rate of type A tympanograms increased from 5 to 61 per cent. Further statistical analysis is inappropriate because of the heterogeneity of the inclusion criteria, techniques and outcome measures in the papers included in this review.

The mechanisms by which eustachian tube balloon dilation improves eustachian tube function is an area of ongoing research, but appear to include both anatomical dilation of the cartilaginous eustachian tube and the initiation of histopathological changes.[7] A recent study examining the histopathological changes associated with eustachian tube balloon dilation found that the balloon had a crushing effect on inflammatory cells within the eustachian tube mucosa while sparing the basal layer, rapidly replacing the inflamed mucosa with a fibrous scar.[7]

One major concern of eustachian tube balloon dilation is the theoretical risk of injury to a dehiscent carotid artery running adjacent to the bony eustachian tube;[18] hence, computed tomography (CT) of the petrous temporal bones was routinely performed as a part of the pre-operative investigations. Abdel-Aziz *et al*.[18] conducted a retrospective analysis of petrous temporal bone CT scans of 285 patients who underwent eustachian tube balloon dilation. The authors found that 24 eustachian tube balloon dilations were performed in 17 patients with carotid canal dehiscence, with no complications or technical difficulties. This suggests that routine petrous temporal bone CT is not indicated before eustachian tube balloon dilation.

Another area of concern for eustachian tube balloon dilation is its use in the paediatric population, where middle-ear disease is more prevalent[19] because of a shorter, more horizontal eustachian tube, with a lumen that is less than half the size of an adult eustachian tube.[15] Currently, there are 2 retrospective case series that describe eustachian tube balloon dilations in 33 children aged 5–14 years (mean, 9 years),[19] and in 66 children aged 4–14 years (mean, 8 years),[20] with no reported complications and an improvement in middle-ear symptoms.

Despite the aforementioned results of this review, Bluestone[21] suggested, in 2014, that the efficacy of eustachian tube balloon dilation remains unverified. This is because the majority of studies have small numbers of patients, limited follow up, a weak definition of 'cure' and do not evaluate the direct effect of eustachian tube balloon dilation on eustachian tube function. This suggests that a more rigorous clinical trial is required.

Any future clinical trial on eustachian tube balloon dilation would require strict inclusion criteria and should use commonly accepted outcome measurements. The authors of this paper believe that the appropriate outcome measures should include: clinical measures of otoscopy and the ability to perform a Valsalva manoeuvre; objective measures of tympanometry, audiometry and/or tubomanometry; and patient-reported measures acquired using a verified questionnaire such as the seven-item Eustachian Tube Dysfunction Questionnaire.[22]

Our evaluation of the evidence for eustachian tube balloon dilation is limited by the quality of the papers

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included, as the highest level of evidence available is prospective case series. Three papers[6,8,10] had less than 20 patients, and only 2 papers[11,12] had an average follow-up period longer than 12 months. Also, there were significant variations in terms of the assessment of patients, indications for eustachian tube balloon dilation and assessment of outcomes.

The diagnosis, investigations and indications for eustachian tube balloon dilation were not standard across the papers. This standardisation is in part limited by the subjective clinical nature by which chronic eustachian tube dysfunction is diagnosed. Although all studies reviewed used clinical history, otoscopy and tympanometry to diagnose chronic eustachian tube dysfunction, the indications for eustachian tube balloon dilation differed. In some papers, eustachian tube dysfunction refractory to conventional treatment was required, while in others a diagnosis of chronic eustachian tube dysfunction was sufficient. In future evaluations of eustachian tube balloon dilation, diagnostic criteria that include objective measurements of tympanometry and the seven-item Eustachian Tube Dysfunction Questionnaire should be used.

In addition, the technique of eustachian tube balloon dilation differed across the nine papers, with the two main techniques being those described in the Results section. In both techniques, the target for balloon dilation is the 8–12 mm segment that acts as a valve within the cartilaginous eustachian tube, as this is where the physiological deficiency in chronic eustachian tube dysfunction is thought to originate.[17] Hence, care is taken to not push the balloon catheter past the cartilaginous and bony isthmus, or to use a balloon size that is too large for the patient.

However, this has meant that a variety of balloon sizes and pressures have been employed, especially among those who use the Acclarent balloon catheters. No 'best' way to perform eustachian tube balloon dilation has yet been established; at the current early stages of evaluating its efficacy, the heterogeneity of techniques confounds the ability to draw conclusions.

Overall, this review found that eustachian tube balloon dilation is a procedure with a low rate of complications and may be considered for refractory chronic eustachian tube dysfunction in adults. More rigorous studies with standardised indications, techniques and outcomes are required to provide a higher level of evidence before its mainstream use. Nevertheless, the current data suggest a potential benefit of this procedure for a condition that can be difficult to manage.

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Severe Inflammatory Skin Disease Guideline Revisions

Question: How should the severe inflammatory skin disease guideline be modified to reflect the Pharmacy and Therapeutic Committee's recommendations for treatments for atopic dermatitis?

Question source: P&T staff, HERC staff, VBBS

Issue: In November 2017, the HERC adopted modifications to the severe inflammatory skin disease guideline for therapies for atopic dermatitis (AD) based on ICD-10 Dermatology reviewer recommendations. However, these therapies do not completely agree with the evidence reviews on medication effectiveness done by the P&T Committee. P&T and HERC staff have worked to propose modifications to the guideline that reflect the evidence reviews done by P&T.

HERC staff brought a proposal to remove the medication therapy paragraphs from the guideline note to the May, 2018 VBBS meeting. At that meeting, VBBS members expressed support for keeping the medication therapy paragraphs in the guideline, as they are useful for the CCOs to use for their own PA criteria or to review medication requests. HERC staff was directed to work with P&T staff to update the guidelines to bring the Prioritized List guideline into agreement with current P&T PA criteria.

On review, the psoriasis section of the guideline was found to have no conflicts with the current P&T criteria. The atopic dermatitis section differs significantly from P&T criteria and staff have worked with P&T staff to align the wording.

HERC staff recommendation:

1) Modify GN21 as shown below

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

Lines 424,480,502,530,539,654

Inflammatory skin conditions included in this guideline are:

A) Psoriasis
B) Atopic dermatitis
C) Lichen planus
D) Darier disease
E) Pityriasis rubra pilaris
F) Discoid lupus

The conditions above are included on line 424 if severe, defined as having functional impairment (e.g. inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction) AND one or more of the following:

A) At least 10% of body surface area involved
B) Hand, foot or mucous membrane involvement.

Otherwise, these conditions above are included on Lines 480, 502, 530, 539 and 654.

For severe psoriasis, first line agents include topical agents, phototherapy and methotrexate. Second line agents include other systemic agents and oral retinoids and should be limited to those who fail, or have contraindications to, or do not have access to first line agents. Biologics are included on this line

only for the indication of severe plaque psoriasis; after documented failure of first line agents and failure of (or contraindications to) a second line agent.

For severe atopic dermatitis/eczema, fist line agents include topical moderate to high potency corticosteroids~~,~~ and narrowband UVB ~~cyclosporine, methotrexate, and azathioprine~~. Second line agents include topical calcineurin inhibitors (e.g. pimecrolimus ~~and topical~~, tacrolimus), topical phosphodiesterase (PDE)-4 inhibitors (e.g. crisaborole), and oral immunomodulatory therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil, or oral corticosteroids). Use of the topical second line agents (e.g. calcineurin inhibitors and phosphodiesterase (PDE)-4 inhibitors) ~~and~~ should be limited to those who fail or have contraindications to first line agents. Biologic agents are included on this line for atopic dermatitis only after failure of or contraindications to at least one agent from each of the following three classes: 1) moderate to high potency topical corticosteroids, 2) topical calcineurin inhibitors or topical phosphodiesterase (PDE)-4 inhibitors, and 3) oral immunomodulator therapy. ~~first and second line agents~~.

Section 8.0

New Discussion Items

PET Scan Guideline

Question: Should the PET scan guideline be changed from a standard guideline attached to lines to a diagnostic guideline?

Question source: HERC staff, HSD staff

Issue: The current PET scan guideline refers to two diagnostic indications for PET scan, evaluation of solitary pulmonary nodules and evaluation of cervical metastases without obvious primary. These diagnostic indications have either ICD-10 codes that are on an unfunded line (C77.0 for cervical metastases without obvious primary on line 589 SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS) or on the Diagnostic Workup File (R91.1 for solitary pulmonary nodule). These indications currently cannot pair in the MMIS system. Initially, HERC staff considered making a separate PET scan diagnostic guideline; however, PET scan CPT codes cannot be both on the Diagnostic Procedures File and on lines on the Prioritized List.

HERC staff recommendations:

1) Remove PET scan CPT codes (CPT 78608-78609, 78811-78816) from all current lines on the Prioritized List and advise HSD to place on the Diagnostic Procedures File
2) Change the current PET guideline to a diagnostic guideline as shown below
    a. Does not change previous intent of coverage
    b. PET CPT codes will now pair with ICD-10 codes for solitary pulmonary nodules and cervical lymph node metastases, as well as with any ICD-10 code on the Prioritized List

~~**GUIDELINE NOTE 19**~~ **DIAGNOSTIC GUIDELINE XX, PET SCAN GUIDELINES**

~~*Lines 113,116,133,135,157,158,163,174,200,201,211,230,260,263,276,287,314*~~

PET Scans are covered for diagnosis of the following cancers only:

- Solitary pulmonary nodules and non-small cell lung cancer
- Evaluation of cervical lymph node metastases when CT or MRI do not demonstrate an obvious primary tumor.

For diagnosis, PET is covered only when it will avoid an invasive diagnostic procedure, or will assist in determining the optimal anatomic location to perform an invasive diagnostic procedure.

PET scans are covered for the initial staging of the following cancers:

- Cervical cancer only when initial MRI or CT is negative for extra-pelvic metastasis
- Head and neck cancer when initial MRI or CT is equivocal
- Colon cancer
- Esophageal cancer
- Solitary pulmonary nodule
- Non-small cell lung cancer
- Lymphoma
- Melanoma

For staging, PET is covered when clinical management of the patient will differ depending on the stage of the cancer identified and either:

A) the stage of the cancer remains in doubt after standard diagnostic work up, OR

B) PET replaces one or more conventional imaging studies when they are insufficient for clinical management of the patient.

Restaging is covered only for cancers for which staging is covered and for thyroid cancer if recurrence is suspected and l131 scintography is negative. For restaging, PET is covered after completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence or to determine the extent of a known recurrence. PET is not covered to monitor tumor response during the planned course of therapy. PET scans are NOT indicated for routine follow up of cancer treatment or routine surveillance in asymptomatic patients.

PET scans are also indicated for preoperative evaluation of the brain in patients who have intractable seizures and are candidates for focal surgery. PET scans are NOT indicated for cardiac evaluation.

Absorbable Implant for Nasal Vestibular Wall Stenosis

Question: Should absorbable implants be added to the Prioritized List for treatment of nasal vestibular wall stenosis?

Question source: HERC staff

Issue: A new HCPCS code was added effective April 1, 2018 which codes for an absorbable implant to help repair vestibular wall stenosis. HCPCS C9749 Repair of nasal vestibular lateral wall stenosis with implant(s). The nasal wall can become stenotic, causing sinus issues. There are various surgical techniques to repair this condition. Currently, CPT 30465 (Repair of nasal vestibular stenosis (eg, spreader grafting, lateral nasal wall reconstruction) is located on lines 463 CHRONIC SINUSITIS, 504 NASAL POLYPS, OTHER DISORDERS OF NASAL CAVITY AND SINUSES, and 573 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT. There are several commercial products now available which are inserted into the lateral nose to support upper and lower lateral cartilage in the nose, reinforcing the nasal wall like traditional cartilage and polymer grafts. The implant is reabsorbed within about 18 months.

Evidence
One study on these types of implants was found, although the actual article is not available through usual library sources.

San Nicoló 2017 (only abstract available)

1) Safety/efficacy study
2) N=30 patients (56 implants)
3) Mean preoperative Nasal Obstruction Symptom Evaluation (NOSE) score was 76.7 ± 14.8, with a range of 55 to 100. At 12 months, the mean score was 35.2 ± 29.2, reflecting an average within-patient reduction of -40.9 ± 31.2 points. The majority (76%) of the subjects were responders defined as having at least one NOSE class improvement or a NOSE score reduction of at least 20%. There were no adverse changes in cosmetic appearance at 12 months postprocedure. Three implants in three subjects required retrieval within 30 days postprocedure and resulted in no clinical sequelae.
4) Conclusion: This study demonstrates safety and effectiveness of an absorbable implant for lateral cartilage support in subjects with NVC at 12 months postprocedure.

HERC staff recommendation

1) Add HCPCS C9749 Repair of nasal vestibular lateral wall stenosis with implant(s)) to line 660/GN173 as experimental
    a. Surgical corrective techniques are available and paired with this diagnosis

GUIDELINE NOTE 173, TREATMENTS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS; UNPROVEN TREATMENTS

The following treatments are prioritized on Line 660, CONDITIONS FOR WHICH CERTAIN TREATMENTS HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS; UNPROVEN TREATMENTS for the conditions listed here:

CPT/HCPCS code	**INTERVENTION**	**Rationale**	**Date of last Review**
C9749	Repair of nasal vestibular lateral wall stenosis with implant(s)	Unproven treatment	August, 2018

Migraine And Botox Botulinum Toxin Guideline Edit

Question: Should the botulinum toxin for migraines guideline be edited?

Question source: Hearings, CCO question

Issue: Through a hearing case a CCO identified that guideline note 42 has a requirement for failure of calcium channel blockers which "*has fallen out of favor clinically and not supported by evidence."*

In 2015 this guideline was adopted based on P&T criteria and prior authorization criteria from North Carolina.

Prioritized List Status

Line:	**409**
Condition:	MIGRAINE HEADACHES (See Guideline Notes 42,64,65,92)
Treatment:	MEDICAL THERAPY
ICD-10:	G43.001-G43.719,G43.B0-G43.C1,G43.801-G43.919,G44.001-G44.1
CPT:	64615,92002-92014,92081-92083,93792,93793,96150-96155,97810-97814, 98966-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285, 99291-99404,99408-99449,99468-99480,99487-99490,99495-99498, 99605-99607
HCPCS:	G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427,G0463-G0467, G0490,G0508-G0511,G0513,G0514

GUIDELINE NOTE 42, CHEMODENERVATION FOR CHRONIC MIGRAINE

Line 409

Chemodenervation for treatment of chronic migraine (CPT 64615) is included on this line for prophylactic treatment of adults who meet all of the following criteria:

A) have chronic migraine defined as headaches on at least 15 days per month of which at least 8 days are with migraine
B) has not responded to or have contraindications to at least three prior pharmacological prophylaxis therapies (beta-blocker, calcium channel blocker, anticonvulsant or tricyclic antidepressant)
C) treatment is administered in consultation with a neurologist or headache specialist.

Treatment is limited to two injections given 3 months apart. Additional treatment requires documented positive response to therapy. Positive response to therapy is defined as a reduction of at least 7 headache days per month compared to baseline headache frequency.

Evidence Summary

Jackson, 2015

*(*http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0130733*)*

- Network meta-analysis of RCTS for the prophylaxis of migraines
- Placebo controlled trials of alpha blockers (n = 9), angiotensin converting enzyme inhibitors (n = 3), angiotensin receptor blockers (n = 3), anticonvulsants (n = 32), beta-blockers (n = 39), calcium channel blockers (n = 12), flunarizine (n = 7), serotonin reuptake inhibitors (n = 6), serotonin norepinephrine reuptake inhibitors (n = 1) serotonin agonists (n = 9) and tricyclic antidepressants (n = 11).
- Comparative effectiveness trials (n=53).
- Results:
- Drugs with at least 3 trials that were more effective than placebo for episodic migraines included
    - amitriptyline (SMD: -1.2, 95% CI: -1.7 to -0.82),
    - flunarizine (-1.1 headaches/month (ha/month), 95% CI: -1.6 to -0.67),
    - fluoxetine (SMD: -0.57, 95% CI: -0.97 to -0.17)
    - metoprolol (-0.94 ha/month, 95% CI: -1.4 to -0.46)
    - pizotifen (-0.43 ha/month, 95% CI: -0.6 to -0.21)
    - propranolol (-1.3 ha/month, 95% CI: -2.0 to -0.62)
    - topiramate (-1.1 ha/month, 95% CI: -1.9 to -0.73)
    - valproate (-1.5 ha/month, 95% CI: -2.1 to -0.8).
- Several effective drugs with less than 3 trials included:
    - 3 ace inhibitors (enalapril, lisinopril, captopril)
    - two angiotensin receptor blockers (candesartan, telmisartan)
    - two anticonvulsants (lamotrigine, levetiracetam)
    - beta-blockers (atenolol, bisoprolol, timolol).
- Calcium channel blockers, 11 studies, 878 participants, 78% women average study duration 11 weeks. No calcium channel blocker was more effective than placebo, including cyclendelate, nicardipine, nifedipine, nimodipine and verapamil. When the dihydropyridines (nicardipine, nifedipine, nimodipine) were pooled, they were no better than placebo at reducing headaches.

Scottish Intercollegiate Guidelines Network (SIGN), 2018

- Low-quality studies, mostly from the 1980s and of variable design and size, reported some, but not consistent, benefit from verapamil, nimodipine, nifedipine or nicardipine over placebo in patients with episodic or chronic migraine.46,53
- Meta-analysis of seven trials of flunarazine at a dose of 10 mg daily reported a moderate benefit in patients with episodic migraine compared to placebo. The standardised mean difference (SMD) for reduction in headache frequency was -0.60 (95% CI -1.2 to 0.005) at eight weeks and -0.84 (95% CI -1.3 to 0.34) at 12

weeks. No significant benefit was found at four weeks.53 The trials included in the meta-analysis were small.

- Recommendations:
  - 1st line therapies = Beta blockers
  - Recommended therapies = topiramate,
  - Consider these therapies = tricyclic antidepressants, candesartan, sodium valproate, calcium channel blockers (flunarizine)
- Botulinum toxin A is recommended for the prophylactic treatment of patients with chronic migraine where medication overuse has been addressed and patients have been appropriately treated with three or more oral migraine prophylactic treatments.

NICE, 2012
Guidance on migraine prophylaxis, published 2012, affirmed 2016
https://www.nice.org.uk/guidance/cg150/chapter/Recommendations#management-2

Prophylactic treatment

1.3.16 Discuss the benefits and risks of prophylactic treatment for migraine with the person, taking into account the person's preference, comorbidities, risk of adverse events and the impact of the headache on their quality of life. **[2012]**

1.3.17 Offer topiramate or propranolol[12] for the prophylactic treatment of migraine according to the person's preference, comorbidities and risk of adverse events. Advise women and girls of childbearing potential that topiramate is associated with a risk of fetal malformations and can impair the effectiveness of hormonal contraceptives. Ensure they are offered suitable contraception if needed. **[2015]**

1.3.18 Consider amitriptyline[13] for the prophylactic treatment of migraine according to the person's preference, comorbidities and risk of adverse events. **[new 2015]**

1.3.19 Do not offer gabapentin for the prophylactic treatment of migraine. **[new 2015]**

1.3.20 If both topiramate and propranolol[12] are unsuitable or ineffective, consider a course of up to 10 sessions of acupuncture over 5–8 weeks according to the person's preference, comorbidities and risk of adverse events. **[2012, amended 2015]**

1.3.21 For people who are already having treatment with another form of prophylaxis and whose migraine is well controlled, continue the current treatment as required. **[2012, amended 2015]**

1.3.22 Review the need for continuing migraine prophylaxis 6 months after the start of prophylactic treatment. **[2012]**

1.3.23 Advise people with migraine that riboflavin (400 mg[14] once a day) may be effective in reducing migraine frequency and intensity for some people. **[2012]**

Botulinum toxin guidance for migraines
https://www.nice.org.uk/guidance/ta260/chapter/1-Guidance

1.1 Botulinum toxin type A is recommended as an option for the prophylaxis of headaches in adults with chronic migraine (defined as headaches on at least 15 days per month of which at least 8 days are with migraine):

- that has not responded to at least three prior pharmacological prophylaxis therapies **and**
- whose condition is appropriately managed for medication overuse.

1.2 Treatment with botulinum toxin type A that is recommended according to 1.1 should be stopped in people whose condition:

- is not adequately responding to treatment (defined as less than a 30% reduction in headache days per month after two treatment cycles) **or**
- has changed to episodic migraine (defined as fewer than 15 headache days per month) for three consecutive months.

1.3 People currently receiving botulinum toxin type A that is not recommended according to 1.1 and 1.2 should have the option to continue treatment until they and their clinician consider it appropriate to stop.

Washington Health Technology Assessment, 2017 https://www.hca.wa.gov/about-hca/health-technology-assessment/treatment-chronic-migraine-and-chronic-tension-type-headache | https://www.hca.wa.gov/assets/program/chronic-migraine-final-rpt-

20170417.pdf | https://www.hca.wa.gov/assets/program/chronic-migraine-final-findings-decision-REVISED-20180720_0.pdf

- Systematic review of the evidence for the treatment of chronic migraine and chronic tension type headache
- 11 trials evaluating the prevention of chronic migraines were included (GRADE table results on pp 34-43 of the pdf)
  - *BoNTA versus Placebo – moderate quality evidence in reduction in migraine, episodes, headache days,*
  - *Acupuncture – low quality evidence in favor of acupuncture at 36 weeks*
  - *Acupuncture versus topiramate – low quality evidence in favor of acupuncture over topiramate*
  - *Spinal manipulation therapy versus amitryptiline – low quality mixed evidence in favor of spinal manipulation*
  - *Transcranial magnetic stimulation – insufficient to low for various outcomes*
- Decision

  For treatment of chronic migraine (as defined by the International Headache Society), OnabotulinumtoxinA is covered when the following criteria are met:

  1) Has not responded to at least three prior pharmacological prophylaxis therapies from two different classes of drugs AND

  2) Condition is appropriately managed for medication overuse

  OnabotulinumtoxinA injections **must be discontinued** when the condition:
  1) Has shown inadequate response to treatment (defined as <50% reduction in headache days per month after two treatment cycles) OR

  2) Has changed to episodic migraine (defined as <15 headache days per month) for three consecutive months.

  Maximum of five treatment cycles. Additional treatment cycles may be considered at agency discretion.

American Academy of Neurology, 2012 Prevention of *Episodic* Migraine
https://www.aan.com/Guidelines/home/GetGuidelineContent/545

- For Calcium-channel Blockers there is Insufficient evidence
  - Evidence is conflicting or inadequate to support or refute the use of nicardipine, nifedipine, nimodipine, or verapamil for migraine prevention (Level U).

HERC Staff Summary
Failure of at least three pharmacologic therapies is standard prior to botulinum toxin. Calcium channel blockers, however, do not have strong evidence to support their use. Standard therapies involve beta blockers, tricyclic antidepressants, and anticonvulsants.

Acupuncture and riboflavin could be additional therapies. There is currently no reference to ruling out or managing medication overuse headache which is an important step in managing chronic migraine and should be addressed prior to escalating therapies (such as with chemodenervation).

Recommendations:

1) Modify guideline note 42:

GUIDELINE NOTE 42, CHEMODENERVATION FOR CHRONIC MIGRAINE

Line 409

Chemodenervation for treatment of chronic migraine (CPT 64615) is included on this line for prophylactic treatment of adults who meet all of the following criteria:

A) have chronic migraine defined as headaches on at least 15 days per month of which at least 8 days are with migraine
B) has not responded to or have contraindications to at least three prior pharmacological prophylaxis therapies (beta-blocker, ~~calcium channel blocker,~~ anticonvulsant, or tricyclic antidepressant)
C) their condition has been appropriately managed for medication overuse
D) treatment is administered in consultation with a neurologist or headache specialist.

Treatment is limited to two injections given 3 months apart. Additional treatment requires documented positive response to therapy. Positive response to therapy is defined as a reduction of at least 7 headache days per month compared to baseline headache frequency.

ACUTE THERAPIES

✓ When starting acute treatment, healthcare professionals should warn patients about the risk of developing medication-overuse headache.

ASPIRIN

R **Aspirin** (900 mg) **is recommended as first-line treatment for patients with acute migraine.**

✓ Aspirin, in doses for migraine, is not an analgesic of choice during pregnancy and should not be used in the third trimester of pregnancy.

NON-STEROIDAL ANTI-INFLAMMATORY DRUGS

R **Ibuprofen** (400 mg) **is recommended as first-line treatment for patients with acute migraine. If ineffective, the dose should be increased to 600 mg.**

PARACETAMOL

R **Paracetamol** (1,000 mg) **can be considered for treatment of patients with acute migraine who are unable to take other acute therapies.**

✓ Due to its safety profile, paracetamol is first choice for the short-term relief of mild to moderate headache during any trimester of pregnancy.

ANTIEMETICS

R **Metoclopramide** (10 mg) **or prochlorperazine** (10 mg) **can be considered in the treatment of headache in patients with acute migraine. They can be used either as an oral or parenteral formulation depending on presentation and setting.**

R **Metoclopramide** (10 mg) **or prochlorperazine** (10 mg) **should be considered for patients presenting with migraine-associated symptoms of nausea or vomiting. They can be used either as an oral or parenteral formulation depending on presentation and setting.**

✓ Metoclopramide should not be used regularly due to the risk of extrapyramidal side effects.

TRIPTANS

R **Triptans are recommended as first-line treatment for patients with acute migraine. The first choice is sumatriptan** (50–100 mg)**, but others should be offered if sumatriptan fails.**

R **In patients with severe acute migraine or early vomiting, nasal zolmitriptan or subcutaneous sumatriptan should be considered.**

R **Triptans are recommended for the treatment of patients with acute migraine associated with menstruation.**

R **Sumatriptan can be considered for treatment of acute migraine in pregnant women in all stages of pregnancy. The risks associated with use should be discussed before commencing treatment.**

COMBINATION THERAPIES

R **Combination therapy using sumatriptan** (50–85 mg) **and naproxen** (500 mg) **should be considered for the treatment of patients with acute migraine.**

PREVENTATIVE THERAPIES

BETA BLOCKERS

R **Propranolol** (80–160 mg daily) **is recommended as a first-line prophylactic treatment for patients with episodic or chronic migraine.**

TOPIRAMATE

R **Topiramate** (50–100 mg daily) **is recommended as a prophylactic treatment for patients with episodic or chronic migraine.**

R **Before commencing treatment women who may become pregnant should be advised of the associated risks of topiramate during pregnancy, the need to use effective contraception and the need to seek further advice on migraine prophylaxis if pregnant or planning a pregnancy.**

TRICYCLIC ANTIDEPRESSANTS

R **Amitriptyline** (25–150 mg at night) **should be considered as a prophylactic treatment for patients with episodic or chronic migraine.**

R **In patients who cannot tolerate amitriptyline a less sedating tricyclic antidepressant should be considered.**

CANDESARTAN

R **Candesartan** (16 mg daily) **can be considered as a prophylactic treatment for patients with episodic or chronic migraine.**

SODIUM VALPROATE

R **Sodium valproate** (400–1,500 mg daily) **can be considered as a prophylactic treatment for patients with episodic or chronic migraine.**

R **Prescribers should be aware that sodium valproate is associated with an increased risk of foetal malformations and poorer cognitive outcomes in children exposed to valproate in utero. For women who may become pregnant sodium valproate should only be considered as a prophylactic treatment when:**

- **other treatment options have been exhausted**
- **patients are using adequate contraception.**

Before commencing treatment women should be informed of:

- **the risks associated with taking valproate during pregnancy**
- **the risk that potentially harmful exposure to valproate may occur before a women is aware she is pregnant**
- **the need to use effective contraception**
- **the need to seek further advice on migraine prophylaxis if pregnant or planning a pregnancy.**

✓ When prescribing sodium valproate for women who may become pregnant the MHRA checklist must be used.

CALCIUM CHANNEL BLOCKERS

R **Flunarizine** (10 mg daily) **should be considered as a prophylactic treatment for patients with episodic or chronic migraine.**

GABAPENTIN

R **Gabapentin should not be considered as a prophylactic treatment for patients with episodic or chronic migraine.**

BOTULINUM TOXIN A

R **Botulinum toxin A is not recommended for the prophylactic treatment of patients with episodic migraine.**

R **Botulinum toxin A is recommended for the prophylactic treatment of patients with chronic migraine where medication overuse has been addressed and patients have been appropriately treated with three or more oral migraine prophylactic treatments.**

✓ Botulinum toxin A should only be administered by appropriately trained individuals under the supervision of a headache clinic or the local neurology service.

MENSTRUAL MIGRAINE PROPHYLAXIS

R **Frovatriptan** (2.5 mg twice daily) **should be considered as a prophylactic treatment in women with perimenstrual migraine from two days before until three days after bleeding starts.**

R **Zolmitriptan** (2.5 mg three times daily) **or naratriptan** (2.5 mg twice daily) **can be considered as alternatives to frovatriptan as prophylactic treatment in women with perimenstrual migraine from two days before until three days after bleeding starts.**

✓ Women with menstrual-related migraine who are using triptans at other times of the month should be advised that additional perimenstrual prophylaxis increases the risk of developing medication overuse headache.

MEDICATION-OVERUSE HEADACHE

R **In patients overusing acute treatment, medication overuse should be addressed.**

R **The choice of strategy to address medication overuse should be tailored to the individual patient and may be influenced by comorbidities. Strategies include:**

- **abrupt withdrawal alone and preventative treatment may then be considered after a delay**
- **abrupt withdrawal and immediately starting preventative treatment**
- **starting a preventative treatment without withdrawal.**

✓ Consider withdrawing regular opioids gradually.

R **Prednisolone should not be used routinely in the management of patients with medication-overuse headache.**

SOURCES OF FURTHER INFORMATION

Association of British Neurologists
www.abn.org

The British Association for the Study of Headache
www.bash.org.uk

The Migraine Trust
www.migrainetrust.org

Migraine Action
www.migraine.org.uk

This Quick Reference Guide provides a summary of the main recommendations in SIGN 155 • Pharmacological management of migraine.

Recommendations R are worded to indicate the strength of the supporting evidence. Good practice points ✓ are provided where the guideline development group wishes to highlight specific aspects of accepted clinical practice.

Details of the evidence supporting these recommendations can be found in the full guideline, available on the SIGN website: www.sign.ac.uk.

This QRG is also available as part of the SIGN Guidelines app.

Download on the App Store

Available from Android Market

Healthcare Improvement Scotland

SIGN

SIGN 155 • Pharmacological management of migraine

Quick Reference Guide *February 2018*

Toward Optimized Practice

Quick Reference: GUIDELINE FOR PRIMARY CARE MANAGEMENT OF HEADACHE IN ADULTS

September 2016

Red flags:

Emergent (address immediately)
- Thunderclap onset
- Fever and meningismus
- Papilloedema (+focal signs or reduced LOC*)
- Acute glaucoma

Urgent (address hours to days)
- Temporal arteritis
- Papilloedema (NO focal signs or reduced LOC*)
- Relevant systemic illness
- Elderly: new headache with cognitive change

Possible indicators of secondary headache:
- Unexplained focal signs
- Atypical headaches
- Unusual headache precipitants
- Onset after age 50
- Aggravation by neck movement; abnormal neck exam. Consider **cervicogenic headache**.
- Jaw symptoms; abnormal jaw exam. Consider **temporomandibular disorder**.

Yes → **Refer and/or investigate**

No

Headache with 2 or more of:
- Nausea
- Light sensitivity
- Interference with activities

Practice points:
- **Migraine historically under diagnosed**
- **Consider migraine diagnosis for recurring "sinus" headache**

Migraine → Yes

Medication overuse:

Assess
- Ergots, triptans, combination analgesics or codeine/other opioids ≥ 10 days a month
  OR
- Acetaminophen or NSAIDs ≥ 15 days a month

Manage
- Educate patient
- Consider prophylactic medication
- Provide an effective acute med for severe attacks with limitations on frequency of use
- Gradual withdrawal if opioid, or combination analgesic with opioid or barbiturate
- Abrupt (or gradual) withdrawal if acetaminophen, NSAIDs, or triptan

Migraine
- Acute medication (Table 1)
- Monitor for medication overuse
- Prophylactic medication (Table 1), if headache:
  > 3 days/month and acute meds not effective
  OR
  > 8 days/month (risk of overuse)
  OR
  Disability despite acute meds

Behavioural management
- **Headache diary:** record frequency, intensity, triggers and medication
- **Adjust lifestyle factors:** reduce caffeine, ensure regular exercise, avoid irregular and/or inadequate sleep or meals

Stress management: relaxation training, CBT*, pacing activity, biofeedback

No

Headache w/o nausea and 2 or more of:
- Bilateral headache
- Non-pulsating pain
- Mild to moderate pain
- Not worsened by activity

Tension-type Headache → Yes

Tension-type headache
- Acute medication (Table 2)
- Monitor for medication overuse
- Prophylactic medication if disability despite acute meds (Table 2)

No

Uncommon headache syndromes

All of:
- Frequent headache
- Severe
- Brief < 3 hours per attack
- Unilateral (always same side)
- Ipsilateral eye redness, tearing and/or restlessness during attacks

Yes → **Cluster headache or another trigeminal autonomic cephalalgia**
- Management primarily pharmacological
- Acute medication (Table 3)
- Prophylactic medication (Table 3)
- **Early specialist referral recommended**

All of:
- Unilateral headache (always same side)
- Continuous
- Dramatically responsive to indomethacin

Yes → **Hemicrania continua**
- **Specialist referral**

Headache continuous since onset

Yes → **New daily persistent headache**
- **Specialist referral**

*LOC - loss of consciousness
*CBT - cognitive behavioural therapy

The above recommendations are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. They should be used as an adjunct to sound clinical decision making.

IHE INSTITUTE OF HEALTH ECONOMICS ALBERTA CANADA

Quick Reference: MEDICATIONS RECOMMENDED FOR HEADACHE MANAGEMENT IN ADULTS

Toward Optimized Practice

Refer to full guideline for migraine treatment in pregnancy and lactation

Table 1: Migraine

Acute Migraine Medication	
1st line	ibuprofen 400 mg, ASA 1,000 mg, naproxen sodium 550 mg, acetaminophen 1,000 mg, diclofenac 50 mg
2nd line	Triptans: oral sumatriptan 100 mg, rizatriptan 10 mg, almotriptan 12.5 mg, zolmitriptan 2.5 mg eletriptan 40 mg, frovatriptan 2.5 mg, naratriptan 2.5 mg ▪ Subcutaneous sumatriptan 6 mg if vomiting early in the attack. Consider for attacks resistant to oral triptans. ▪ Oral wafer: rizatriptan 10 mg, zolmitriptan 2.5 mg, if fluid ingestion worsens nausea ▪ Nasal spray: zolmitriptan 5 mg, sumatriptan 20 mg, if nausea Antiemetics: domperidone 10 mg, metoclopramide 10 mg, for nausea
3rd line	550 mg naproxen sodium in combination with triptan
4th line	Fixed-dose combination analgesics (with codeine if necessary - not recommended for routine use)

Prophylactic Migraine Medication		Starting Dose	*Titration: Daily Dose Increase	Target Dose / Therapeutic Range	Notes
1st line	propranolol	20 mg bid	40 mg/week	40-120 mg bid	Avoid in asthma
	metoprolol	50 mg bid	50 mg/week	50-100 mg bid	
	nadolol	20-40 mg once daily	20 mg/week	80-160 mg daily	
	amitriptyline	10 mg hs	10 mg/week	10-100 mg hs	Consider if depression, anxiety, insomnia or tension-type headache
	nortriptyline	10 mg hs	10 mg week	10-100 mg hs	
2nd line	topiramate	25 mg once daily	25 mg/week	50 mg bid	Consider 1st line if overweight
	candesartan	8 mg once daily	8 mg/week	16 mg once daily	Few side effects; avoid in pregnancy or when pregnancy is planned
	lisinopril	10 mg once daily	10 mg/week	20 mg once daily	More side effects than candesartan; avoid in pregnancy or when pregnancy is planned
Other	divalproex sodium	250 mg once daily	250 mg/week	750-1,500 mg daily, divided bid	Avoid in pregnancy or when pregnancy is planned
	pizotifen	0.5 mg daily	0.5 mg/week	1-2 mg bid	Monitor for somnolence and weight gain
	OnabotulinumtoxinA	155-195 units	No titration needed	155-195 units every 3 months	For chronic migraine only – headache on ≥15 days per month
	flunarizine	5-10 mg hs		10 mg hs	Avoid in depression
	venlafaxine	37.5 mg once daily	37.5 mg/week	150 mg once daily	Consider in migraine with depression and/or anxiety
Over the Counter	magnesium citrate	300 mg bid	No titration needed	300 mg bid	Efficacy may be limited; few side effects
	riboflavin	400 mg daily		400 mg daily	
	co-enzyme Q10	100 mg tid		100 mg tid	

*Titration: Dosage may be increased every two weeks to avoid side effects

- For most drugs, slowly increase to target dose
- Therapeutic trial requires several months
- Expected outcome is reduction, not elimination of attacks
- If target dose not tolerated, try lower dose
- If med effective and tolerated, continue for at least six months
- If several preventive drugs fail, consider specialist referral

Table 2: Tension-Type Headache

Acute Medication
▪ ibuprofen 400 mg ▪ ASA 1,000 mg ▪ naproxen sodium 550 mg • acetaminophen 1,000 mg

Prophylactic Medication	
1st line	amitriptyline 10-100 mg hs *OR* nortriptyline 10-100 mg hs
2nd line	mirtazapine 30 mg hs *OR* venlafaxine 150 mg once daily

Table 3: Cluster Headache (consider early specialist referral)

Acute Medication
▪ subcutaneous sumatriptan 6 mg ▪ intranasal zolmitriptan 5 mg or sumitriptan 20 mg *OR* 100% oxygen at 12 litres/minute for 15 minutes through non-rebreathing mask

*Prophylactic Medication	
1st line	verapamil 240-480 mg per day (higher doses may be required)
2nd line	lithium 900-1,200 mg per day
Other	topiramate 100-200 mg per day *OR* melatonin up to 10 mg hs

*Note: If more than two attacks per day, consider transitional therapy while verapamil is built up (e.g., prednisone 60 mg for five days, then reduced by 10 mg every two days until discontinued, or occipital nerve blockage with steroids by trained physicians).

Abbreviations: **hs** – at bedtime; **bid** – twice a day; **tid** – three times a day

September 2016

INSTITUTE OF HEALTH ECONOMICS ALBERTA CANADA

These recommendations are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. They should be used as an adjunct to sound clinical decision making.

KEY MESSAGES*

DIAGNOSIS AND IMAGING

- Rule out secondary headache when making a diagnosis of a primary headache disorder.
- Neuroimaging is not indicated in patients with recurrent headache with the clinical features of migraine, a normal neurological examination, and no red flags.
- Neuroimaging, sinus X-rays, cervical spine X-rays, and EEG are not recommended for the routine assessment of the patient with headache. History and physical/neurological examination is usually sufficient to make a diagnosis of migraine or tension-type headache.

DIFFERENTIAL DIAGNOSIS

- Migraine is by far the most common headache type in patients seeking help for headache from physicians.
- Migraine is historically under-diagnosed and under-treated. Many patients with migraine are not diagnosed with migraine when they consult a physician.
- Migraine should be considered in patients with recurrent moderate or severe headaches and a normal neurological examination.
- Patients consulting for bilateral headaches which interfere with their activities are likely to have migraine rather than tension-type headache and may require migraine specific medication.
- Consider a diagnosis of migraine in patients with a previous diagnosis of recurring “sinus” headache.
- Monitor for medication overuse.
- Medication overuse is considered present when patients with migraine or tension-type headache use combination analgesics, opioids, or triptans on 10 or more days per month or acetaminophen or NSAIDs on 15 or more days a month.

MANAGING MIGRAINE

- Comprehensive migraine therapy includes management of lifestyle factors and triggers, acute and prophylactic medications, and migraine self-management strategies.
- ASA, acetaminophen, NSAIDs, and triptans are the primary medications for acute migraine treatment.
- A triptan should be used when NSAIDs are not effective.
- Opioid-containing analgesics are not recommended for routine use for migraine.
- Butalbital-containing combination analgesics should be avoided.
- Vast amounts of over-the-counter analgesics are taken for headache disorders and treatment is often sub-optimal.
- A substantial number of people who might benefit from prophylactic therapy do not receive it.

**Refer to Guideline for Primary Care Management of Headache in Adults 2nd edition, for management details: www.topalbertadoctors.org/cpgs/10065*

Computer-Assisted surgery for Musculoskeletal Procedures

Question: Where should computer-assisted surgical navigational procedure for musculoskeletal procedures be prioritized?

Question source: OHA Ombudsperson, HERC staff

Issue: All computer-assisted surgical codes are on lines on the Prioritized List, except CPT 20985 (Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less). CPT 20985 is listed as Ancillary, but is currently not open for payment in the MMIS system. Most computer assisted surgeries are on line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS, other than brain and spine procedures, which are on various lines with CNS diagnoses.

Computer-assisted navigation (CAN) is the application of computer tracking systems to assist with alignment in a variety of orthopedic procedures (i.e. total hip arthroplasty, total knee arthroplasty). The goal of CAN is to increase surgical accuracy and reduce the chance of malposition of an implant. The data can be acquired from fluoroscopy, computed tomography (CT) scans or magnetic resonance imaging (MRI) scans, or imageless systems.

Evidence

Knee ligament repair

1) **Eggerding 2014**, Cochrane review of computer assisted ACL or PCL reconstruction (http://cochranelibrary-wiley.com/doi/10.1002/14651858.CD007601.pub4/epdf)
    a. N=5 RCTs with 366 participants, all ACL repair
    b. moderate quality evidence (three trials, 193 participants) of no clinically relevant difference between CAS and conventional surgery in International Knee Documentation Committee (IKDC) subjective scores (self-reported measure of knee function; scale of 0 to 100 where 100 was best function). Pooled data from two of these trials (120 participants) showed a small, but clinically irrelevant difference favoring CAS (MD 2.05, 95% CI -2.16 to 6.25). A third trial (73 participants) also found minimal difference in IKDC subjective scores (reported MD 0.2).
    c. We found low quality evidence (two trials, 120 participants) showing no difference between the two groups in Lysholm scores, also measured on a scale 0 to 100 where 100 is best function (MD 0.25, 95% CI -3.75 to 4.25). We found very low quality evidence (one trial, 40 participants) showing no difference between the two groups in Tegner scores.
    d. We found low quality evidence (three trials, 173 participants) showing the majority of participants in both groups were assessed as having normal or nearly normal knee function (86/ 87 with CAS versus 84/86 with no CAS; RR 1.01, 95% CI 0.96 to 1.06).
    e. no differences were found for our secondary outcome measures of knee stability, loss in range of motion and tunnel placement.
    f. CAS use was associated with longer operating times compared with conventional operating techniques: the mean difference in operating times reported in the studies ranged between 9 and 27 minutes.
    g. **Authors' conclusions** From the available evidence, we are unable to demonstrate or refute a favorable effect of CAS for cruciate ligament reconstructions of the knee

compared with conventional reconstructions. However, the currently available evidence does not indicate that CAS in knee ligament reconstruction improves outcome.

Total knee arthroplasty

1) **Burnett 2013**, systematic review of computer assisted TKA vs conventional surgery (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3528921/pdf/11999_2012_Article_2528.pdf)
    a. N=19 RCTs (2180 patients)
        i. Follow up ranged from immediately postoperative to 5 years. Most were 2-3 months
    b. Coronal plane alignment is improved with navigated TKA with fewer radiographic outliers. We found limited evidence of improvements in any other variable, and function was not improved.
    c. The duration of surgery is increased and there are unique complications related to navigated TKA.
    d. The long-term benefits of additional increase in accuracy of alignment are not supported by any current evidence.
    e. Conclusions: There are few short and medium- and no long-term studies demonstrating improved clinical outcomes using navigated TKA. Longer-term studies demonstrating improved function, lower revision rates, and acceptable costs are required before navigated TKA may be widely adopted.
2) **Dyrhovden 2016**: 8 year follow up of computer assisted (CAN) vs conventional (CON) TKA
    a. CAS, N=3,665. CON, N=20,019
        i. Norwegian Arthroplasty Registry study
    b. Prosthesis survival and risk of revision were similar for CAS and CON. CAS had significantly fewer revisions due to malalignment. Otherwise, no statistically significant difference was found between the groups in analyses of secondary outcomes.
    c. Mean operating time was 13 minutes longer in CAS.
    d. Interpretation: At 8 years of follow-up, CAS and CON had similar rates of overall revision, but CAS had fewer revisions due to malalignment.

Total hip replacement

Note: no newer systematic review or meta-analysis was found

1) **Gandhi 2009**, meta-analysis of computer-aided total hip replacement
    a. N=3 studies (250 patients)
    b. The beneficial odds ratio for the number of outliers was 0.285 (95% confidence interval [CI]: 0.143 to 0.569; $p<0.001$).
    c. We conclude that navigation in hip arthroplasty improves the precision of acetabular cup placement by decreasing the number of outliers from the desired alignment.

<u>Other payer policies</u>:

1) MODA 2017
    a. Considers computer assisted musculoskeletal procedures to be experimental
2) Wellmark BCBS 2017
    a. Considers computer assisted musculoskeletal procedures to be experimental

HERC staff summary: Computer-assisted navigation for orthopedic joint surgeries appears to result in improved placement of prosthetic immediately after surgery, but there is no difference in long-term need for revision or in functional outcomes compared to conventional surgery. There is a longer operative time reported for these procedures compared to conventional surgery. It currently does not appear to be standard of care, as it is considered experimental by the commercial payers surveyed.

HERC staff recommendations:

1) Place CPT 20985 (Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less) on line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
    a. Advise HSD to remove CPT 20985 from the Ancillary list
2) Add the following entry to GN173

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

660

The following Interventions are prioritized on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
20985	Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less	Insufficient evidence of effectiveness	August 2018

Survivorship and relative risk of revision in computer-navigated versus conventional total knee replacement at 8-year follow-up

A study of 23,684 cases reported to the Norwegian Arthroplasty Register, 2005–2014

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Background and purpose — The long-term effects of computer-assisted surgery in total knee replacement (CAS) compared to conventionally operated knee replacement (CON) are still not clear. We compared survivorship and relative risk of revision in CAS and CON based on data from the Norwegian Arthroplasty Register.

Patients and methods — We assessed primary total knee replacements without patellar resurfacing reported to the Norwegian Arthroplasty Register from 2005 through 2014. The 5 most used implants and the 3 most common navigation systems were included. The groups (CAS, n = 3,665; CON, n = 20,019) were compared using a Cox regression analysis adjusted for age, sex, ASA category, prosthesis brand, fixation method, previous surgery, and diagnosis with the risk of revision for any reason as endpoint. Secondary outcomes were reasons for revision and effects of prosthesis brand, fixation method, age (± 65 years), and hospital volume.

Results — Prosthesis survival and risk of revision were similar for CAS and CON. CAS had significantly fewer revisions due to malalignment. Otherwise, no statistically significant difference was found between the groups in analyses of secondary outcomes. Mean operating time was 13 minutes longer in CAS.

Interpretation — At 8 years of follow-up, CAS and CON had similar rates of overall revision, but CAS had fewer revisions due to malalignment. According to our findings, the benefits of CAS at medium-term follow-up are limited. Further research may identify subgroups that benefit from CAS, and it should also emphasize patient-reported outcomes.

In total knee replacement (TKR), alignment of the implant is considered important to achieve a satisfactory outcome (Jeffery et al. 1991, Ritter et al. 2011, Huang et al. 2012). Computer-assisted surgery (CAS) is widely used to improve implant positioning, and several randomized trials and meta-analyses have concluded that CAS provides more accurate alignment of the implant (Choong et al. 2009, Hetaimish et al. 2012, Cip et al. 2014, Rebal et al. 2014, Shi et al. 2014). CAS has been shown to have a short learning curve and is claimed to be useful in training of inexperienced surgeons (Jenny et al. 2008, Smith et al. 2010). Still, the long-term effects on survival and causes of revision for CAS as opposed to conventionally operated TKR (CON) are not clear (Burnett and Barrack 2013).

A randomized, controlled trial in Norway found improved alignment and marginally better functional outcome with CAS 1 year after surgery (Gothesen et al. 2014). Nevertheless, a 2-year follow-up from the Norwegian Arthroplasty Register (NAR) in 2011 showed a higher revision rate with use of computer navigation (Gothesen et al. 2011). Data from the New Zealand National Joint Registry with 5 years of follow-up showed similar revision rates and functional outcomes between navigated and non-navigated TKR (Roberts et al. 2015). On the other hand, a recent study from the Australian Orthopaedic Association National Joint Replacement Registry found a lower cumulative revision rate for computer navigation in patients less than 65 years (de Steiger et al. 2015).

The purpose of this study was to use the large cohort from the nationwide Norwegian Arthroplasty Register to investigate medium-term effects of computer navigation in primary total knee replacement by comparing CAS and CON, with risk of

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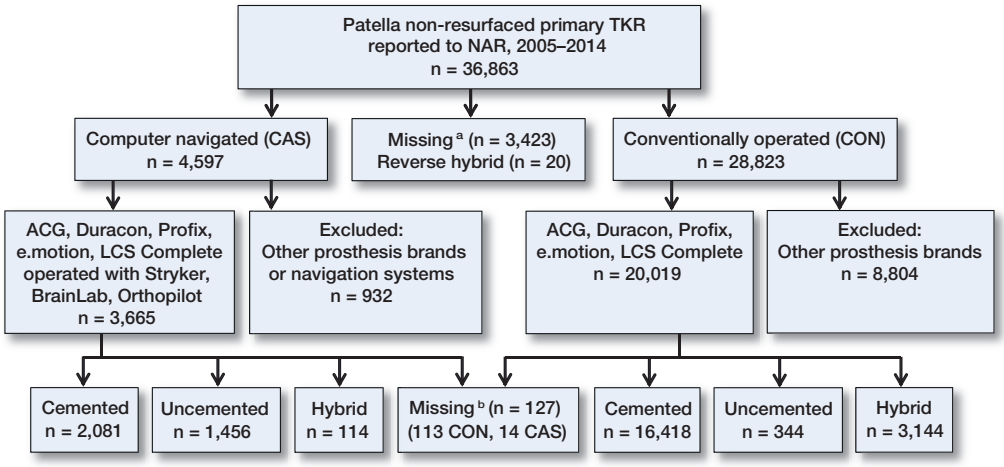


Figure 1. Selection of patients. TKR: total knee replacement; NAR: Norwegian Arthroplasty Register; CAS: computer-navigated knee replacement; CON: conventionally operated knee replacement. [a] No information on use of computer navigation. [b] No information on fixation method.

revision for any reason as endpoint. We also wanted to determine how CAS affected the rate and causes of revision in different prosthesis brands, fixation methods, and age groups, and to analyze the learning curve and the impact of hospital volume.

Patients and methods

Sources of data

This prospective observational study was based on data from the Norwegian Arthroplasty Register (NAR). The NAR was established in 1987 as a national hip registry (Havelin et al. 2000). From 1994, registration also included knee prostheses and other joint replacements (Furnes et al. 2002). The registry covers a population of approximately 5.2 million and the completeness of registration is 95% for primary TKR and 89% for revision TKR (Espehaug et al. 2006, Havelin et al. 2015). Registration of CAS started in 2005. In 2014, 8% of knee prostheses were implanted with CAS (Havelin et al. 2015).

36,863 primary total knee replacements without patellar resurfacing were reported to the NAR from January 1, 2005 through December 31, 2014. As only 2.5% of the knees were patella resurfaced during this period, prostheses with a patellar component were excluded. Hinged (n = 48), bi-compartmental (n = 3), and reverse hybrid implants (cemented femur and uncemented tibia, n = 10) were also excluded due to low numbers. The cohort was divided into 2 groups according to the surgical technique used for the implantation: either the CAS technique or CON (Figure 1).

In the short-term follow-up study from the NAR in 2011, the 5 most used prosthesis brands (AGC, Duracon, e.motion, LCS complete, and Profix) and the 3 most frequently used navigation systems (Brainlab, Orthopilot, and Stryker) were selected for analysis. We used the same selection criteria to compare the results with the study from 2011 (Gothesen et al. 2011).

Statistics

Baseline characteristics of the groups were investigated by descriptive analysis. Differences in demographic variables were calculated using chi-square test and Student's t-test, assuming equal variances. Median follow-up was calculated using reverse Kaplan-Meier (Schemper and Smith 1996). Implant survival (time from operation to first revision) was estimated by Kaplan-Meier analysis after 5 and 8 years of follow-up, with censoring at the time of death, emigration, or at the end of inclusion (December 31, 2014). Information about deaths and emigrations until December 31, 2014 was obtained from the National Population Register. To ensure that deaths and emigrations did not affect the results, this was tested in a competing-risk model (Fine and Gray 1999).

The null hypothesis was that there would be no difference in survival or relative risk of revision in total knee arthroplasty performed with CAS and with CON. The relative risk (RR) was calculated using a Cox multiple regression model, to make a statistical comparison of the survival rates of the groups, adjusted for age (continuous), sex, prosthesis brand, ASA category (1/2/3+), fixation method (cemented/uncemented/hybrid (uncemented femur, cemented tibia)), diagnosis (osteoarthritis/other), and previous surgery of the knee (yes/no). The Cox regression analyses were also performed with adjustments for a propensity score with the same covariates as above in addition to side (left/right), peroperative complications (yes/no), and deficiency of anterior cruciate ligament preoperatively and posterior cruciate ligaments preoperatively and postoperatively (yes/no). The proportional hazards assumption of the Cox regression model was assessed by visual inspection (log-minus-log plot).

Main causes of revision were determined based on the hierarchy from the Australian Orthopaedic Association National Joint Replacement Registry (2015), modified according to causes of revision registered in the NAR (Table 3). The adjusted RR estimates for CAS relative to CON are reported with 95% confidence intervals (CIs) and p-values. Survival curves were constructed by Cox regression with CAS as stratification factor, with the same adjustments as described above.

In subanalyses, we investigated the effect of CAS on survival in different brands of prosthesis, in different fixation methods, and in patients younger or older than 65 years of age. To investigate possible effects of a learning curve, we split the data file in order to analyze the first 30 computer-navigated

Table 1. Demographic data for computer-navigated total knee replacement (CAS) and conventionally operated total knee replacement (CON)

	CAS	CON	p-value
Number	3,665	20,019	
Men, %	38	35	< 0.001
Age, years	68.4	69.2	< 0.001
95% CI	68.1–68.7	69.1–69.3	
Right knee, %	54	54	0.9
MIS [a], n (%)	21 (0.6)	65 (0.4)	0.02
ASA category [b], n (%)			0.01
1	602 (16)	3316 (17)	
2	2,378 (65)	12,506 (62)	
3+	640 (18)	3,944 (20)	
Missing	45 (1)	253 (1)	
Diagnosis preoperatively, %			0.02
Primary gonarthritis	82	84	
Other	18	16	
Missing	0.1	0.2	
Fixation method, n (%)			< 0.001
Cemented	2,081 (57)	16,418 (82)	
Uncemented	1,456 (40)	344 (2)	
Hybrid (uncemented femur)	114 (3)	3,144 (16)	
Missing	14 (0.4)	113 (0.6)	
Prosthesis brand, n (%)			< 0.001
AGC	94 (3)	2,054 (10)	
Duracon	629 (17)	1,368 (7)	
e.motion	352 (10)	8 (0)	
LCS complete	1,387 (38)	8,408 (42)	
Profix	1,203 (33)	8,181 (41)	
Previous operations of the knee, %	38	31	< 0.001
Osteosynthesis affecting the knee joint	2.7	1.9	< 0.001
Osteotomy	3.5	3.3	0.6
Synovectomy	1.3	1.9	0.02
Other	33	25	< 0.001
Peroperative complication, %	1.8	2.1	0.2
Intact ACL c preoperatively, %	76	81	< 0.001
Intact PCL [d] preoperatively, %	95	94	0.1
Intact PCL postoperatively, %	57	56	0.3
Hospital volume 2005–2014, n [e]			
1–30	6	12	
31–100	7	9	
101–200	6	11	
> 200	3	33	
Total number of hospitals	22	65	

[a] MIS: minimally invasive surgery.
[b] ASA category: American Society of Anesthesiologists physical status classification system.
[c] ACL: anterior cruciate ligament.
[d] PCL: posterior cruciate ligament.
[e] Number of hospitals.

procedures (learning group) at each center and the remaining procedures (experienced group) separately, since the learning curve for computer navigation in TKR has been shown to stabilize after 30 procedures (Nizard et al. 2004, Jenny et al. 2008). Operation time is presented as median and interquartile range (IQR) and differences in operation time were calculated using Mann-Whitney tests.

All tests were 2-sided, and the significance level was set at 0.05. Statistical analyses were performed using IBM SPSS Statistics version 22.

Ethics

The NAR has permission from the Norwegian Data Inspectorate to collect patient data, based on obtaining written consent from the patient. (Permission was last issued September 15, 2014; reference number 03/00058-20/CGN).

Results

In the CAS group, the patients were 1 year younger on average, with males predominating, and they had a lower mean ASA score than the CON group (Table 1). Use of uncemented prostheses, previous surgery of the knee, and preoperative deficiency of the ACL was more frequent in the CAS group. Median follow-up was 5.3 years in the CAS group and 5.0 years in the CON group. 65 different hospitals were represented. All 22 hospitals that used CAS performed both techniques. For the implants included, the number of CAS operations during the study period varied between > 200 TKRs in 3 hospitals and < 30 TKRs in 5 hospitals. In the CON group, 33 hospitals had a volume of > 200.

Overall survivorship (Table 2)

At 5-year follow-up, the survival rate in the CON group was 95.5% (CI: 95.1–95.9) and it was 95.7% (CI: 94.9–96.5) in the CAS group. At 8 years, the survival rate was 94.9% (CI: 94.5–95.3) in the CON group and 94.8% (CI: 93.8–95.8) in the CAS group (Figure 2). The Cox regression analysis did not show any statistically significant difference in risk of revision between the CAS group and the CON group (RR = 0.8, CI: 0.7–1.0; p = 0.1); nor did the propensity score-adjusted Cox regression analysis (RR = 0.8, CI: 0.7–1.1; p = 0.1). The robustness of the analysis was investigated further with a simpler Cox regression model adjusted for age, sex, and diagnosis, and this RR estimate was 0.95 (CI: 0.80–1.13; p = 0.6). The Cox-adjusted RR was also tested for 0–2 years and 2–8 years after surgery, separately, but there was still no statistically significant difference in relative risk of revision between the groups. The proportion of deaths was 8.0% in the CAS group and 10% in the CON group, and the proportion of emigrations was 0.4% in both groups. In the competing-risk model, the overall relative risk of revision for CAS versus CON was 0.9 (CI: 0.8–1.2; p = 0.7) and for patients < 65 years, the relative risk of revision was 0.9 (CI: 0.8–1.2, p = 0.8).

Secondary outcomes

We also performed Cox regression analyses comparing CAS and CON for each selected prosthesis brand. In analyses adjusted for age, sex, ASA category, fixation method, and diagnosis, there was no statistically significant difference in risk of revision for Profix, LCS complete, AGC, or Duracon. For the e.motion prosthesis (352 CAS, 8 CON), there were 6 revisions in the CAS group and no revisions in the CON group, so an RR could not be estimated.

Table 2. Kaplan-Meier survival (KM) and Cox-adjusted relative risk of revision for computer-navigated total knee replacement (CAS) and for conventionally operated total knee replacement (CON)

	MF [a], years (95 % CI)	5 years At risk	5 years KM survival (95 % CI)	8 years At risk	8 years KM survival (95 % CI)	Cox-adjusted RR [b] (95% CI)	p-value	Cox regression adjusted by PS [c] (95% CI)	p-value
All ages									
CAS	5.3 (5.2–5.4)	1,965	95.7 (94.9–96.5)	354	94.8 (93.8–95.8)	0.8 (0.7–1.0)	0.1	0.8 (0.7–1.1)	0.1
CON	5.0 (4.9–5.0)	9,509	95.5 (95.1–95.9)	2,836	94.9 (94.5–95.3)	1		1	
< 65 years									
CAS	6.1 (5.7–6.5)	695	93.6 (92.2–95.0)	126	93.6 (92.2–95.0)	0.8 (0.6–1.1)	0.1	0.8 (0.6–1.1)	0.1
CON	5.4 (5.2–5.5)	3,102	93.1 (92.5–93.7)	955	92.4 (91.6–93.2)	1		1	

[a] MF: median follow-up (reversed KM).
[b] RR: relative risk, CAS versus CON, adjusted for age, sex, ASA category, diagnosis, previous surgery of the knee, prosthesis brand, and fixation method.
[c] PS: propensity score. Covariates included in PS are the same as in the Cox-adjusted RR in addition to side, peroperative complications, and deficiency of anterior cruciate ligament preoperatively and posterior cruciate ligaments preoperatively and postoperatively.

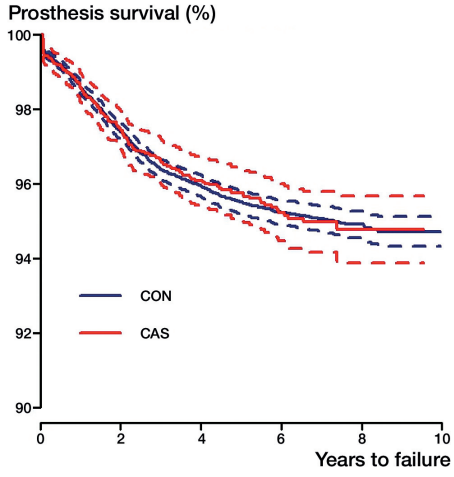


Figure 2. Kaplan-Meier survival curves with 95% confidence intervals (broken lines) for computer-navigated total knee replacement (CAS) and conventionally operated (CON) total knee replacement. Log-rank test: p = 0.9. 8 years at risk: CAS, n = 354; CON, n = 2,836.

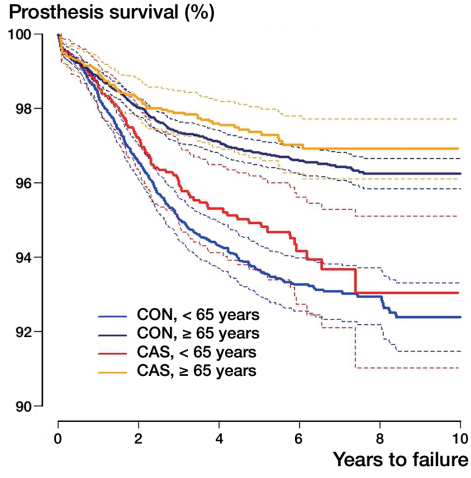


Figure 3 Cox regression survival curves with 95% confidence intervals (broken lines) for computer-navigated total knee replacement (CAS) and conventionally operated total knee replacement (CON) in patients who were more than or less than 65 years of age, adjusted for sex, ASA category, diagnosis, previous surgery, prosthesis brand, and fixation method. 8 years at risk: ≥ 65 years old: CAS, n = 228; CON, n = 1,881; < 65 years old: CAS, n = 126; CON, n = 955.

When selecting cemented prostheses only (2,080 CAS, 16,418 CON), there was still no significant difference in our Cox-adjusted estimates for risk of revision (RR = 0.9, CI: 0.7–1.1; p = 0.4). For hybrid implants (114 CAS, 3,143 CON), the Cox-adjusted relative risk was 1.2 (CI: 0.4–3.9; p = 0.7). Only Profix and LCS complete were used as uncemented implants. Uncemented Profix implants (836 CAS, 27 CON) had 6 revisions reported, all in the CAS group. For the uncemented LCS compete (619 CAS, 316 CON), no significant difference was found (RR = 0.8, CI: 0.5–1.3; p = 0.3).

We did not find any statistically significant difference in overall risk of revision between CAS and CON in patients who were older and younger than 65 years (Figure 3). Patients < 65 years of age had a lower risk of revision in the CAS group, with RR = 0.8, but this was not statistically significant (CI: 0.6–1.1; p = 0.1). For patients ≥ 65 years of age, the relative risk was 0.9 (CI: 0.7–1.2; p = 0.6). Analyses of fixation method in patients < 65 years of age did not indicate that CAS affected the revision risk differently for cemented, uncemented, or hybrid implants. The use of computer navigation did not affect the Kaplan-Meier survival rate after 5 or 8 years (Table 2).

3 hospitals were using both techniques (CAS and CON), and were regarded as high-volume centers with more than 300 computer-navigated TKRs. 1 hospital mainly used Profix (hospital A: 917 CAS, 137 CON), and the other 2 used LCS complete (hospital B: 342 CAS, 183 CON; hospital C: 578 CAS, 55 CON). We compared the 2 techniques in these hos-

Table 3. Reasons for revision in computer-navigated total knee replacement (CAS) and conventionally operated total knee replacement (CON) for all patients and for patients less than 65 years of age

No [a]		All ages CAS n	% [b]	CON n	% [b]	CAS vs. CON [c] RR (95% CI)	p-value	< 65 years old CAS n	% [b]	CON n	% [b]	CAS vs. CON [c] RR (95% CI)	p-value
1	Deep infection	40	26	202	24	1.0 (0.6–1.4)	0.8	17	20	81	20	0.7 (0.4–1.3)	0.3
2	Malalignment	15	10	90	11	0.5 (0.3–0.9)	0.02	5	6	49	12	0.3 (0.1–0.8)	0.01
3	Aseptic loosening	33	21	190	23	1.1 (0.7–1.6)	0.7	17	20	99	24	1.0 (0.6–1.8)	0.9
4	Instability	29	19	112	14	0.7 (0.4–1.2)	0.2	22	27	63	15	0.9 (0.5–1.7)	0.7
5	Periprosthetic fracture	4	3	14	1.7	0.5 (0.1–2.1)	0.4	1	1	4	1.0	0.6 (0.04–7.9)	0.7
6	Decreased range of motion [d]	5	3	34	4.1	0.8 (0.3–2.3)	0.7	5	6	22	5.4	1.4 (0.4–4.5)	0.6
7	Other [e]	6	4	56	6.8	0.6 (0.2–1.6)	0.3	1	1	26	6.3	0.1 (0.01–1.0)	0.05
8	Pain only	24	15	125	15	1.1 (0.6–1.9)	0.7	15	18	66	16	1.2 (0.6–2.5)	0.6
	Missing	0	0	4	0.5			0	0	1	0.2		
	No. of revisions	156		827				83		411			
	No. of total knee replacements	3,665		20,019				1,292		6,481			

[a] Listed in the same order as hierarchy for determination of main cause of revision.
[b] Percentage of number of revisions.
[c] Adjusted for age, sex, prosthesis brand, ASA category, fixation method (cemented, uncemented, hybrid), diagnosis (OA, other), and previous surgery of the knee (yes, no).
[d] Including arthrofibrosis and joint stiffness.
[e] Including dislocation (patella and other), polyethylene wear, and progression of arthrosis.

pitals separately. All 3 high-volume hospitals had small, statistically insignificant differences in the risk of revision when CAS and CON were compared.

Median operating time was 100 min (IQR: 35) in the CAS group and 89 min (IQR: 25) in the CON group ($p < 0.001$). When only cemented implants were selected, median operating time was 111 min (IQR: 31) for CAS and 90 min (IQR: 32) for CON ($p < 0.001$).

Learning curve

The learning group involved 533 computer-navigated (CAS) knee procedures in 22 different hospitals and the experienced group involved 3,140 CAS procedures in 15 different hospitals. Comparison of the learning group with the entire CON group did not reveal any difference in risk of revision (RR = 1.1, CI: 0.7–1.5; $p = 0.9$). Median operating time for the learning CAS group was 31 min longer than for CON ($p < 0.001$). In the experienced CAS group, the risk of revision relative to CON was 0.8 (CI: 0.7–1.0; $p = 0.09$). Median operation time was 17 min longer with CAS ($p < 0.001$) for all fixation methods and 19 minutes longer with CAS for cemented implants ($p < 0.001$).

Causes of revision (Table 3)

Deep infection and aseptic loosening were the most common causes of revision, except in CAS patients aged < 65 years, where revision due to instability was more frequent. When we adjusted for age, sex, ASA class, diagnosis, prosthesis brand, and fixation method, the CAS group had fewer revisions due to malalignment, with RR = 0.5 (CI: 0.3–0.9; $p = 0.02$) in all patients and RR = 0.3 (CI: 0.1–0.8; $p = 0.01$) in patients who were < 65 years old. Otherwise, there were no statistically significant differences in risk of revision for the causes reported.

Discussion

We used data from the Norwegian Arthroplasty Register to compare survival, relative risk of revision, and causes of revision in total knee replacements performed with conventional methods or computer navigation. After 8 years of follow-up, we did not find any statistically significant differences in survival between groups. In subanalyses, we could not detect any difference in RR of revision for CAS and CON, either for different prosthesis brands or hospital volumes. Computer navigation did not affect the outcome differently with certain fixation methods or in patients less than 65 years. Risk of revision was not elevated in the first 30 computer-navigated cases at each center compared to the risk for the later procedures. CAS had statistically significantly fewer revisions due to malalignment.

Strengths and limitations

This registry-based study involved a large number of patients from all surgical units that perform total knee replacements in Norway (Espehaug et al. 2006, Havelin et al. 2015). Selection of the 5 most frequently used prosthesis brands and the 3 most frequently used navigation systems strengthened the applicability and external validity. The high completeness of reporting led to good external validity and 8 years of follow-up enabled us to discover possible complications of computer navigation, such as higher rates of infection and fracture, or advantages.

Despite the high quality of the NAR database and the registry study design, there were some limitations. Because of the low revision rate of knee prostheses, a large cohort and a long follow-up time were required to uncover benefits or

small disadvantages in the study group. Serving a population of approximately 5.2 million citizens, the Norwegian registry has smaller numbers of operations than registries in larger countries, and is thus underpowered to detect small differences. This limitation was especially noticeable in some subanalyses with low numbers of revisions, and these results are less conclusive. Additionally, the different prosthesis brands and the use of computer navigation were unequally distributed among the hospitals. Consequently, the effect of single surgeons or differences in patient demographics between the hospitals may have affected the results, especially in the subanalyses where the number of patients was low. Complications that do not lead to revision of the prosthesis are not registered in the database. Thus, fractures or infections in pinholes after CAS are usually not registered. Common confounding factors were treated by adjustments in the statistical analyses, but we cannot account for unmeasured differences such as surgeon volume and postoperative treatment. In contrast to randomized trials, uncontrolled confounders might also have had a role. Adjustment for many different confounding factors increases the risk of overadjustment bias (Schisterman et al. 2009) and a Cox model only adjusted for age, sex, and diagnosis was performed to address this problem. However, inclusion of death in a competing risks model, and also the Cox model with fewer adjustments, did not alter the conclusions in our study.

Comparison with other studies

In a short-term follow-up from the NAR (Gothesen et al. 2011), the risk of revision was higher with CAS than with CON, and the LCS complete had inferior results than other prosthesis brands in the CAS group. At 8-year follow-up, we could no longer detect these differences. The short-term results might be caused by challenges during the introduction period of this new technology. Even so, we could not detect a learning curve, which supports previous findings that surgeons achieve satisfactory results with computer navigation shortly after introduction (Jenny et al. 2008, Chinnappa et al. 2015). There have been few studies comparing different implant designs in computer-aided navigation, but the LCS complete has also shown inferior results in registry-based studies both in Norway and in the USA (the Kaiser Permanente Total Joint Arthroplasty Registry) with conventional surgery (Paxton et al. 2011, Gothesen et al. 2013) and with mobile-bearing knee replacement in general (Namba et al. 2014). Baker et al. (2012) found that implant brand and hospital type affected patient-reported outcome. Thus, it is likely that the inferior results with the LCS complete in the short term were mainly caused by the prosthesis design and challenges during introduction of new technology, rather than by the use of CAS.

In 2015, arthroplasty registries in New Zealand and Australia published studies on computer navigation in TKA, with 5 and 9 years of follow-up (respectively). The Australian registry reported a reduced revision rate for computer-navigated procedures in patients less than 65 years of age, and there was a reduction in revision rate due to loosening (de Steiger et al. 2015), but only with adjustment for age and sex. In a group of equivalent age, the arthroplasty registry in New Zealand found a trend of a higher revision rate for Triathlon implants inserted with computer-assisted navigation (not statistically significant) (Roberts et al. 2015). We found a statistically insignificantly lower revision rate and also lower risk of loosening in patients who were less than 65 years in the CAS group, supporting the Australian results. The smaller number of cases in our registry may explain why we were unable to detect a significant difference.

Improved alignment with CAS is expected to give better resistance to aseptic loosening and lower wear of the implant, as well as better functional results. We found a lower risk of revision due to malalignment, but this did not affect the overall survival or the risk of revision. There is evidence that malalignment is associated with implant failure (Jeffery et al. 1991, Huang et al. 2012) and a recent review article by Gromov et al. (2014) recommended aiming for optimal alignment of the components in TKA. On the other hand, Parratte et al. (2010) found no difference in survivorship for knees with mechanical axis within 3° of neutral compared to malaligned knees in a retrospective study with 15 years of follow-up. Bellemans et al. (2012) emphasized the importance of recognizing patients with constitutional varus, and Vanlommel et al. (2013) showed that these patients had superior clinical outcomes when the alignment was left in mild varus. In these cases, computer navigation could in theory cause a poorer outcome by correcting the patient's natural alignment. As an alternative to mechanically aligned TKA, some surgeons prefer to have the prostheses kinematically aligned. A study by Howell et al. (2013) showed similar Oxford knee scores in kinematically aligned knees regardless of alignment, and a randomized, controlled trial by Dossett et al. (2014) found superior functional outcome and pain relief in kinematically aligned TKAs than in mechanically aligned TKAs. These different approaches might also play an important role in the success of TKA.

Analysis of registry data is limited to the information collected in the registry. The Norwegian Arthroplasty Register contains no information on radiological measurements or functional outcomes. In order to claim causality between alignment and survival, radiological measurements of the revised cases are required. Our results illustrate that computer-assisted navigation alone does not change large trends in survival of knee prostheses. The patient's health status has been suggested to be more important than surgical factors (Baker et al. 2012), and alignment may be of less importance than previously assumed.

Future research

Registry studies with a longer follow-up time will provide useful information in future assessment of computer naviga-

tion in TKR. However, to investigate correlations between malalignment and functional results, long-term follow-up of randomized trials should also be conducted. Radiostereometric analysis can be helpful in detecting early loosening as a predictor of implant failure (Ryd et al. 1995). Collection of revised implants for laboratory studies and radiographs for alignment measurements from revisions might be useful in addition to collection of patient-reported outcome measures in arthroplasty registries. These modalities would enable researchers to assess revision rates in the context of patient satisfaction and function, with a view to improving the quality of life of the patients.

Summary

This study has shown similar 8-year survivorship in computer-navigated TKR and conventionally operated TKR, but CAS had fewer revisions for malalignment. We were unable to find specific benefits of CAS in particular age groups or regarding particular prosthesis brands.

The study was planned and designed by OG, GSD, and OF. GSD and AMF performed the statistical analyses. GSD drafted the manuscript. All the authors took part in interpretation of the study findings and revision and final approval of the manuscript before submission.

We thank all the orthopedic surgeons in Norway for reporting data to the NAR, and the patients who gave their consent to be included to the NAR database.

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ORIGINAL PAPER

Computer navigation in total hip replacement: a meta-analysis

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Abstract Proponents of navigated hip arthroplasty have suggested that it may increase the precision of acetabular component placement. We conducted a systematic review and meta-analysis to evaluate the validity of this theory. We searched, in duplicate, MEDLINE, EMBASE and the Cochrane Central Register of Controlled Trials for randomised trials comparing the use of computer navigation with the freehand technique for acetabular cup placement within the desired alignment. We assessed the methodological quality of the studies and abstracted the relevant data. Tests of heterogeneity and publication bias were performed. From the three studies included, there was no evidence of heterogeneity between studies. A total of 250 patients were entered into the analysis. The beneficial odds ratio for the number of outliers was 0.285 (95% confidence interval [CI]: 0.143 to 0.569; $p<0.001$). We conclude that navigation in hip arthroplasty improves the precision of acetabular cup placement by decreasing the number of outliers from the desired alignment.

Résumé On peut penser que l'utilisation de la navigation au cours des prothèses de hanche va améliorer la précision du positionnement cotyloïdien. Nous avons conduit une étude systématique et une méta analyse de façon à valider cette théorieMéthode : les recherches ont été réalisé sur MEDLINE, EMBASE et COCHRANE, essais randomisés comparant l'utilisation de la navigation et l'utilisation des techniques classiques à main levée. Différents tests statistiques ont été réalisés.Résultat : à partir de 3 études inclues, il n'y a pas de différence entre ces 3 études. Un total de 250 patients ont été analysés, le ratio des hanches en dehors de la moyenne a été de 0,285 (95% CI: 0,143 et 0,569; $p<0,001$). Nous pouvons affirmer que la navigation au cours de la prothèse totale de hanche permet une meilleure précision du positionnement de la cupule et diminue le nombre de cupules en mauvaise position.

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Introduction

The position of the acetabular component is critical to the function and outcome of total hip arthroplasty (THA). Achieving the correct abduction and anteversion could potentially improve the longevity of a THA, improve the range of motion (ROM) and decrease the dislocation rate [1, 8, 14]. Lewinnek et al. recommended an abduction angle of 40±10° and an anteversion angle of 15±10° as the safe zone for cup orientation [10].

The correct placement of implants is guided by pre-operative radiographs and templating, intra-operative anatomical landmarks and mechanical alignment guides on the instrumentation sets. However, patient positioning on the table is variable and mechanical alignment guides have not improved the accuracy of acetabular positioning [2].

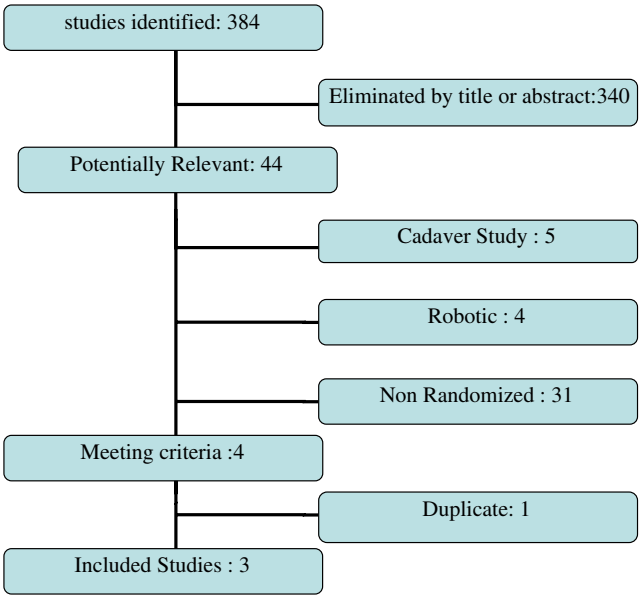


Fig. 1 Search results and the selection procedure

Computer-assisted surgery is growing in popularity to help control and minimise the error in cup placement. Two forms of computer-assisted surgery exist for total hip replacements (THR); one is an active system, which uses a robot to implant the cup, and the other is a passive system, whereby the surgeon navigates the instruments and components within a virtual picture intra-operatively. Within the passive systems, there are two variations. Image-based systems require the collection of anatomical data from preoperative computed tomography (CT) or intra-operative fluoroscopy. Imageless systems use a virtual model supplemented by intra-operative registration data. We focus on the passive navigation systems in this paper.

A number of observational-type studies have been published on computer navigation in THR, but the potential for selection bias in these studies limits the generalisation of their results [3, 5, 6, 12, 15–17]. Randomised clinical trials (RCT) represent the best available evidence, as they control for potential confounding errors between groups.

A systematic review of the literature was conducted for RCTs to determine if computer navigation improves the precision of acetabular cup placement in hip arthroplasty. We report our meta-analysis as recommended by the Quality of Reporting of Meta-analyses (QUOROM) statement [11].

Materials and methods

Study identification

Two of the authors (RG and AM) independently completed a computerised search of the electronic databases PubMed, MEDLINE and Ovid MEDLINE (1966 to Mar 2007), and EMBASE (1980 to 2007) with the following search terms (computer OR computer navigation OR navigation) AND (hip arthroplasty OR joint replacement OR joint prosthesis OR arthroplasty). We also searched the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials, the web site of the United Kingdom National Research Register (https://portal.nihr.ac.uk/Pages/NRRArchive.aspx) and http://clinicaltrials.gov/. After reviewing the title of the study, we retrieved the abstract if we felt that it was an appropriate study. We independently reviewed these abstracts and chose the studies that were potentially relevant. The full text article was then reviewed to determine final inclusion into the study. We then reviewed the bibliography of each article that met our inclusion criteria for any further relevant studies.

Eligibility criteria

We included those articles relevant to: (1) those patients undergoing primary THR; (2) the intervention was the use of computer navigation as compared to the freehand technique for placing the acetabular component; (3) the outcome measure was the number of outliers of acetabular cups outside the desired alignment range and (4) the study was a published or unpublished randomised controlled trial.

Assessment of study quality

Each study was evaluated for its methodological quality. To determine the random allocation sequence, one study used a computerised random number generator [13], one study used

Table 1 Demographic data of the study patients

Study	Mean age (SD)		Mean BMI kg/m^2 (SD)	
	Control	Navigation	Control	Navigation
Kalteis et al., n=90	64.7 (8.6)	63.5 (8.6)	28.5 (4.1)	27.7 (3.85)
Leenders et al., n=100	64.9	61		
Parratte et al., n=60	62.6 (9.6)	61.2 (13.15)	25.2 (4.1)	25.6 (4.53)

Table 2 Data for the individual studies of acetabular alignment and outliers from the desired alignment

Study	Percentage of outliers		Mean abduction angles (SD)		Mean anteversion angles	
	Control	Navigation	Control	Navigation	Control	Navigation
Kalteis et al., n=90	16/30 (53%)	7/60 (11.7%)	43.7 (7.3)	42.4 (4)	22 (14.2)	13.0 (5.4)
Leenders et al., n=100	13/50 (26%)	2/50 (4%)	46	47		
Parratte and Argenson, n=60	17/30 (57%)	6/30 (20%)	34.0 (7.62)	34.0 (5.7)	16.2 (9.6)	14.4 (4.5)

sealed envelopes [9] and one did not report their technique [7]. Two studies described a 100% follow-up rate [7, 13], while one did not discuss their follow-up rate [9]. All co-interventions between groups were comparable. All post-operative alignment measurements were taken by an independent observer blinded to the randomisation group of the patient. Two papers discussed analysing the final outcomes by the intention-to-treat principle [7, 13], while one did not [9]. All papers were considered to be of satisfactory quality.

Data extraction

For each eligible study, two of the authors extracted the relevant data for both the intervention and control groups. This included demographic data (age, sex and body mass index [BMI]), the number of acetabular outliers from the desired range, intervention protocol, duration of the study, loss to follow-up and sources of funding.

Study characteristics

All papers were published in English. One study compared the freehand technique with an imageless navigation system [13], one compared freehand to a CT-based navigation system [9] and one study compared all three techniques [7]. Patients undergoing CT-based and imageless navigation were combined into one navigation group in our analysis. Two studies measured the post-operative acetabular position with CT scans and one employed radiographs. All acetabular components were of the press-fit type. One study indicated that the surgeon had experience of 50 prior navigation cases before the commencement of the study.

Statistical analysis

The study heterogeneity was assessed and a p-value of <0.1 was considered to be suggestive of statistical heterogeneity. Publication bias was assessed with funnel plots, which demonstrate the relationship between the sample size of the studies and the precision in estimating the treatment effect. Bias can be seen if the plots are widely skewed compared to a plot resembling an inverted triangle, which represents no bias [4].

For the categorical outcome of acetabular alignment within the desired range, we used the odds ratio as the summary statistic. This ratio represents the odds of acetabular outliers from the accepted range of alignment occurring in the computer navigation group compared with the freehand group. An odds ratio of less than 1 favours the treatment group and the point estimate of the odds ratio is considered to be statistically significant if the 95% confidence interval does not include the value 1. We used the Mantel-Haenszel method to combine the odds ratio for the outcome of interest using the fixed effects model, as there was no evidence of heterogeneity between studies. Analysis was carried out by using Comprehensive Meta-analysis version 1.0 (Englewood, NJ).

Results

We identified 384 studies from our searches and, after applying our eligibility criteria, we had three manuscripts for systematic

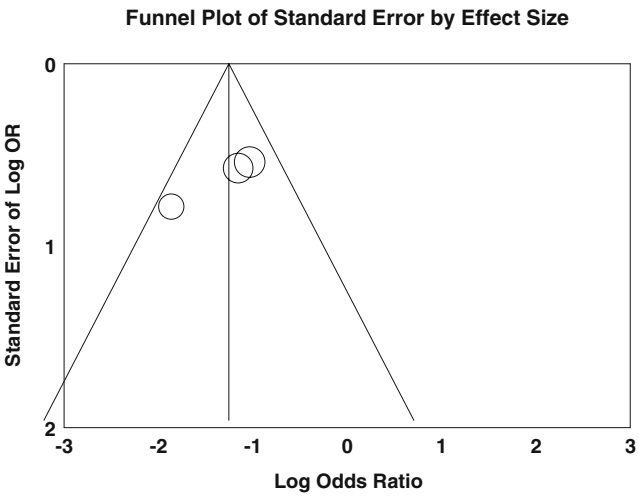


Fig. 2 Funnel plot calculation demonstrating no evidence of publication bias

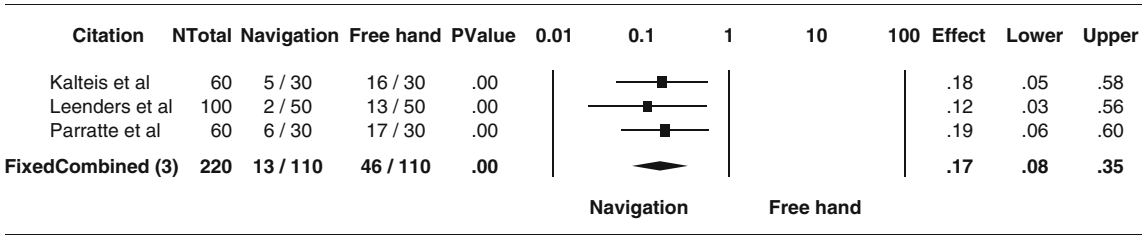


Fig. 3 Odds ratio for outliers from the accepted range comparing the navigation and control groups

review and data synthesis [7, 9, 13]. Forty-four abstracts were potentially relevant; however, we excluded five studies because they were cadaveric studies, four studies were using active navigation systems, such as robots, 31 studies did not fit the criteria of randomised controlled studies and one study was a duplicate. The details of the search is depicted in Fig. 1.

The patient groups were well matched at baseline for the available demographic data. The navigated group consisted of 140 patients with a mean age of 62.1 years and the freehand group (control group) comprised 110 patients with a mean age of 64.2 years. A total of 250 patients were entered into the analysis. The mean BMI in the control group was 27.2 kg/m^2, compared to 26.9 kg/m^2 in the navigation group. One study did not report the BMI of their two study groups [9]. Table 1 describes the characteristics of these studies. Table 2 shows the outcome data from the individual studies.

Figure 2 shows a funnel plot for these studies, reporting acetabular outliers from the accepted range of alignment. The studies are distributed within the 95% confidence interval axis.

The number of acetabular outliers in the navigation group was 15/140 (10.7%), compared to 46/110 (41.8%) in the freehand group. The statistically significant beneficial odds ratio for the number of outliers was 0.285 (95% CI: 0.143 to 0.569; $p<0.001$). There was no evidence of statistical heterogeneity between studies ($p=0.88$; Fig. 3).

Two studies commented on complications [7, 13], while one study did not [9]. Overall, there were no reported complications in the navigation group and one dislocation in the freehand group (1.3%). Two studies [7, 13] commented on an increased surgical time for computer navigation, ranging from 8 to 17 min.

Discussion

The results of our study show that computer navigation significantly improved the surgeon's ability to place the acetabular cup within the desired alignment as defined by Lewinnek et al. [10]. It is unclear at present whether this improved surgical precision will translate to improved long-term clinical outcomes.

A further important finding of our study is that, despite computer navigation becoming an increasingly popular tool amongst surgeons, there are only three randomised trials documenting its efficacy, and all with small numbers.

The cost issues surrounding computer navigation in THR have not been well explored. Whether these systems prove to be cost-effective in the long-term by reducing the revision burden remains to be seen.

Our meta-analysis has several potential limitations. From an internal validity point of view, the interventions were not consistent throughout the studies. One study compared freehand technique to a CT-based system, one compared freehand technique with an imageless system and the final study compared all three methods. Patients undergoing CT-based and imageless navigation were combined into one navigation group in our analysis. We feel that this is justified because CT-based navigation and imageless navigation were compared in a randomised trial and were found to have no significant differences in any outcome measures ($p=0.23$) [13]. Moreover, although we didn't find any evidence of publication bias, funnel plots have limited power in detecting bias if the number of studies is small. From an external validity point of view, one study [13] excluded those patients weighing greater than 100 kg, and this may limit the generalisation of their findings to the more obese patients.

In conclusion, our meta-analysis shows that computer navigation decreased the number of acetabular cups implanted outside the desired range of alignment. At present, there is a need for a well-designed RCT to report on both clinical and radiographic outcome parameters, complications and survival rates, quality of life years gained and cost analyses.

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Section 9.0

New Discussion Items

Prioritization of FDA Approved Drugs on Unfunded Lines on the Prioritized List

Issue: Several FDA-approved drugs have guideline entries that restrict their use beyond FDA approved indications. Over the past several months the Oregon Health Authority has been analyzing the referral of FDA-approved drugs and their on-label uses for considered prioritization on unfunded lines of the Prioritized List. Based on our current understanding of federal requirements set out in section 1927 of the Social Security Act (the federal Medicaid rebate law) and Oregon's 1115 Medicaid Demonstration Waiver, OHA is recommending that HERC remove guidelines restricting FDA approved medications from the Prioritized List, other than step therapy and similar restrictions.

OHA is committed to the foundational role of the HERC, P&T Committee and evidence reviews. OHA remains committed to exploring its options regarding coverage for these treatments under the Oregon Health Plan as responsible stewards of public funds.

Current Prioritized List Status:

Implantable buprenorphine

Entry on Guideline Note 172

11981 G0516, G0518	Implantable buprenorphine for opioid use disorder for patients who are clinically stable on 8 mg daily or less of buprenorphine or equivalent for at least 6 months	Not cost effective compared to equally efficacious alternative formulations	November, 2017

Entry on Guideline Note 173

11981 G0516, G0518	Implantable buprenorphine for opioid use disorder for patients other than those who are clinically stable on 8 mg daily or less of buprenorphine or equivalent for at least 6 months	Unproven treatment	November, 2017

FDA Label: PROBUPHINE is indicated for the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphinecontaining product (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablet or generic equivalent).

Enzyme replacement therapy

Guideline Note 173 entry:

S9357	Enzyme replacement therapy (e.g. idursulfase and similar medications) for all inborn error of metabolism conditions except infantile Pompe's disease	No clinically important benefit	August, 2012

GUIDELINE NOTE 67, ENZYME REPLACEMENT THERAPY

Lines 60,147,660

Enzyme replacement therapy for infantile Pompe's disease is included on Line 147. All other enzyme replacement therapies for inborn errors of metabolism are included on Line 660.

Note: Pompe's disease is E74.02, which appears on line 147 GLYOCOGENESIS. Other diseases for which enzyme replacement therapy has FDA indications for inborn errors of metabolism appear on lines 60, 147 and 454 in the funded region (as well as lines for related dysfunction). In 2017, line 60 was supposed to have been added to this guideline note, but it was not added to the published list due to an administrative omission.

Analysis from P&T staff identifies a large number of drugs in this category for rare conditions, and the agents have FDA indications (see Appendix A). While only a few inborn errors of metabolism are on lines 60 and 147, the phrase "all other" may be interpreted to apply to all conditions on this list (notably, lines 14 and 454). Meeting materials and minutes from 2012, 2013 and 2017 consistently reflect that intent, though not all the conditions are referenced. These are rare diseases, and the placement of their diagnosis codes on the List is listed in Appendix A.

Human growth hormone (HGH) treatment

See the separate document dealing with this topic

Prioritization of FDA Approved Drugs on Unfunded Lines on the Prioritized List

HERC staff recommendations:

Changes effective January 1, 2019

Buprenorphine

1) Delete the following entry from Guideline Note 172. P&T will create appropriate PA criteria which will determine coverage.

~~11981 G0516, G0518~~	~~Implantable buprenorphine for opioid use disorder for patients who are clinically stable on 8 mg daily or less of buprenorphine or equivalent for at least 6 months~~	~~Not cost effective compared to equally efficacious alternative formulations~~	~~November, 2017~~

2) Delete the following entry from Guideline Note 173. P&T will create appropriate PA criteria that will determine coverage.

~~11981 G0516, G0518~~	~~Implantable buprenorphine for opioid use disorder for patients other than those who are clinically stable on 8 mg daily or less of buprenorphine or equivalent for at least 6 months~~	~~Unproven treatment~~	~~November, 2017~~

3) Add buprenorphine implant insertion procedure codes to line 4 SUBSTANCE USE DISORDER to be used for buprenorphine implants per P&T PA criteria
    a. CPT 11981-11983 (Insertion, removal, and removal with re-insertion, non-biodegradable drug delivery implant)
    b. HCPCS G0516-G0518 (Insertion removal, and removal with re-insertion, of non-biodegradable drug delivery implants, 4 or more)

Enzyme replacement therapy

1) Delete GN67. P&T will create appropriate PA criteria to determine coverage. All inborn errors of metabolism diagnoses are on funded lines.

~~**GUIDELINE NOTE 67, ENZYME REPLACEMENT THERAPY**~~

~~*Lines 60,147,660*~~

~~Enzyme replacement therapy for infantile Pompe's disease is included on Line 147. All other enzyme replacement therapies for inborn errors of metabolism are included on Line 660.~~

2) Delete the following entry from Guideline Note 173.

~~S9357~~	~~Enzyme replacement therapy (e.g. idursulfase and similar medications) for all inborn error of metabolism conditions except infantile Pompe's disease~~	~~No clinically important benefit~~	~~August, 2012~~

3) Delete the following ICD-10 codes from Line 650, ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY. All of these codes appear on funded lines.
    a. E75.21 Fabry (-Anderson) disease
    b. E75.22 Gaucher disease
    c. E75.24 Niemann-Pick disease
    d. E76 series (Disorders of glycosaminoglycan metabolism)

Human growth hormone therapy
See separate summary document

Prioritization of FDA Approved Drugs on Unfunded Lines on the Prioritized List

Appendix A: Inborn errors of metabolism

Brand name highlighted if any noncoverage (generic name) condition/indication ICD-10 code, Prioritized List lines red text if any below funding line

- Alpha-1 antitrypsin products (Prolastin-C, Aralast NP, Zemaira, Glassia; IV): alpha1-antitrypsin deficiency E88.01: line 454
- Strensiq (asfotase alfa; SubQ): E83.31 (Familial hypophosphatemia), E83.39 (other disorders of phosphorus metabolism): line 151
- Vimizim (elosulfase alfa; IV): E76.210 Morquio A mucopolysaccharidoses, line 60,71,292,345,377,650
- Elaprase (idursulfase; IV): E76.1 (Hunter Syndrome), E76.3: lines 60,71,292,345,377,650
- Fabrazyme (agalsidase beta; IV): Fabry Disease E75.21: lines 60,71,100,292,345,377,650
- Kanuma (sebelipase alfa; IV): E75.5 Lines 71,292,345,377,650, E75.6: lines 60,71,292,345,377
- Naglazyme (galsulfase; IV): mucopolysaccharidosis VI (MPS VI) E 76.29: lines 60,71,292,345,377,650
- Vpriv (velaglucerase alfa; IV): E75.22 Gaucher disease (type 1): lines 60,71,100,292,345,377,650
- Elelyso (taliglucerase alfa; IV): Gaucher disease (type 1) E75.22: lines 60,71,100,292,345,377,650
- Aldurazyme (laronidase; IV): MPS I (Hurler syndrome, Hurler-Scheie, and Scheie forms) E76.01, E76.02, E76.03: lines 60,71,292,345,377,650
- Lumizyme (alglucosidase alfa; IV): Pompe disease (noninfantile, late-onset) E74.02: lines 71,147,242,292,345,377; Guideline Note 67 = covers infantile, noninfantile is on line 650

Human Growth Hormone Deficiency

Questions:

1) Should the generic ICD-10 code used to code for adult growth hormone deficiency be added to an uncovered line with a coding specification?
2) How should the guideline for human growth hormone deficiency and GN173 be modified to comply with federal law regarding rebatable drugs?

Issues:

1) It is the longstanding policy of the HSC/HERC that adult human growth hormone deficiency was not a covered condition for treatment with human growth hormone. The Health Outcomes Subcommittee of the Health Services Commission discussed adult treatment with human growth hormone in June, 2009 and in January, 2010. In both cases, the members clearly stated that they did not intend to cover human growth hormone treatment in adults. Wording was added to GN74 in June, 2009 to show this intent. GN74 GROWTH HORMONE TREATMENT contained a statement to this effect: "Treatment is not included for isolated deficiency of human growth hormone or other conditions in adults." However, the ICD-10 code used to code for adult growth hormone deficiency (ICD10 E23.0 Hypopituitarism) is only on covered lines: 40 PANHYPOPITUITARISM, IATROGENIC AND OTHER PITUITARY DISORDERS and 386 PITUITARY DWARFISM. The guideline and the coding appear to be in conflict. The US Endocrine Society (2011) (https://academic.oup.com/jcem/article/96/6/1587/2833853) recommends treatment of adult human growth hormone deficiency with human growth hormone for reasons not normally considered by the HERC: body composition, exercise capacity, skeletal integrity, and quality of life measures. There has been no mortality benefit shown for patients with hypopituitarism with human growth hormone. There are no treatments for adult human growth hormone deficiency other than human growth hormone therapy.
1) GN74 currently restricts HGH use to children with certain conditions until adult bone age is achieved. The FDA-approved indications that are therefore completely restricted include:
    a. Children with idiopathic short stature (but not HGH deficiency/pituitary dwarfism). This condition is coded with E34.3 (Short stature due to endocrine disorder) on line 650 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY. R62.52 (Short stature (child)) is on the Diagnostic Workup File. According to the state's legal interpretation, non-coverage of these conditions is acceptable due to the prioritization of their diagnosis codes.
    b. Unfunded diagnoses (wasting/cachexia/lipodystrophy) that are a result of a funded condition (HIV). When related to HIV, the treatment for these conditions are covered by appropriately coding the principle diagnosis code of B20 (HIV disease).
    c. Childhood onset growth hormone deficiency resulting from conditions other than the conditions listed in the guideline. These would be very rare (other than idiopathic short stature above).
    d. Childhood onset growth hormone deficiency treatment after adult height is achieved as determined by bone age.

GUIDELINE NOTE 74, GROWTH HORMONE TREATMENT
Lines 40,386,467
Treatment with growth hormone is included only for children with: pituitary dwarfism, Turner's syndrome, Prader-Willi-syndrome, Noonan's syndrome, short stature homeobox-containing gene (SHOX), chronic kidney disease (stages 3, 4, 5 or 6) and those with renal transplant. Treatment with growth hormone should continue only until adult height as determined by bone age is achieved. Treatment is not included for isolated deficiency of human growth hormone or other conditions in adults.

HERC staff recommendations:
Changes effective January 1, 2018

1) Add ICD-10 E23.0 (Hypopituitarism) to line 650 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY and leave on lines 40 PANHYPOPITUITARISM, IATROGENIC AND OTHER PITUITARY DISORDERS and 386 PITUITARY DWARFISM
2) Add the following coding specifications to lines 40 PANHYPOPITUITARISM, IATROGENIC AND OTHER PITUITARY DISORDERS and 386 PITUITARY DWARFISM
    a. "ICD-10 E23.0 is included on this line for conditions other than adult human growth hormone deficiency."
3) Add the following coding specification to line 650
    a. "ICD-10 E23.0 is included on this line only for adult human growth hormone deficiency."
4) Modify GN74 as shown below. P&T will create appropriate PA criteria to determine coverage.
    a. Adds line 650 per change in #1 above
    b. Removes restrictions other than treatment covered only until adult height is achieved

GUIDELINE NOTE 74, GROWTH HORMONE TREATMENT
Lines 40,386,467,650
~~Treatment with growth hormone is included only for children with: pituitary dwarfism, Turner's syndrome, Prader-Willi-syndrome, Noonan's syndrome, short stature homeobox-containing gene (SHOX), chronic kidney disease (stages 3, 4, 5 or 6) and those with renal transplant.~~
Treatment with growth hormone should continue only until adult height as determined by bone age is achieved. ~~Treatment is not included for isolated deficiency of human growth hormone or other conditions in adults.~~

Should Diabetes Prevention Programs (DPP) for prediabetes be added to the Prioritized List?

Question: How should the Prioritized List be modified to enable coverage of Diabetes Prevention Programs?

Question source: HERC staff and other OHA staff

Issue: The Diabetes Prevention Program (DPP) is an evidence-based program for prediabetics. It is recommended by the Centers for Disease Control and Prevention (CDC) based on substantial evidence it reduces the development of diabetes. https://www.cdc.gov/diabetes/prevention/index.html

Currently in OHP there is coverage for overweight and obesity, but not for prediabetes. The Prediabetes codes appears on the diagnostic workup file which generally does not allow treatment to pair with it. The other major consideration is that DPP programs are community-based longitudinal programs, and some of them are led by individuals who would not be licensed health providers in our state.

The CDC has developed a national registry of recognized diabetes prevention programs that adhere to the evidence-based standards using a CDC-approved curriculum that meets the duration, intensity, and reporting requirements described in the DPRP Standards https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf. Certified programs are led by a trained lifestyle coach; are delivered in a yearlong period, with at least 16 sessions in the first half of the program, and at least six sessions in the second half of the program; are conducted in person or online; and use a CDC-approved curriculum (CDC, 2016). Certified programs must be able to report on attendance, weight loss, and physical activity every 12 months (CDC, 2016).

To be eligible for referral to a CDC-recognized lifestyle change program, patients must meet the following requirements:

- Be at least 18 years old and
- Be overweight (body mass index ≥25; ≥23 if Asian) and
- Have no previous diagnosis of type 1 or type 2 diabetes and
- Have a blood test result in the prediabetes range within the past year:
    - Hemoglobin A1C: 5.7%–6.4% or
    - Fasting plasma glucose: 100–125 mg/dL or
    - Two-hour plasma glucose (after a 75 gm glucose load): 140–199 mg/dL or
- Be previously diagnosed with gestational diabetes

There are currently 30 programs in Oregon that have pending, preliminary, or full recognition by the CDC. Most of these are in-person programs although a few are online programs. Many of the programs have not had administrative capacity or

readiness to bill Medicaid and some do not have a licensed provider to enable billing of DPP codes to health plans.

There have been three pilot DPP programs in Oregon's CCO population. These, along with ongoing work with OHA, the CDC, and the National Association of Chronic Disease Directors have helped to ascertain necessary changes to the payment structure to enable DPP to be a funded-OHP benefit. The current plan is to have CDC-recognized programs be eligible for payment.

Screening for prediabetes should be done as part of a USPSTF recommendation:
USPSTF, 2015 Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening

> The USPSTF recommends screening for abnormal blood glucose as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or obese. Clinicians should offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity.

Prioritized List Status

Code	Code Description	Current Placement
R73.03	Prediabetes	Diagnostic Workup File (DWF)
R73.09	Other abnormal glucose	Diagnostic Workup File (DWF)
Z86.32	Personal history of gestational diabetes	1 PREGNANCY
0403T	Preventive behavior change, intensive program of prevention of diabetes using a standardized diabetes prevention program curriculum, provided to individuals in a group setting, minimum 60 minutes, per day	Not on List, temporary code
0488T	Preventive behavior change, online/electronic intensive program of prevention of diabetes using a standardized diabetes prevention program curriculum, provided to an individual, per 30 days	Not on List, temporary code
99411	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to individuals in a group setting (separate procedure); approximately 30 minutes	On >500 lines, including line 3.
99412	Group prevention counseling	On >500 lines, including line 3.

Should Diabetes Prevention Programs (DPP) for prediabetes be added to the Prioritized List?

Code	Code Description	Current Placement
98962	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5-8 patients	1 Pregnancy 8 Type1 DM 27 Type 2 DM
98969	Online assessment and management service provided by a qualified nonphysician health care professional to an established patient or guardian, not originating from a related assessment and management service provided within the previous 7 days, using the Internet or similar electronic communications network	On >600 lines, including line 3

Line: 3

Condition: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS (See Coding Specification Below) (See Guideline Notes 1,17,64,65,106,122,140)

Treatment: MEDICAL THERAPY

ICD-10: Z00.00-Z00.01,Z00.110-Z00.5,Z00.70-Z00.8,Z01.00-Z01.10,Z01.110-Z01.118, Z01.411-Z01.42,Z08,Z11.1-Z11.4,Z11.51,Z12.11,Z12.2,Z12.31,Z12.4,Z13.1, Z13.220,Z13.4-Z13.6,Z13.820,Z13.88,Z20.1-Z20.7,Z20.810-Z20.89,Z23, Z29.11-Z29.12,Z29.14,Z29.8,Z39.1,Z71.41,Z71.7,Z76.1-Z76.2,Z80.0,Z80.41, Z91.81

CPT: 44392,44394,45333,45338,45384,45385,76706,77067,90378,90460-90472, 90620,90621,90630-90674,90680-90688,90696-90716,90723-90736, 90739-90748,90750,90756,92002-92014,92551,93792,93793,96110,96150-96155,98966-98969,99051,99060,99070,99078,99173,99188,99201-99215, 99281-99285,99341-99378,99381-99404,99408-99449,99487-99490, 99495-99498,99605-99607

HCPCS: D0191,D1206,G0008-G0010,G0104,G0105,G0121,G0248-G0250,G0296, G0297,G0396,G0397,G0438-G0445,G0463-G0468,G0490,G0511,G0513, G0514,H0049,H0050,S0285,S0610-S0613,S9443

CPT code 96110 can be billed in addition to other CPT codes, such as evaluation and management (E&M) codes or preventive visit codes.

Line: 320

Condition: OBESITY IN ADULTS AND CHILDREN; OVERWEIGHT STATUS IN ADULTS WITH CARDIOVASCULAR RISK FACTORS (See Guideline Notes 5,8,64,65)

Treatment: BEHAVIORAL INTERVENTIONS INCLUDING INTENSIVE NUTRITIONAL AND PHYSICAL ACTIVITY COUNSELING; BARIATRIC SURGERY

ICD-10: E66.01-E66.9,Z46.51,Z68.30-Z68.45,Z68.54,Z71.3,Z71.82

CPT: 43644,43645,43771-43775,43846-43848,93792,93793,96150-96155, 97802-97804,98966-98969,99051,99060,99070,99078,99201-99215,

99281-99285,99341-99378,99381-99404,99408-99449,99487-99490, 99495-99498

HCPCS: G0248-G0250,G0396,G0397,G0447,G0463-G0467,G0473,G0490,G0511, G0513,G0514,S2083

GUIDELINE NOTE 5, OBESITY AND OVERWEIGHT

Line 320

Medical treatment of overweight (with known cardiovascular risk factors) and obesity in adults is limited to intensive counseling on nutrition and physical activity, provided by health care professionals. Intensive counseling is defined as face-to-face contact more than monthly. A multidisciplinary team is preferred, but a single clinician could also deliver intensive counseling in primary care or other settings.

Intensive counseling visits are included on this line for 6 months. Intensive counseling visits may continue for an additional 6 months (up to 12 months) as long as there is evidence of continued weight loss or improvement in cardiovascular risk factors based on the intervention. Maintenance visits at the conclusion of the intensive treatment are included on this line no more than monthly after this intensive counseling period. The characteristics of effective behavioral interventions include: high intensity programs; multicomponent (including at a minimum diet and exercise), group-based commercial programs; Mediterranean diet; and the following sub-elements -- calorie counting, contact with a dietician, and comparison to peers.

Known cardiovascular risk factors in overweight persons for which this therapy is effective include: hypertension, dyslipidemia, prediabetes, or the metabolic syndrome.

Medical treatment of obesity in children is limited to comprehensive, intensive behavioral interventions. For treatment of children up to 12 years old, interventions may be targeted only to parents, or to both parents and children.

Pharmacological treatments and devices (e.g. gastric balloons, duodenal jejunal bypass liners, and vagus nerve blocking devices) for obesity are not intended to be included as services on this line or any other line on the Prioritized List.

<u>Evidence Summary</u>

MED, 2017 (below studies excerpted from MED report)

- Participants in a combined diet and physical activity program had risk reduction for diabetes of 50% (high strength of evidence)
- More intensive programs are more effective than less intensive programs
- Older adults benefited the most
- No difference in racial and ethnic subgroups

Balk, 2015

- Systematic review for the Community Preventive Services Task Force
- Good quality
- Studies involved combined diet and physical activity promotion programs to prevent T2DM among individuals at high risk for diabetes.
- 16 studies (13 RCTs)
- Follow up 1-23 years
- Comparative effectiveness of diet and exercise programs compared to usual care for:
    - Incident diabetes summary RR 0.59 (95% CI, 0.52-0.66, no heterogeneity). Median risk difference -11%
    - Return to normoglycemia RR 1.53 (95% CI, 1.26-1.71), median risk difference 12% points
    - Body weight -2.2% (95% CI, -2.9 to -1.4%), range -0.2% to -10.5%, high heterogeneity
    - All-cause mortality based on US DPP study alone, risk difference -0.6 per 1,000 person-years. Not statistically significant.
    - HbA1c -0.049% (95% CI, -0.087 to -0.008%), no heterogeneity

- Limitations included: poor descriptions of population or intervention, high dropout rates and loss to f/u
- This systematic review led to the Community Preventive Services Task Force recommending combined diet and physical activity programs

Mudaliar, 2016

- U.S. Community based adaptations of the DPP
- Systematic review and meta-analysis
- 44 studies, 8,895 individuals
- Mostly 1 year f/u
- mean weight loss of 3.77 kg (95% CI, 4.55 to 2.99 lower than baseline)
- Changes in HbA1c -0.21% [95% CI, -0.29 to -0.13]
- Improvements were less than the original DPP

Jonier, 2017

- eHealth approaches to delivering DPP
- Systematic review
- Greater number of white participants and participants with higher education level
- Weight loss -3.34% after 15 months
- Slightly less effective than in-person behavioral counselor

Neamah, 2016

- Systematic review of cultural adaptations
- Programs with fewer modifications reported greater BMI reductions

Li, 2015

- Systematic review of economic evaluations, good quality
- Economic evaluations on cost, cost-effectiveness, and cost-benefit estimates of programs promoting diet and physical activity.
- Considered impact to health system and the societal perspective
- Median ICER overall $13,761 per QALY saved
- Median ICER for individual $15,846 per QALY versus $1,819 per QALY for group intervention delivery
- Median ICER per life-year gained $2,684
- 3 studies found cost-savings
- DPP is cost-effective, moreso for group intervention delivery than individual intervention delivery

Dall, 2015

- Economic evaluation, good quality
- Based on findings from the DPP study were applied to a nationally reflective sample: the National Health and Nutrition Examination Survey (NHANES) 2003 to 2010 data set of 3,700 adults with prediabetes.
- Cost of $3,770 per participant (2013 dollars)
- Over 10 years
    - 11.4 million cases of diabetes averted
    - $539 billion dollars in medical costs avoided
    - $992 billion dollars in nonmedical benefits, mostly through employment
    - $30 million in QALY gained

Recommendations from others

Centers for Disease Control and Prevention 6/18 initiative

https://www.cdc.gov/sixeighteen/docs/6-18-evidence-summary-diabetes.pdf

Recommendations for Payers

- Expand access to the National Diabetes Prevention Program (the National DPP), a lifestyle change program for preventing type 2 diabetes.

Community Preventive Services Task Force, 2014

Summary of CPSTF Finding

The Community Preventive Services Task Force (CPSTF) recommends combined diet and physical activity promotion programs for people at increased risk of type 2 diabetes to reduce new-onset diabetes.

Combined diet and physical activity promotion programs also increase the likelihood of reverting to normoglycemia (normal blood sugar) and improve diabetes and cardiovascular disease risk factors, including overweight, high blood glucose, high blood pressure, and abnormal lipid profile.

Based on the evidence, combined diet and physical activity promotion programs are effective across a range of counseling intensities, settings, and implementers. Programs commonly include a weight loss goal, individual or group sessions (or both) about diet and exercise, meetings with a trained diet or exercise counselor (or both), and individually tailored diet or exercise plans (or both). Higher intensity programs lead to greater weight loss and reduction in new-onset diabetes.

Economic evidence indicates that these interventions are cost-effective.

Summary of Economic Evidence

More details about study results are available in the CPSTF Finding and Rationale Statement

An economic review of 28 studies (search period January 1985 - April 2015) shows that combined diet and physical activity promotion programs for people at increased risk for type 2 diabetes are cost-effective. All monetary values reported are in 2013 U.S. dollars.

Cost of the programs

- All programs: median $653 per participant (12 studies)
- Group-based programs: median $417 per participant (8 studies)
- Programs that translated the U.S. DPP into community or primary care settings: median $424 per participant (8 studies)

Cost-effectiveness of the program (from the health system perspective, which included only the direct medical costs of the programs and healthcare costs averted, based on either data collected in actual programs or estimates from simulation models)

- Cost per quality-adjusted life year (QALY) saved
    - All programs: median $13,761 (16 studies)
    - Group-based programs: median $1,819 (5 studies)
    - Individual-based programs: median $15,846 (5 studies)
- Cost per disability-adjusted life year (DALY) averted
    - $21,195 and $50,707 (2 studies)
- Cost per life year gained (LYG)
    - Median $2,684 (6 studies)

The variation in program costs per participant is partly explained by the number of sessions, delivery mode of the core sessions (individual vs. group), setting (clinical trial vs. community or primary care), and type of personnel used (health professionals vs. trained laypeople). The variation in cost-effectiveness is partially explained by variation in cost and effectiveness of the programs, program delivery modes, patient follow-up times, and delivery settings.

Other Payers

Medi-Cal http://www.dhcs.ca.gov/services/medi-cal/Pages/Diabetes-Prevention-Program.aspx

Legislature approved funding for Medicaid recipients to receive DPP starting July 2018.

DPP services are provided through trained peer coaches who use a Centers for Disease Control and Prevention (CDC)-approved curriculum. The DPP core benefit lasts one year, and consists of sixteen sessions over the first six months, and at least one session per month for the next six months, for a total of twenty-two sessions. Additional less intensive, ongoing maintenance sessions are also provided for eligible beneficiaries who achieve and maintain a required minimum weight loss of five percent from the first core session.

Medi-Cal providers can recommend participation in the DPP to eligible Medi-Cal beneficiaries who meet all of the following requirements:

- The beneficiary is at least 18 years of age.
- As of the date of the provider recommendation, the beneficiary has a body mass index (BMI) of at least 25 if the beneficiary does not self-identify as Asian, or a BMI of at least 23 if the beneficiary self-identifies as Asian.
- Within the 12-month period prior to the provider recommendation, the beneficiary has had one of the following:
    - A hemoglobin A1c test with a value between 5.7 and 6.7%.
    - A fasting plasma glucose of 110-125 mg/dL.
    - A two-hour plasma glucose of 140-199 mg/dL.
- The beneficiary has no previous diagnosis of type 1 or type 2 diabetes, excluding gestational diabetes.
- The beneficiary does not have end-stage renal disease.

Medicare

Medicare has developed the Medicare Diabetes Prevention Program Expanded Model https://innovation.cms.gov/Files/x/MDPP_Overview_Fact_Sheet.pdf

The model includes:

- Structured sessions with a coach, using a CDC-approved curriculum to provide training in dietary change, increased physical activity, and weight loss strategies

- 12 months of core sessions for beneficiaries with an indication of prediabetes, and an additional 12 months of ongoing maintenance sessions for participants who meet weight loss and attendance goals.

Eligible beneficiaries are those who:

• Are enrolled in Medicare Part B

• Have a body mass index (BMI) of at least 25, or at least 23 if self-identified as Asian

• Meet 1 of the following 3 blood test requirements within the 12 months of the first core session:

- A hemoglobin A1c test with a value between 5.7 and 6.4% , or
- A fasting plasma glucose of 110-125 mg/dL, or
- A 2-hour plasma glucose of 140-199 mg/dL (oral glucose tolerance test)

• Have no previous diagnosis of type 1 or type 2 diabetes (other than gestational diabetes)

• Do not have end-stage renal disease (ESRD)

Payment considerations

There are Medicaid G codes G9873-G9879 and G9880-3, however, given how payments are made, reimbursements using these G codes would not lead to a sustainable reimbursement pattern. Some plans may choose to use the temporary codes and others the 99412/99411 codes.

HERC Staff Summary

Diabetes Prevention Programs (DPPs) are effective at reducing incident diabetes and returning individuals to a normoglycemic state based on high strength of evidence. They also reduce HbA1c and reduce weight. They are highly cost-effective.

Prioritized List modifications are necessary to enable coverage. There is still ongoing work needed to establishment payment mechanisms for CDC-recognized DPP programs, necessitating a slightly delayed implementation.

HERC Staff Recommendations:

1. Move R73.03 *Prediabetes* from the Diagnostic File to Line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
2. Add Z86.32 *Personal history of gestational diabetes* to Line 3
3. Add 98962 *Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5-8 patients* to Line 3.
4. Add the temporary codes for DPP to Line 3

a. 0403T *Preventive behavior change, intensive program of prevention of diabetes using a standardized diabetes prevention program curriculum, provided to individuals in a group setting, minimum 60 minutes, per day*
b. 0488T *Preventive behavior change, online/electronic intensive program of prevention of diabetes using a standardized diabetes prevention program curriculum, provided to an individual, per 30 days*

5. Adopt a guideline note:

GUIDELINE NOTE XXX Diabetes Prevention Program
Line 3
Prediabetes (R73.03) and personal history of gestational diabetes (Z86.32) are included on this line only for the Diabetes Prevention Program (DPP). The only programs included are CDC-recognized lifestyle change programs for DPP.

To be eligible for referral to a CDC-recognized lifestyle change program, patients must meet the following requirements:

- Be at least 18 years old and
- Be overweight (body mass index ≥25; ≥23 if Asian) and
- Have no previous diagnosis of type 1 or type 2 diabetes and
- Not have end-stage renal disease and
- Have a blood test result in the prediabetes range within the past year:
  - Hemoglobin A1C: 5.7%–6.4% or
  - Fasting plasma glucose: 100–125 mg/dL or
  - Two-hour plasma glucose (after a 75 gm glucose load): 140–199 mg/dL or
  - Be previously diagnosed with gestational diabetes

6. Modify guideline note 5 as follows:
GUIDELINE NOTE 5, OBESITY AND OVERWEIGHT

Line 320

Medical treatment of overweight (with known cardiovascular risk factors) and obesity in adults is limited to intensive counseling on nutrition and physical activity, provided by health care professionals. Intensive counseling is defined as face-to-face contact more than monthly. A multidisciplinary team is preferred, but a single clinician could also deliver intensive counseling in primary care or other settings.

Intensive counseling visits are included on this line for 6 months. Intensive counseling visits may continue for an additional 6 months (up to 12 months) as long as there is evidence of continued weight loss or improvement in cardiovascular risk factors based on the intervention. Maintenance visits at the conclusion of the intensive treatment are included on this line no more than monthly after this intensive counseling period. The characteristics of effective

behavioral interventions include: high intensity programs; multicomponent (including at a minimum diet and exercise), group-based commercial programs; Mediterranean diet; and the following sub-elements -- calorie counting, contact with a dietician, and comparison to peers.

Known cardiovascular risk factors in overweight persons for which this therapy is effective include: hypertension, dyslipidemia, prediabetes, or the metabolic syndrome. Treatment of prediabetes with the Diabetes Prevention Program (DPP) is addressed on Line 3 in Guideline Note XXX.

Medical treatment of obesity in children is limited to comprehensive, intensive behavioral interventions. For treatment of children up to 12 years old, interventions may be targeted only to parents, or to both parents and children.

Pharmacological treatments and devices (e.g. gastric balloons, duodenal jejunal bypass liners, and vagus nerve blocking devices) for obesity are not intended to be included as services on this line or any other line on the Prioritized List.

7. Recommend all these changes for implementation on January 1, 2019 Prioritized List.

Form Approved
OMB No. 0920-0909
Exp. Date: 02/28/2021

CENTERS FOR DISEASE CONTROL AND PREVENTION

Centers for Disease Control and Prevention Diabetes Prevention Recognition Program

Standards and Operating Procedures

www.cdc.gov/diabetes/prevention/recognition

March 1, 2018

Public reporting burden of this collection of information is estimated to average one hour per responses for the Diabetes Prevention Recognition Program Application Form and one hour per response for the submission of Evaluation Data, including the time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30329; ATTN: PRA #0920-0909

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2018 Centers for Disease Control and Prevention Diabetes Prevention Recognition Program

I. Overview

The Centers for Disease Control and Prevention (CDC) established the CDC Diabetes Prevention Recognition Program (DPRP) (https://www.cdc.gov/diabetes/prevention/lifestyle-program/index.html) as part of the National Diabetes Prevention Program (National DPP) (https://www.cdc.gov/diabetes/prevention/index.html). The DPRP provides information to people at high risk of type 2 diabetes, their health care providers, and health payers about the location and performance of type 2 diabetes prevention programs across organizations with various delivery modes (in-person, online, and combination). The purpose of the DPRP is to recognize organizations that have demonstrated their ability to effectively deliver a proven type 2 diabetes prevention lifestyle change program. The recognition program helps to assure that decisions about individual participation, patient referral, and health insurance benefits are based on accurate, reliable, and trustworthy information. The DPRP is further committed to ensuring health equity by increasing access to type 2 diabetes prevention lifestyle change programs among vulnerable populations, including those living in geographically hard to reach or rural areas, through a variety of modalities.

The DPRP assures the quality of recognized organizations and provides standardized reporting on their performance. The original 2011 DPRP Standards for type 2 diabetes prevention lifestyle change programs and requirements for recognition were based on successful efficacy and effectiveness studies. In one such efficacy study, the U.S. Diabetes Prevention Program research trial (DPP), participants in the lifestyle intervention losing 5-7% of their bodyweight experienced a 58% lower incidence of type 2 diabetes than those who did not receive the lifestyle intervention (see https://www.niddk.nih.gov/about-niddk/research-areas/diabetes/diabetes-prevention-program-dpp/Documents/DPP_508.pdf). The current standards, though still grounded in the earlier research, incorporate innovations from further translational studies, best practices, and expert opinion.

The DPRP has three key objectives:

- Assure program quality, fidelity to scientific evidence, and broad use of effective type 2 diabetes prevention lifestyle change programs throughout the United States;
- Develop and maintain a registry of organizations that are recognized for their ability to deliver effective type 2 diabetes prevention lifestyle change programs to people at high risk;
- Provide technical assistance to organizations to assist staff in effective program delivery and in problem-solving to achieve and maintain recognition status.

This document—*CDC Diabetes Prevention Recognition Program Standards and Operating Procedures* (or *DPRP Standards*, for short)—describes in detail the DPRP standards for type 2 diabetes prevention lifestyle change programs and explains how an organization may apply for, earn, and maintain CDC recognition.

II. Standards and Requirements for Recognition

Any organization that has the capacity to deliver an approved type 2 diabetes prevention lifestyle change program may apply for recognition. It is strongly recommended that potential applicants thoroughly read the *DPRP Standards* (this document) and conduct a capacity assessment (see guidance titled Organizational Capacity Assessment) before submitting an application for recognition.

A. Participant Eligibility

Recognized organizations will enroll participants according to the following requirements:

1. All of a program's participants must be 18 years of age or older and not pregnant at time of enrollment. These programs are intended for adults at high risk for developing type 2 diabetes.

2. All of a program's participants must have a body mass index (BMI) of ≥25 kg/m^2 (≥23 kg/m^2, if Asian American).

3. All of a program's participants must be considered eligible based on either:

   a. a recent (within the past year) blood test (may be self-reported for CDC recognition purposes; but, for Medicare DPP suppliers, a self-reported blood test is not permitted) meeting one of these specifications:
      i. Fasting glucose of 100 to 125 mg/dl (CMS eligibility requirement for Medicare DPP suppliers is 110 to 125 mg/dl)
      ii. Plasma glucose measured 2 hours after a 75 gm glucose load of 140 to 199 mg/dl
      iii. A1c of 5.7 to 6.4
      iv. Clinically diagnosed gestational diabetes mellitus (GDM) during a previous pregnancy (may be self-reported; allowed for CDC, but not for Medicare beneficiaries.); or

   b. a positive screening for prediabetes based on the CDC Prediabetes Screening Test (available in the Guidance section of this document or accessible online at https://www.cdc.gov/diabetes/prevention/pdf/prediabetestest.pdf) or a screening result indicating high risk for type 2 diabetes on the hard copy or electronic version of the American Diabetes Association Type 2 Diabetes Risk Test (http://www.diabetes.org/are-you-at-risk/diabetes-risk-test/). Note: These are not options for eligibility for Medicare beneficiaries.

4. Participants cannot have a previous diagnosis of type 1 or type 2 diabetes prior to enrollment.

5. A health care professional may refer potential participants to the program, but a referral is not required for participation in CDC-recognized programs.

Recognized organizations can retain participants if the following occurs:

1. Participants who develop type 2 diabetes while in the program should be referred to their primary care provider for referrals to ADA-recognized or AADE-accredited diabetes self-management education and support (DSMES) programs and other resources such as Medical Nutrition Therapy (MNT) as appropriate. See Submitting Evaluation Data to the DPRP section for details on how to code these participants.

2. Lifestyle change programs for type 2 diabetes prevention emphasize weight loss and are not appropriate for women who are currently pregnant. Participants who become pregnant may continue at the discretion of their health care provider and the CDC-recognized program delivery organization. See Submitting Evaluation Data to the DPRP section for details on how to code these participants.

B. Safety of Participants and Data Privacy

Lifestyle change programs for type 2 diabetes prevention typically do not involve physical activity during class time. If physical activity is offered, it is the organization's responsibility to have procedures in place to assure safety. This may include obtaining a liability waiver from the participant and/or having the participant obtain clearance from his/her primary care provider to participate in physical activity.

Along with the physical safety of the participants, organizations should also be mindful of the need to ensure the privacy and confidentiality of participants' data. It is the organization's responsibility to be versed in and to comply with any federal, state, and/or local laws governing individual-level identifiable data, including those laws related to the Health Insurance Portability and Accountability Act (HIPAA), data collection, data storage, data use, and disclosure.

C. Location

If the lifestyle change program is offered in-person, organizations may use any suitable venue. Organizations should provide private settings in which participants can be weighed or meet individually with Lifestyle Coaches. Some may choose to deliver the lifestyle change program online or via one or more distance learning modalities (e.g., telehealth, remote classroom). Those organizations can obtain weights via digital technology, such as Bluetooth-enabled scales, or accept a self-report from a participant's own at-home digital scale. (Bluetooth-enabled scales refer to scales that transmit weights securely via wireless or cellular transmission.)

D. Delivery Mode

Organizations may offer the program through any or all of the following delivery modes, **but are required to submit a single application for each delivery mode being used**. This will result in a separate organization code (orgcode) for each delivery mode. Data for each orgcode will be submitted every 6 months starting from the effective date.

1. **In-person.** Yearlong lifestyle change program delivered 100% in-person for all participants by trained Lifestyle Coaches; meaning, participants are physically present in a classroom or classroom-like setting. Lifestyle Coaches may supplement in-person sessions with handouts, emails, or reminder texts; although none of these may be the sole method of participant communication. Organizations that conduct make-up sessions online, via some other virtual modality, or over the phone are still considered to be delivering the program in-person.

2. **Online.** Yearlong lifestyle change program delivered 100% online for all participants; meaning, participants log into course sessions via a computer, laptop, tablet, or smart phone. Participants also must interact with Lifestyle Coaches at various times and by various communication methods, including online classes, emails, phone calls, or texts.

3. **Distance Learning.** Yearlong lifestyle change program delivered 100% by trained Lifestyle Coaches via remote classroom or telehealth (i.e., conference call or Skype) where the Lifestyle Coach is present in one location and participants are calling in or video-conferencing from

another location is considered Distance Learning.

4. **Combination.** Yearlong lifestyle change program delivered as a combination of any of the previously defined delivery modes (1. – 3. above) for all participants by trained Lifestyle Coaches.

Make-up sessions can be provided in any delivery mode, but only one make-up session can be held on the same date as a regularly scheduled session. Furthermore, only one make-up session per participant per week can be held. Make-up sessions must be comparable to regularly scheduled sessions in content and length (approximately one hour). Timeframes for conducting make-up sessions are as follows: 1) missed core sessions must be made up within months 1-6, and 2) missed core maintenance sessions must be made up in months 7-12. Make-up sessions must be offered within these timeframes in order for data to be analyzed. Make-up sessions will be analyzed in the same way as regularly scheduled sessions. See Submitting Evaluation Data to the DPRP section for details on how to code these participants.

E. Staffing

The eligibility criteria, skills, knowledge, qualities, and training required of Lifestyle Coaches and Diabetes Prevention Program Coordinators (Program Coordinators) are described in the guidance section of this document titled Guidelines for Staff Eligibility, Roles, Responsibilities, and Sample Job Descriptions.

Recognized organizations are responsible for hiring, training, and supporting their Lifestyle Coaches. Lifestyle Coaches should have the ability to help participants make and sustain positive lifestyle changes. They should also have the understanding and sensitivity to help participants deal with a range of issues and challenges associated with making important lifestyle changes.

Organizations should designate an individual to serve as the Program Coordinator. Program Coordinators should have the ability to serve both as the primary external champions of the program and as the organizational experts for program implementation consistent with the DPRP Standards. Program Coordinators should supervise daily operations of the lifestyle change program, and should provide guidance and support for the Lifestyle Coaches. They should understand the DPRP data collection and submission requirements, including the importance of monitoring program data to ensure quality performance outcomes.

Program Coordinator functions and responsibilities are described in more detail in the position description in the guidance section. When an organization is ready to expand their program, they may require accessing or adding business or leadership support. Leaders and/or business staff may help increase referrals, enrollment, and reimbursement by serving as community spokespersons, by contacting physician offices to encourage referrals, and by working with employers and insurers to increase coverage and benefit uptake for the lifestyle change program.

It is the organization's responsibility to determine staffing needs for effective implementation. If an organization serves a large number of participants at the same time, it should consider hiring additional Lifestyle Coaches and designating more than one Program Coordinator. Similarly, if an organization serves only a small number of participants at one time, it may consider allowing a single person to serve as both the Lifestyle Coach and the Program Coordinator.

F. Training

Recognized organizations are responsible for ensuring that an adequate and well-trained workforce is available prior to launching a first class (see the Organizational Capacity Assessment). All Lifestyle Coaches must be trained to the specific curriculum being used by the recognized organization before offering their first class. The recommended minimum length of formal training for new Lifestyle Coaches is at least 12 hours or two days. Formal training is defined as training conducted by one of the four methods listed in Section III. Applying for Recognition, Lifestyle Coach Training Entity. Shortly after completing formal training, Lifestyle Coaches should begin facilitating program sessions and, ideally, should receive on-the-job coaching from a Program Coordinator or other trained Lifestyle Coach.

Since Program Coordinators are responsible for overall program implementation, they must also complete formal training as Lifestyle Coaches. This will permit them to mentor Lifestyle Coaches and serve as back-up Coaches if required.

Recognized organizations are responsible for the ongoing support and continued training of Lifestyle Coaches. They are further responsible for ensuring continued success, quality, and adherence of Lifestyle Coaches to the DPRP Standards. They should provide new Lifestyle Coaches with an opportunity to attend CDC-sponsored webinar trainings on specialized topics such as program delivery ("Welcome to the DPRP"), data submission ("Submit for Success"), and any others offered by CDC. Additional new or refresher training for experienced Coaches is highly recommended, since program evaluation findings have demonstrated that well trained and highly motivated Lifestyle Coaches have a significant impact on participant outcomes. All Lifestyle Coaches should receive additional training each time CDC revises the DPRP Standards, and CDC will offer such training at no cost to organizations.

Training entities that provide formal training to a CDC-approved curriculum are listed on CDC's website at http://www.cdc.gov/diabetes/prevention/lifestyle-program/staffing-training.html. These entities are not officially endorsed by CDC, but they sign a Memorandum of Understanding (MOU) agreeing to train to a CDC-approved curriculum and to provide training nationally or regionally to organizations recognized by CDC. These entities further agree to provide quality training aligned with the DPRP Standards, which should help ensure competent Lifestyle Coaches. In addition to the training entities listed on the CDC website, training may be provided by 1) a private organization with a national network of program sites, 2) a CDC-recognized virtual organization with national reach, or 3) a Master Trainer (has completed at least 12 hours of formal training as a Lifestyle Coach, has successfully offered the National DPP lifestyle change program for at least one year, and has completed a Master Trainer program offered by a training entity listed on the CDC website.). CDC may conduct random quality assurance assessments of any program, organization, or Master Trainer providing formal training for Lifestyle Coaches to ensure that training requirements are being met.

G. Required Curriculum Content

The National DPP lifestyle change program consists of a series of sessions that present information, provide outside-of-class activities, and offer feedback in stages to optimize behavioral change. The program may be presented in-person, online, via distance learning, or as a combination modality as described in the Delivery Mode section of this document. As demonstrated in the DPP and other diabetes prevention research trials, the lifestyle change

program, as well as the behavioral and motivational content, must be geared toward the overarching goal of preventing type 2 diabetes. In addition, the content should emphasize the need to make lasting lifestyle changes.

The participant's body weight must be recorded at all sessions. Goals for the yearlong program should focus on moderate changes in both diet and physical activity to achieve modest weight loss in the range of 5-7% of baseline body weight. Strategies used to achieve these goals must include a focus on self-monitoring of diet and physical activity, building self-efficacy and social support for maintaining lifestyle changes, and problem solving strategies for overcoming common challenges to sustaining weight loss.

Recognized organizations must emphasize that the lifestyle change program is specifically designed for prevention of type 2 diabetes in persons at high risk for type 2 diabetes. Therefore, rather than focusing solely on weight loss, the lifestyle change program must also emphasize long-term improvements in nutrition and physical activity. To support learning and lifestyle modification, programs should provide appropriate materials for all participants. The format of the materials (e.g., hard copy, electronic, web-based, etc.) is determined by the program.

Although lifestyle change programs may incorporate innovative ideas and expert opinion, these programs should be based on evidence from efficacy and effectiveness trials. The CDC-developed PreventT2 curriculum is freely available for use and can be found at https://www.cdc.gov/diabetes/prevention/lifestyle-program/curriculum.html. However, organizations may also use other curricula that have been approved by CDC as meeting the standards.

Names of corresponding sessions from the 2012 National DPP and PreventT2 curricula are listed below. Organizations developing their own alternate curricula must use similar session titles and evidence-based content supporting their sessions, and must submit their curricula to CDC for review against the session topics below.

Table 1. Curriculum Topics (Months 1-6)

During the first 6 months (weeks 1-26) of the lifestyle change program, all of these curriculum topics must be covered in at least 16 weekly sessions. Organizations may repeat core modules or use core maintenance modules to offer additional sessions in months 1-6 after they have offered the 16 required weekly core sessions. In this case, organizations must code the use of core maintenance modules in months 1-6 as core sessions. Below are the corresponding sessions from the 2012 National DPP and PreventT2 curricula. All alternate curricula should contain similar session titles and content.

2012 National DPP Curriculum	PreventT2 Curriculum
Welcome to the National Diabetes Prevention Program	Program Overview & Introduction to the Program
Being Active - A Way of Life	Get Active to Prevent T2
Move Those Muscles	Track Your Activity
Be a Fat and Calorie Detective	Track Your Food
Three Ways to Eat Less Fat and Fewer Calories	Eat Well to Prevent T2
Jump Start Your Activity Plan	Get More Active

Tip the Calorie Balance	Burn More Calories Than You Take In
Healthy Eating	Shop and Cook to Prevent T2
You Can Manage Stress	Manage Stress
The Slippery Slope of Lifestyle Change	Find Time for Fitness
Make Social Cues Work for You & Talk Back to Negative Thoughts	Cope with Triggers
Can use Heart Health from months 7-12	Keep Your Heart Healthy
Problem Solving	Take Charge of Your Thoughts
Take Charge of What's Around You	Get Support
Four Keys to Healthy Eating Out	Eat Well Away from Home
Ways to Stay Motivated	Stay Motivated to Prevent T2

Table 2. Curriculum Topics (Months 7-12)

During the last 6 months (weeks 27-52) of the lifestyle change program, organizations must include at least one session delivered in each of the 6 months (for a minimum of 6 sessions). Organizations wishing to deliver more sessions (going beyond the minimum requirement of one session each month) are encouraged to do so, as this may be beneficial to participants needing additional support. An organization may use a core module to offer additional sessions in months 7-12 after they have offered the required 6 core maintenance modules. In this case, the organization must code the use of the core module in months 7-12 as a core maintenance session. Sessions must focus on topics that reinforce and build on the content delivered during the first 6 months of the lifestyle change program.

Lifestyle Coaches will select topics from either curriculum below based on participants' needs and interests. Lifestyle Coaches must select from the following topics, and may choose the order in which they are presented.

2012 National DPP Curriculum	**Prevent T2 Curriculum**
Welcome to Sessions 7-12	N/A
Balance Your Thoughts for Long-Term Maintenance	When Weight Loss Stalls
Staying on Top of Physical Activity	Take a Fitness Break
Stepping up to Physical Activity	Stay Active Away from Home
A Closer Look at Type 2 Diabetes	More About T2
More Volume, Fewer Calories	More About Carbs
Fats - Saturated, Unsaturated, and Trans Fat	Can repeat Eat Well to Prevent T2 from months 1-6
Healthy Eating - Taking it One Meal at a Time & Food Preparation and Recipe Modification	Have Healthy Food You Enjoy
Stress and Time Management	Get Enough Sleep
Preventing Relapse	Get Back on Track
Handling Holidays, Vacations, and Special Events	Can repeat Eat Well Away from Home from months 1-6
Heart Health	Stay Active to Prevent T2
Healthy Eating with Variety and Balance	Can repeat Shop and Cook to Prevent T2 from months 1-6
Looking Back and Looking Forward	Prevent T2—for Life!

Medicare DPP suppliers and ongoing maintenance sessions. Organizations that are Medicare DPP suppliers may repeat any curriculum topic from months 1-6 or months 7-12, with the exception

of the introductory session, for use in ongoing maintenance sessions. See the Data Submissions section for details on how to code these sessions.

Use of an alternate curriculum. If an organization chooses to use an alternate curriculum (a curriculum not previously approved or developed by CDC), it must send the curriculum to CDC to be reviewed for consistency with the evidence-based curriculum topics listed above. An organization can submit a culturally adapted curriculum in English to CDC for review before translating it into an appropriate language. An organization must submit all final versions (in English) to CDC for final evaluation and feedback. CDC review of alternate curricula takes approximately 4-6 weeks.

Changes made to a current curriculum. If an organization chooses to change its curriculum to another CDC-approved curriculum, an e-mail notification to CDC at DPRPAsk@cdc.gov is required, and no further steps are needed. If an organization chooses to develop its own curriculum during its tenure in the DPRP, it must notify CDC of the new curriculum at DPRPAsk@cdc.gov. CDC will explain next steps for submission and review of the new curriculum. If an organization chooses to change its curriculum to one that is culturally adapted for a specific population, or translated into another language, or to make other changes to its currently approved curriculum, it must notify CDC at DPRPAsk@cdc.gov. CDC will explain next steps for submission and review of the adapted or translated curriculum. Four to 6 weeks should be allowed for review and approval of new or changed curricula.

H. Requirements for Pending, Preliminary, and Full Recognition

The DPRP awards three categories of recognition: pending, preliminary, and full recognition. Organizations are required to submit data every 6 months regardless of recognition status achieved.

Pending Recognition

To begin the process, an organization must submit an application to the DPRP. When the DPRP determines that the organization has met requirements 1-4 in **Table 3**, the DPRP will assign an approval date and award pending recognition. Concurrent with the initial approval date, the organization will also be assigned an effective date. The effective date is the first day of the month following the approval date and is used to determine due dates for required data submissions. An organization may begin offering classes immediately upon approval and is required to start offering classes no later than 6 months after its effective date.

An organization with pending recognition is required to make its first data submission 6 months after its effective date. An organization may remain in pending status for up to 36 months if it continues to submit the required data every 6 months. The 36 month limitation applies regardless of which version of the DPRP Standards was in effect at the time of application. If an organization has not obtained either preliminary or full recognition by that time, it will be withdrawn from the DPRP and will need to wait 6 months before reapplying. Note: In order to have a data submission every 6 months, an organization must start at least one class every 12 months, with no gaps (i.e., each new class must begin in the month the previous class started, if only holding one class per year).

Preliminary Recognition

Preliminary or full recognition is required to become a Medicare DPP supplier. Any organization that has Medicare DPP preliminary recognition will automatically move to CDC preliminary recognition on January 1, 2018. All other transitioning organizations will be evaluated for

preliminary recognition based on the criteria listed below.

Organizations will be evaluated for preliminary recognition only at the time of required data submissions. To be evaluated for preliminary recognition, organizations must have submitted a full 12 months of data on at least one completed cohort. A completed cohort is a set of participants that entered into a lifestyle change program that has a fixed first and last session and runs for 12 months. An organization can have multiple cohorts running at the same time.

Organizations will be awarded preliminary recognition when they meet the following criteria:

1. The requirements for pending recognition.

2. Have at least 5 eligible participants who attended their first session at least one year but not more than 18 months before the submission due date, who attended at least 3 sessions in the first 6 months, and whose time from first session attended to last session of the lifestyle change program was at least 9 months (a statistical package used by the DPRP calculates months lapsed; this is an automated process).

3. Among participants meeting the criteria for evaluation in #2, at least 60% attended at least 9 sessions in months 1-6, and at least 60% attended at least 3 sessions in months 7-12 (Requirement 5 in **Table 3**). Note: The attendance benchmark for months 7-12 is assessed only after a full 12 months has passed from the date of the first session.

PLEASE NOTE: The DPRP will only evaluate organizations for preliminary recognition at the time of their required data submissions. If a new organization wants to be eligible for an evaluation for preliminary recognition at its first 12-month data submission, it will need to begin offering classes immediately after approval of its application and before the effective date. This is the only way that the organization will have the full 12 months of data required for a preliminary recognition evaluation. Organizations that are not eligible for an evaluation for preliminary recognition at 12 months will need to wait until their next required data submission at 18 months.

Organizations may remain in preliminary recognition status for four consecutive 6-month data submission periods (i.e., two years), provided they continue to meet the requirements for preliminary recognition at the 12 month mark. The 24 month limit in preliminary recognition applies regardless of how many months the organization was in pending status. Organizations that either do not maintain preliminary recognition at 12 months or fail to achieve full recognition at 24 months will lose recognition and will need to wait 6 months before reapplying. Loss of preliminary recognition will preclude an organization from participation as a Medicare DPP supplier until preliminary recognition is reachieved.

Full Recognition

Full recognition is required to remain a Medicare DPP supplier after the 24 months of preliminary recognition expires.

Organizations will be evaluated for full recognition only at the time of required data submissions. To be evaluated for full recognition, organizations must have submitted a full 12 months of data on at least one completed cohort.

Organizations will be awarded full recognition when they meet the following criteria:

1. The requirements for pending recognition.

2. Have at least 5 eligible participants who attended their first session at least one year but not more than 18 months before the submission due date, who attended at least 3 sessions in the first 6 months, and whose time from first session attended to last session of the lifestyle change program was at least 9 months (a statistical package used by the DPRP calculates months lapsed; this is an automated process).

3. Among participants meeting the criteria for evaluation in #2, the requirement for preliminary recognition.

4. Among participants meeting the criteria for evaluation in #2, requirements 6-9 in **Table 3**.

Organizations may remain in full recognition status for four consecutive 6-month data submission periods (i.e., two years). If organizations do not continue to meet full recognition at 24 months, but do meet the requirements for preliminary recognition, they can remain in full recognition status on a Corrective Action Plan for an additional 12 months. Organizations that do not re-achieve full recognition requirements at the 36 month mark will lose recognition and will need to wait 6 months before reapplying. Loss of full recognition will preclude an organization from participation as a Medicare DPP supplier until preliminary recognition is reachieved.

PLEASE NOTE: Organizations can voluntarily withdraw at any point in their timeline, but regardless of circumstances of the withdrawal, they must wait 6 months prior to reapplying.

Data Submissions

There must be at least one session record per participant in the organization's submission at 6 months post effective date and at least 6 months of participant data in the organization's submission at 12 months post effective date. This will allow for timely data analysis and provide opportunities for the organization to receive interim feedback on its progress in meeting recognition requirements.

Data may be submitted at any time during the month of the effective date. Data submissions should include data for all participant cohorts held during the data collection period. Organizations failing to submit complete and acceptable data in the month in which it is due or failing to report attendance in a 6-month period will lose recognition and must wait 6 months before reapplying. The DPRP will offer technical assistance to all organizations to help assess their progress toward achieving preliminary or full recognition.

If, after the first evaluation where an organization has at least one complete 12-month cohort, the organization has not achieved all of the requirements for preliminary or full recognition, it will continue in pending recognition status for an additional 6 months. During this period, the DPRP will offer technical assistance to the organization to help it achieve preliminary or full recognition. The DPRP will conduct evaluations for preliminary and full recognition every 6 months when data are submitted. These evaluations will be based on data from participants who attended their first session at least one year but not more than 18 months before the submission due date. If the organization is not successful in achieving preliminary or full recognition by the 36 month evaluation, it will lose pending recognition and must wait 6 months before reapplying.
The Description of the Data Submission and Evaluation Timeline, with Examples section summarizes the data submission and evaluation plan described above and provides examples.

Requirements for Pending, Preliminary, and Full Recognition Status

1. **Application for recognition.** Submit completed application at https://nccd.cdc.gov/DDT_DPRP/applicationForm.aspx.

2. **Lifestyle curriculum.** The lifestyle change program must be based on evidence from efficacy and effectiveness trials on type 2 diabetes prevention. The required curriculum topics can be found in the Required Curriculum Content section of this document and the CDC-approved curricula at http://www.cdc.gov/diabetes/prevention/recognition/curriculum.htm.
   If the organization chooses to use an alternate curriculum, it must submit it to the DPRP for review to ensure that it meets all of the key elements of the curriculum used in the DPP research trial.

3. **Intervention duration.** The lifestyle change program must have a duration of one year. If organizations choose to continue the intervention for a period longer than one year, only the first 365 days of data from each participant will be analyzed to determine recognition.

4. **Intervention intensity.** The lifestyle change program must begin with an initial 6-month phase during which a minimum of 16 weekly sessions are offered over a period lasting at least 16 weeks and not more than 26 weeks. Each session must be of a sufficient duration to convey the session content (approximately one hour).

   The initial 6-month phase must be followed by a second 6-month phase consisting of at least one session delivered each month (for a minimum of 6 sessions). Organizations wishing to deliver additional sessions (going beyond the minimum requirement of one session each month) are encouraged to do so, as this may be beneficial to participants needing additional support. Each session must be of a sufficient duration to convey the session content (approximately one hour).

   There must be regular opportunities for direct, individual, or group interaction between the Lifestyle Coach and the participants either in-person, online, by phone, or through a combination of these. For sessions delivered in-person, participants should be provided a private opportunity for measurement of body weight. Either participants or Lifestyle Coaches may take body weight measurements. However, only Coaches or other trained on-site facilitators may officially record weights and other evaluation data elements used to determine recognition status (described below in requirements 5-9). For sessions delivered online, weights may be either objectively obtained through the use of digital or Bluetooth-enabled scales or by self-report and must be reported during each session. For online Medicare DPP participants, weights can only be obtained through Bluetooth-enabled scales. For guidance on measuring weights, see the DPRP Recommended Procedures for Measuring Weight section of this document.

   If participants miss a session during any phase of the intervention, organizations may offer a make-up session. This make-up session can be held either on a day other than a regular class session day or, for the convenience of the participant, on the same day as a regular class session. Only one make-up session per participant can be held per week. Weight recorded at a make-up session should reflect the weight of the participant on the date the make-up session is attended. Physical activity minutes recorded at a make-up session should reflect the number of physical activity minutes logged by participants for the week preceding the missed session.

5. **Session attendance during months 1-6 and 7-12 (requirement for preliminary and full recognition)**

   Months 1-6: Session attendance in months 1-6 will be considered for participants who attended at least 3 sessions in months 1-6 and whose time from first session to last session is at least 9 months.

   Months 7-12: Session attendance in months 7-12 will be considered for participants who attended at least 3 sessions in months 1-6 and whose time from first session to last session is at least 9 months.

   At least 5 participants per submission who meet the above criteria are required for evaluation. (See requirement 5 in **Table 3.**)

   A yearlong cohort must have at least 60% of its participants attending at least 9 sessions during months 1-6 and at least 60% of its participants attending at least 3 sessions in months 7-12. Note: The attendance benchmark for months 7-12 is assessed only once a full 12 months has passed from the date of the first session.

6. **Documentation of body weight (requirement for full recognition)**

   A yearlong cohort of participants must have body weight documented during at least 80% of the sessions. Evaluation for this requirement is based on all participants attending at least 3 sessions during months 1-6 and whose time from first session to last session is at least 9 months. At least 5 participants per submission who meet this criterion are required for evaluation.

   The DPRP recommended procedures for measuring weights are included in the section titled DPRP Recommended Procedures for Measuring Weight.

7. **Documentation of physical activity minutes (requirement for full recognition)**

   A yearlong cohort of participants must have physical activity (PA) minutes documented during at least 60% of the sessions. Evaluation for this requirement is based on all participants attending at least 3 sessions during months 1-6 and whose time from first session to last session is at least 9 months. At least 5 participants per submission who meet this criterion are required for evaluation. Zero (0) minutes reported will not count as documented PA minutes. It is unlikely that participants are not completing any PA minutes, since the curriculum indicates that even simple activities such as house cleaning and gardening can count as PA minutes.

8. **Weight loss achieved at 12 months (requirement for full recognition)**

   The average weight loss across all participants in the yearlong cohort must be a minimum of 5% of starting body weight. The first and last weights recorded for each participant during months 1-12 will be used to calculate this measure. Evaluation for this requirement is based on all participants attending at least 3 sessions during months 1-6 and whose time from first session to last session is at least 9 months. At least 5 participants per submission

who meet this criterion are required for evaluation. Note: While CDC is only analyzing average weight loss at 12 months, individual payers, including Medicare, may require more frequent individual weight loss reporting for reimbursement purposes.

9. **Program eligibility requirement (requirement for full recognition)**

A minimum of 35% of all participants in a yearlong cohort must be eligible for the lifestyle change program based on either a blood test indicating prediabetes or a history of GDM. The remainder (a maximum of 65% of participants) must be eligible based on the CDC Prediabetes Screening Test or the American Diabetes Association (ADA) Type 2 Diabetes Risk Test. If a participant comes into a program on the basis of a risk test score, organizations are permitted to make a one-time change to the participant's eligibility status based on a post-enrollment blood test. Evaluation for this requirement is based on all participants attending at least 3 sessions during months 1-6 and whose time from first session to last session is at least 9 months. At least 5 participants per submission who meet this criterion are required for evaluation. If a recognized organization is also a Medicare DPP supplier, all Medicare participants must be eligible based solely on a blood test indicating prediabetes. Refer to the Participant Eligibility section for more information. Note: While CDC is setting an organizational requirement for eligibility, individual payers, including Medicare, may impose higher or lower participant level eligibility requirements for blood testing for reimbursement purposes.

Table 3. Summarizes the requirements for recognition. An example of how CDC's DPRP evaluates organizational performance is included in the Example of Using Data for Evaluation section of this document. The DPRP will calculate all performance indicators for organizations seeking recognition.

Table 3. Requirements for Recognition

	Standard	Requirement	How Evaluated	When Evaluated	Recognition Status
1	Application for recognition	Must provide the organization's identifying information to the DPRP	- Name of organization - Address - Contact persons	Upon receipt of application	Pending
2	Lifestyle curriculum	Must meet requirements for curriculum content described in the Required Curriculum Content section	- Check box on application form agreeing to use the recommended curriculum —*or*— - Provide alternate curriculum to the DPRP for approval	Upon receipt of application	Pending
3	Intervention duration	1 year duration	Curriculum review	Upon receipt of application	Pending

4	Intervention intensity	Minimum of 16 sessions delivered approximately once per week during months 1-6, followed by a minimum of 6 sessions delivered approximately once per month during months 7-12	Curriculum review	Upon receipt of application	Pending
5	Session attendance during months 1-6 and 7-12	At least 60% of participants attending at least 9 sessions during months 1-6 and at least 60% of participants attending at least 3 sessions in months 7-12.	Session attendance in months 1-6 will be considered for participants who attended at least 3 sessions in months 1-6 and whose time from first session to last session is at least 9 months. Session attendance in months 7-12 will be considered for participants who attended at least 3 sessions in months 1-6 and whose time from first session to last session is at least 9 months. At least 5 participants per submission who meet these criteria are required for evaluation.	Every 6 months beginning at 12 or 18 months from the effective date, depending on when an organization starts delivering classes	Preliminary and Full
6	Documentation of body weight	Body weights are recorded at a minimum of 80% of the sessions attended	A yearlong cohort of participants must have body weight documented during at least 80% of the sessions. Includes all participants attending at least 3 sessions during months 1-6 and whose time from first session to last session is at least 9 months. At least 5 participants per submission who meet these criteria are required for evaluation.	Every 6 months beginning at 12 or 18 months from the effective date, depending on when an organization starts delivering classes	Full
7	Documentation of physical activity minutes	Physical activity minutes are recorded at a minimum of 60% of all sessions attended	A yearlong cohort of participants must have physical activity minutes documented during at least 60% of the sessions. Includes all participants attending at least 3 sessions during months 1-6 and whose time from first session to last session is at least 9 months. At least 5 participants per submission who meet these criteria are required for evaluation. Zero (0) minutes reported will not count as documented physical activity minutes.	Every 6 months beginning at 12 or 18 months from the effective date, depending on when an organization starts delivering classes	Full

8	Weight loss achieved at 12 months	Average weight loss achieved over the entire 12-month intervention period must be a minimum of 5% of starting body weight	The average weight loss across all participants in the yearlong cohort must be a minimum of 5% of starting body weight. The first and last weights recorded for each participant during months 1-12 will be used to calculate this measure. Includes all participants attending at least 3 sessions during months 1-6 and whose time from first session to last session is at least 9 months. At least 5 participants per submission who meet these criteria are required for evaluation.	Every 6 months beginning at 12 or 18 months from the effective date, depending on when an organization starts delivering classes	Full
9	Program eligibility requirement	Minimum of 35% of participants must be eligible for the yearlong lifestyle change program based on either a blood test indicating prediabetes or a history of GDM. The remainder (maximum of 65% of participants) must be eligible based on the CDC Prediabetes Screening Test or the ADA Type 2 Diabetes Risk Test.	The last entry for eligibility is used in determining this outcome. Includes all participants attending at least 3 sessions during months 1-6 and whose time from first session to last session is at least 9 months. At least 5 participants per submission who meet these criteria are required for evaluation. **For CDC-recognized organizations that are also Medicare DPP suppliers:** All Medicare participants in the yearlong cohort must be eligible based on a blood test indicating prediabetes.	Every 6 months beginning at 12 or 18 months from the effective date, depending on when an organization starts delivering classes	Full

III. Applying for Recognition

CDC welcomes organizations that offer a yearlong lifestyle change program to prevent or delay type 2 diabetes to apply for recognition through the DPRP. Any organization with the capacity to deliver a lifestyle change program meeting DPRP Standards may apply for recognition.

Before an organization applies, leadership and staff should read the *Diabetes Prevention Recognition Program Standards and Operating Procedures* contained in this document, which describes the criteria for delivering lifestyle change programs that achieve and sustain CDC recognition. The DPRP Standards also contains a capacity assessment. This is a list of questions designed to help an organization determine its readiness to deliver a CDC-recognized lifestyle change program (see section titled Organizational Capacity Assessment). All organizations are strongly encouraged to complete this assessment.

An organization must be ready to start classes immediately or within 6 months after its effective date (the first day of the month immediately following CDC approval of its application). If an organization is not ready to start classes within 6 months, it should postpone submitting an application.

To apply for recognition, an organization should complete the online application at https://www.cdc.gov/diabetes/prevention/lifestyle-program/apply_recognition.html. The organization must indicate whether it will be using a CDC-approved curriculum, such as the PreventT2 curriculum (https://www.cdc.gov/diabetes/prevention/lifestyle-program/curriculum.html), or submitting an alternate curriculum for review. After submitting the application form, the organization will receive a confirmation email. Organizations using a CDC-approved curriculum will normally be notified of the results of the CDC review within 15 working days. Organizations submitting an alternate curriculum for review will normally be notified of the results of the CDC review within 4-6 weeks.

Any organization in the DPRP and assigned a DPRP organization code that contracts with another CDC-recognized organization to deliver their lifestyle change program must ensure that the contracted organization uses a CDC-approved curriculum and follows the requirements set forth herein. Upon approval, DPRP staff will inform the organization of its effective date.

Each organization will be required to complete the following elements in the online application form:

1. **Type of Application.** Select *Initial* if this is the first application being submitted. Select *Reapplying* if this is a subsequent application due to previous withdrawal or loss of recognition.

2. **Organization Code**. This code is assigned by the DPRP. Choose *Not applicable* if this is an initial application. For re-applicants, enter the previously assigned organization code. Organization codes will be published in the DPRP registry corresponding to the organization name on the CDC website here: https://nccd.cdc.gov/DDT_DPRP/Registry.aspx.

3. **Organization Name.** Upon application approval, the organization name will be published in the DPRP registry on the CDC website.

4. **Delivery Mode.** An applicant organization can select one delivery mode per each application submitted (either in-person only, online only, distance learning, or combination). Delivery modes will be published in the DPRP registry on the CDC website. For definitions, see the Standards and Requirements for Recognition, Delivery Mode section.

5. **Class Type.** Select all applicable class types offered: **public** (open to anyone who qualifies for the lifestyle change program without further restrictions), **employee** (open only to employees of the organization or the host organization), **member-only** (open only to member insureds; membership required) or **other** (write in target audience served such as American Indians/Alaskan Natives, patients, clients, etc.). Organizations offering classes to the public should provide the physical addresses of the classes, or online link to class offerings, to DPRPApply@cdc.gov. Upon application approval, the class type as well as public class locations will be published in the DPRP registry on the CDC website. If public classes are added, deleted, or changed, organizations should email updated public class location addresses at least every 6 months to DPRPAsk@cdc.gov.

6. **Organization Physical Address.** Provide the main organization's business office or headquarters address. Upon application approval, this will be published in the DPRP registry and on the CDC website.

7. **Organization Mailing Address.** Include if different from the Organization Physical Address. DPRP staff will use this address to communicate by mail with the organization (i.e., mailing the certificate of achievement of full recognition if/when achieved).

8. **Organization Web Address or URL.** Optional. Upon application approval, this will be published in the DPRP registry and on the CDC website. All web addresses must link directly to a location where participants can find information about the organization's CDC-recognized lifestyle change program and enroll in the program. CDC will not accept or host any other web addresses.

9. **Organization Phone Number.** Provide the number that participants, payers, and others should call to obtain information about the program. Organizations should not provide a 1-800 number unless a live operator is available. Upon application approval, this will be published in the DPRP registry on the CDC website.

10. **Organization Type**. Choose the option that best describes the organization type. This refers to an organization's main headquarters location or main office: Local or community YMCAs; Universities/Schools; State/Local Health Departments; Hospitals/Healthcare Systems/Medical Groups/Physician Practices; Community-Based Organizations/Community Health Centers/Federally Qualified Health Centers; Pharmacies/Drug Stores/Compounding Pharmacies; Indian Health Service/Tribal/Urban Indian Health Systems; Business Coalitions on Health/Cooperative Extension Sites; Worksites/Employee Wellness Programs; Senior/Aging/Elder Centers; Health Plans/Insurers; Faith-Based Organizations/Churches; For-profit Private Businesses; Other (please specify).

11. **Program Coordinator Name.** Provide the name of the individual who will be the applicant organization's Program Coordinator. Provide a salutation [e.g., Mr., Mrs., Dr., Ms., Miss, other (please specify)], last name, first name, middle initial, and academic credentials, if applicable [e.g., MD, RN, MPH, MPA, PhD, other (please specify)]. The Program Coordinator's information will not be included in the DPRP registry.

12. **Program Coordinator Contact Information.** Provide an email address, phone number, and fax number (if applicable) of the organization's Program Coordinator. DPRP staff will use this information to communicate with the organization. All DPRP-related documents, reports, and emails will go to the Program Coordinator.

13. **Secondary Contact Name.** Provide the name of the individual who will be the applicant organization's Secondary Contact, if applicable. This person would be contacted in the event an organization's Program Coordinator cannot be reached for routine communication. Provide a salutation [e.g., Mr., Mrs., Dr., Ms., Miss, other (please specify)], last name, first name, middle initial, and academic credentials, if applicable [e.g., MD, RN, MPH, MPA, PhD, other (please specify)]. The Secondary Contact's information will not be included in the DPRP registry.

14. **Secondary Contact Information.** Provide the email address, phone number, and fax number of the organization's Secondary Contact, if applicable. DPRP staff will use this information to communicate with the organization in the event an organization's Program Coordinator cannot be reached for routine communication, including data-related communication.

15. **Lifestyle Coach Training Entity.** Provide the name of the training entity the applicant organization will use or has used to train their main Lifestyle Coaches. Choose from 1) a training entity that has an MOU with CDC and is listed on the CDC website (found here: https://www.cdc.gov/diabetes/prevention/lifestyle program/staffing training.html), 2) a private organization with a national network of program sites, 3) a CDC-recognized virtual organization with national reach, or 4) a Master Trainer (has completed at least 12 hours of formal training as a Lifestyle Coach, has successfully offered the National DPP lifestyle change program for at least one year, and has completed a Master Trainer program offered by a training entity listed on the CDC website).

16. **Data Preparer Name.** Provide the name of the individual who will be the organization's Data Preparer. This can be either the Program Coordinator or the Lifestyle Coach if a third person is not designated at this time. Provide a salutation [(e.g., Mr., Mrs., Dr., Ms., Miss, other (please specify)], last name, first name, middle initial, and academic credentials, if applicable [(e.g., MD, RN, MPH, MPA, PhD, other (please specify)]. The Data Preparer's contact information will not be included in the DPRP registry.

17. **Data Preparer Contact Information.** Provide the email address, phone number, and fax number of the organization's Data Preparer. (This can be either the Program Coordinator or Lifestyle Coach if a third person is not designated at this time.) DPRP staff will use this information to communicate with the organization about data submission issues, if required.

18. **Curriculum.** Select either a CDC-approved curriculum (one that CDC has either developed or previously approved for use by your organization) or 'Other Curriculum' if the applicant organization is submitting an alternate curriculum for review and approval. If selecting Other Curriculum, provide the completed yearlong curriculum with any supplemental materials, handouts, or web-based content together with the application.

Certification of Application:

Electronic signature. Submitting the application asserts that the organization has thoroughly reviewed the *CDC Diabetes Prevention Recognition Program Standards and Operating Procedures* and is voluntarily seeking participation in the CDC recognition program. The organization agrees to comply with all of the recognition criteria contained in *DPRP Standards*, including the transmission of data to CDC every 6 months from the CDC-assigned effective date, for the purpose of program evaluation, continuing recognition, and technical assistance. (Enter name of authorized representative, title of authorized representative, organization name, and date.)

Once an organization's application has been reviewed and approved, the DPRP will send an email to the organization's Program Coordinator indicating that the organization has been awarded pending recognition. This email will include the unique organization code assigned by the DPRP, the organization's effective date (which determines the date the organization's evaluation data is due to the DPRP) and instructions for data submission. At the same time, the organization

will be listed in the DPRP Registry on the CDC website. This entire process takes approximately 15 days.

If an organization submits an alternate curriculum for review and approval by CDC, an initial email indicating receipt will be sent. Organizations should allow 4-6 weeks for review and approval of the application and assignment of an organization code. If an alternate curriculum is not approved by CDC, the application will not be approved. CDC will delineate the reasons why a curriculum is not approved in writing and allow the organization an opportunity to correct any issues and reapply for recognition once the curriculum is amended. Any questions about an organization's application or the DPRP should be directed to DPRPAsk@cdc.gov.

IV. Submitting Evaluation Data to the DPRP

Each CDC-recognized organization (with pending, preliminary, or full recognition) must submit evaluation data to the DPRP every 6 months. This requirement begins 6 months from the organization's effective date. Four weeks prior to an organization's first data submission due date, the DPRP will send an email reminder to the organization's Program Coordinator and other contacts. A second data submission reminder (if necessary) will be sent to the organization's Program Coordinator and other contacts, as a courtesy, approximately 2 weeks after the data submission due date. If, after this second reminder, the DPRP still does not receive the first evaluation data submission within an additional 4 weeks, the organization will lose recognition and will be removed from the DPRP Registry.

Each data submission must include one record per participant for each session attended during the preceding 6 months. The first data submission must also include records for any sessions attended between the application approval date and the effective date. Subsequent data submissions should not include participant data previously submitted.

All of the data elements listed below must be transmitted to the DPRP. Data must be transmitted as a data file using the comma separated value (CSV) format, which is compatible with the majority of statistical, spreadsheet, and database applications. A CSV template file is provided by CDC. Each row in the data file should represent one session date attended by one participant (i.e., participant will have a new row for each session date). If a participant is absent from a session, no record should be submitted for that participant for that session. Each column in the data file should represent one field containing specific data for the evaluation data elements listed below. There should be no empty fields and no empty cells. When a data value is unknown, the default value should be entered.

Transmitted data must conform to the specifications in the data dictionary included below. The variable names, codes, and values contained in the data dictionary (**Table 4.**) must be used. Do not make any changes in the spelling. Variables (columns) in the data submission file should have the same names (column headings) and appear in the same order as in the data dictionary. Organizations should take time to become familiar with all of the data elements and specifications.

No personally identifiable information (PII) from Lifestyle Coaches or participants should be transmitted to the DPRP. All identifiers (except the orgcode, which is provided by CDC) will be assigned and maintained by the organization according to the specifications outlined in the data

dictionary.

Evaluation Data Elements (Numbers correspond with Table 4. Data Dictionary: Evaluation Data Elements)

1) **Organization Code.** Will be assigned by the DPRP when the organization's application is approved. Each applicant will have a unique organization code. This code must be included by the applicant organization on all data records submitted.

2) **Participant ID.** Will be assigned by the organization to uniquely identify and track participants across sessions. The participant ID must be included on all session attendance records generated for an individual participant. The participant ID should not be based on social security number or other PII. If a participant re-enrolls in a new class, the organization should assign this participant a new participant ID.

3) **Enrollment Source.** Will identify the source (person, place, or thing) which led the participant to enroll in the yearlong program (see data dictionary for the appropriate code).

4) **Payer Type.** Will identify one, main payment method that participants are using to pay for their participation in the yearlong program (see data dictionary for the appropriate code).

5) **Participant State.** The state in which a participant resides should be recorded at enrollment and included on all session attendance records generated for that participant. The two-letter postal abbreviation for the U.S. state or territory should be used. Organizations choosing to deliver the lifestyle program to U.S. citizen participants residing outside of the U.S. or its territories should default to the participant's U.S. resident state or U.S. Army Post Office (APO) address state.

6- 8) **Participant's Prediabetes Determination.** Should be recorded at enrollment and included on all session attendance records generated for an individual participant. This indicates whether a participant's prediabetes status was determined by a blood test, a previous diagnosis of GDM, or by screening positive on the CDC Prediabetes Screening Test (see guidance titled CDC Prediabetes Screening Test) or the ADA Type 2 Diabetes Risk Test. Multiple responses are allowed and may be added. For example, if a participant was originally enrolled on the basis of a risk test and then subsequently received a blood test indicating prediabetes, the risk test value remains the same, and the blood test value is changed to a positive.

9) **Participant's Age.** Should be recorded at enrollment and the recorded age used throughout all records regardless of a birthday occurring during the yearlong program. If the participant's age is incorrectly recorded at enrollment (or at the first session), then the age should be corrected on all records. If an organization's recordkeeping system automatically adjusts the age on a participant's birthday, then the two recordings of age are okay.

10) **Participant's Ethnicity.** Should be recorded at enrollment and included on all session attendance records generated for an individual participant. The participant should self-identify and have the opportunity to choose one of the following: Hispanic/Latino, Not Hispanic/ Latino, or not reported.

11–15) **Participant's Race.** Should be recorded at enrollment and included on all session attendance records generated for an individual participant. The participant should self-identify and have the opportunity to choose one or more of the following: American Indian or Alaska Native, Asian or Asian American, Black or African American, Native Hawaiian or Other

Pacific Islander, and White. Multiple responses are allowed. This element requires responses for five fields, and each field includes a response for not reported (refer to Table 2, the data dictionary).

16) **Participant's Sex.** Should be recorded at enrollment and included on all session attendance records generated for an individual participant. The data record should indicate male, female, or not reported.

17) **Participant's Height.** Should be recorded at enrollment and included on all session attendance records generated for an individual participant. Height may be self-reported (i.e., it is not necessary to measure the participant's height; the participant may simply be asked, "What is your height?" or "How tall are you?"). The participant's height should be recorded to the nearest whole inch.

18) **Education.** Will identify the highest grade or year of school the participant completed. This information should be recorded at enrollment and included on all session attendance records generated for an individual participant.

19) **Delivery Mode.** Will identify the delivery mode, as defined in the Applying for Recognition section, for this specific participant and session (i.e., in-person, online, distance learning).Please note that since this is a session level variable, combination mode does not apply.

20) **Session ID.** Will identify weekly sessions offered throughout the yearlong program. Session IDs in months 1-6 could be numbered 1 through 26 depending on the frequency of weekly offerings. Session IDs in months 7-12 will all be numbered as 99, and sessions in ongoing maintenance months (for Medicare DPP supplier organizations or other organizations that choose to offer ongoing maintenance sessions) will all be numbered as 88. If a 7-12 month curriculum module (such as one from PreventT2) is used in months 1-6, it should be coded as 1 through 26, since it is being delivered during that timeframe. If a 1-6 month curriculum module is used in months 7-12, it should be coded as 99, since it is being delivered during that timeframe.

21) **Session Type.** Will identify the session attended within months 1-6 (scheduled core sessions) as "C", core maintenance sessions attended within months 7-12 as "CM", or ongoing maintenance sessions as "OM" in the second year (post-yearlong lifestyle change program) for Medicare DPP suppliers or other organizations that choose to offer ongoing maintenance sessions. Medicare DPP suppliers must collect and report data for ongoing maintenance sessions in the same way they do for core and core maintenance sessions, including recording participant weights. CDC will collect these data for Medicare to assist with their continued implementation and assessment of the Medicare DPP expanded model.

    Make-up sessions will be identified as "MU" and should be used with the corresponding Session ID that was previously missed by the participant (i.e., the session they are making up). If a 7-12 month curriculum module (such as one from PreventT2) is used in months 1-6, it should be coded as a "C", since it is being utilized as a core session. If a 1-6 month curriculum module is used in months 7-12, it should be coded as a "CM", since it is being utilized as a core maintenance session.

22) **Session Date.** Each time a participant attends a session, the actual date of the session should be recorded. The date should be recorded in mm/dd/yyyy format. A participant should not

have more than one record (line of data) for any specific session date, with the exception of make-up sessions. One make-up session per week may be held on the same date as a regularly scheduled session for the convenience of the participant. For online sessions, organizations should record the date each session is completed.

23) **Participant's Weight.** Each time a participant attends a session, his or her body weight should be measured and recorded to the nearest whole pound. The weight should be included on the record for that participant and session. For online programs, organizations should record the weight associated with the session completion date.

24) **Participant's Physical Activity Minutes.** Once physical activity monitoring has begun in the curriculum, participants will be asked to report the number of minutes of moderate or brisk physical activity completed during the preceding week. This information should be included on the record for that participant and session. If a participant reports doing no activity during the preceding week, then zero (0) minutes should be recorded. Note: Zero (0) minutes reported will not count as documented physical activity minutes.

Table 4. Data Dictionary: Evaluation Data Elements

Data element description	**Variable name**	**Coding/valid values**	**Comments**
1. Organization Code	ORGCODE	Up to 25 alphanumeric characters*	Required, provided by DPRP
2. Participant ID	PARTICIP	Up to 25 alphanumeric characters*	Required. Participant ID is uniquely assigned and maintained by the applicant organization and must not contain any PII.

3. Enrollment Source	ENROLL	1 Non-primary care health professional (e.g., pharmacist, dietitian) 2 Primary care provider/office or specialist (e.g., MD, DO, PA, NP, or other staff at the provider's office) 3 Community-based organization or community health worker. 4 Self (decided to come on own) 5 Family/friends 6 An employer or employer's wellness program 7 Insurance company 8 Media (radio, newspaper, billboard, poster/flyer, etc.), national media (TV, Internet ad), and social media (Twitter, Facebook, etc.) 9 Other 10 Not reported	Required. At enrollment, participants are asked by whom they were referred to this lifestyle change program. If a participant's referral source is not provided, this variable will be coded as '9'.
4. Payer Type	PAYER	1 Medicare 2 Medicaid 3 Private Insurer 4 Self-pay 5 Dual Eligible (Medicare and Medicaid) 6 Grant funding 7 Employer 8 Other 9 Not reported	Required. At enrollment, participants are asked "Who is the primary payer for your participation in this lifestyle change program?" If a participant's payer source is not provided, this variable will be coded as '9'.
5. Participant State	STATE	Two-letter abbreviation for the U.S. state or territory in which the participant resides	Required
6. Participant's Prediabetes Determination (1 of 3)	GLUCTEST	1 Prediabetes diagnosed by blood glucose test 2 Prediabetes NOT diagnosed by blood glucose test (default)	Required; acceptable tests include FG, oral glucose tolerance test (OGTT), A1c, or claim code indicating diagnosis of prediabetes.

7. Participant's Prediabetes Determination (2 of 3)	GDM	1 Prediabetes determined by clinical diagnosis of GDM during previous pregnancy 2 Prediabetes NOT determined by GDM (default)	Required
8. Participant's Prediabetes Determination (3 of 3)	RISKTEST	1 Prediabetes determined by risk test 2 Prediabetes NOT determined by risk test (default)	Required
9. Participant's Age	AGE	18 to 125 (in years, rounded with no decimals)	Required
10. Participant's Ethnicity	ETHNIC	1 Hispanic or Latino 2 NOT Hispanic or Latino 9 Not reported (default)	Required; if ethnicity is not reported by the participant, this variable will be coded as '9'.
11. Participant's Race (1 of 5)	AIAN	1 American Indian or Alaska Native 2 NOT American Indian or Alaska Native (default)	Required; if race is not reported by the participant, all of the 5 race variables will be coded as '2'.
12. Participant's Race (2 of 5)	ASIAN	1 Asian or Asian American 2 NOT Asian or Asian American (default)	Required; if race is not reported by the participant, all of the 5 race variables will be coded as '2'.
13. Participant's Race (3 of 5)	BLACK	1 Black or African American 2 NOT Black or African American (default)	Required; if race is not reported by the participant, all of the 5 race variables will be coded as '2'.
14. Participant's Race (4 of 5)	NHOPI	1 Native Hawaiian or Other Pacific Islander 2 NOT Native Hawaiian or Other Pacific Islander	Required; if race is not reported by the participant, all of the 5 race variables will be coded as '2'.
15. Participant's Race (5 of 5)	WHITE	1 White 2 NOT White (default)	Required; if race is not reported by the participant, all of the 5 race variables will be coded as '2'.
16. Participant's Sex	SEX	1 Male 2 Female 9 Not reported	Required
17. Participant's Height	HEIGHT	30 to 98 (in inches)	Required
18. Education	EDU	1 Less than grade 12 (No high school diploma or GED) 2 Grade 12 or GED (High school graduate) 3 College- 1 year to 3 years (Some college or technical school) 4 College- 4 years or more (College graduate) 9 Not reported (default)	Required
19. Delivery Mode	DMODE	1 In-person 2 Online 3 Distance learning	Required

20. Session ID	SESSID	1 to 26 Core or makeup session —or— 99 Core maintenance or makeup session —or— 88 Ongoing maintenance or makeup session (for Medicare DPP supplier organizations or other organizations that choose to offer ongoing maintenance sessions)	Required. Core sessions and any core make-up sessions should be numbered 1 through 26. The session ID should correspond to the specific session attended. Core maintenance and any core maintenance make-up sessions should all be coded as '99'. Ongoing maintenance and any ongoing maintenance make-up sessions should all be coded as '88'.
21. Session Type	SESSTYPE	C Core session CM Core maintenance session OM Ongoing maintenance sessions (for Medicare DPP supplier organizations or other organizations that choose to offer ongoing maintenance sessions) MU Make-up session	Required. Any session delivered in months 1-6, even if pulled from months 7-12 of the PreventT2 curriculum content, for example, must be coded as a Core session, C. Any session delivered in months 7-12, even if pulled from months 1-6 of curriculum content, must be coded as a Core Maintenance session, CM.
22. Session Date	DATE	mm/dd/yyyy	Required. Each data record represents attendance by one participant at one session; must specify actual date of the session. One make-up session per week may be recorded on the same session date as a regularly scheduled session.
23. Participant's Weight	WEIGHT	70 to 997 (in pounds) *—or—* 999 Not recorded (default)	Required. At each session, participants are weighed; weight must be included on the record for that session and participant. Weight may be obtained by the Lifestyle Coach or participant or a Bluetooth-enabled scale. For Medicare DPP suppliers, participants cannot self-report weight.

24. Participant's Physical Activity Minutes	PA	0 to 997 (in minutes) *—or—* 999 Not recorded (default)	Required. At some or all program sessions, participants are asked to report the number of minutes of brisk physical activity they completed in the preceding week. If the number of minutes is greater than or equal to 997, 997 should be used. If a participant reports doing no activity during the preceding week, then zero (0) minutes should be recorded. The default value of 999 should only be used until physical activity monitoring begins in the curriculum.

A1c: Hemoglobin A1c test; FG: fasting glucose test; GDM: Gestational Diabetes Mellitus; PII: personally identifiable information (directly or indirectly identifiable); OGTT: oral glucose tolerance test

*All alphanumeric coding values are case sensitive and should not include any spaces or special characters.

Questions about the evaluation data elements or their transmission should be addressed to DPRPAsk@cdc.gov.

V. Technical Assistance

Technical assistance is currently available to all recognized organizations through a variety of mechanisms.

1. Monthly informational webinars to review the standards and data submission requirements;
2. Additional webinars as needed;
3. Detailed progress and evaluation reports that include organization-specific summaries and recommendations provided with each report;
4. Technical assistance calls available to organizations as needed;
5. Direct access through DPRPAsk@cdc.gov to ask questions/seek clarification, request information, update contact information, or request a technical assistance call;
6. Downloadable tools and resources on CDC's National DPP website at http://www.cdc.gov/diabetes/prevention/lifestyle-program/resources/index.html;
7. Additional resources as available;
8. Customer Support Center.

VI. Quality Assurance Assessments

Quality assurance assessments and site visits will be conducted to assure that organizations are implementing quality programs aligned with the evidence-based standards, collecting and reporting data properly, and addressing all of the DPRP requirements for CDC-recognized organizations. Technical assistance will be provided as needed during the assessment process.

VII. National Registry of Organizations with CDC Recognition

A list of CDC-recognized organizations with pending, preliminary, and full recognition will be published on the CDC website at https://nccd.cdc.gov/DDT_DPRP/Registry.aspx. Other data fields

listed on the CDC website include: organization name, code, main address, state, zip code, phone number, public website (where available and provided to CDC), class type, and who can participate (e.g., public, members only, employees, etc.).

VIII. Guidance Documents

Appendix A. Organizational Capacity Assessment

Introduction

The CDC Diabetes Prevention Recognition Program (DPRP) is a voluntary program for organizations interested in establishing local evidence-based lifestyle change programs for people at high risk for type 2 diabetes. Organizations interested in applying to become a CDC-recognized diabetes prevention program are strongly advised to read the *CDC DPRP Standards and Operating Procedures* and complete this Capacity Assessment prior to applying for recognition.

Benefits of Completing the Capacity Assessment

Assessing your organization's capacity will identify areas that may need to be enhanced, prior to applying for CDC recognition, to ensure the organization is able to deliver the yearlong lifestyle change program with quality and fidelity to the evidence-based DPRP Standards and sustain the program long term. Sustainable lifestyle change programs are those that have the capacity to implement the lifestyle change program without federal, state, or local government or other non-governmental grant dollars long-term. In addition, it is necessary for the organization to have appropriate staff with the knowledge, skills, and abilities listed in the Guidelines for Staff Eligibility, Skills and Roles, and Sample Job Descriptions in the *CDC DPRP Standards and Operating Procedures* document.

Directions for Completing the Capacity Assessment

1. Refer to the *CDC DPRP Standards and Operating Procedures* document, available at https://www.cdc.gov/diabetes/prevention/lifestyle-program/apply_recognition.html, when completing this questionnaire.
2. DPRP Standards Reference - indicates the location of the relevant information in the *CDC DPRP Standards and Operating Procedures* document.
3. Organizational capacity assessment questions - read the question and check one box: "yes", "no", "unsure", or "Not Applicable (N/A)". The "N/A" might apply to online/virtual organizations.
4. Total the number of "yes", "no", "unsure", and "N/A" responses at the bottom of the questionnaire. If the total number of "no" and "unsure" responses outnumber the "yes" responses, then consider applying at a later date when your organization is ready.
5. For each Capacity Assessment topic with a "no" or "unsure" response, consider working with your organization's leadership to enhance your readiness before applying for recognition. Partnering with an existing CDC-recognized organization in your community or contacting CDC's DPRP for technical assistance through DPRPAsk@cdc.gov may be helpful.

Organizational Capacity Assessment for Applicant Organizations to the Centers for Disease Control and Prevention's (CDC's) Diabetes Prevention Recognition Program (DPRP)

Capacity Topic	DPRP Standards Reference	Organizational Capacity Assessment Questions	Yes	No	Unsure	N/A
DPRP Standards	CDC DPRP Standards and Operating Procedures- https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf	A. Have the following people from your organization read the CDC DPRP Standards and Operating Procedures (DPRP Standards)?				
		1. Leadership/management				
		2. Program Coordinator (if already hired)				
		3. Lifestyle Coach(es) (if already hired)				
Leadership and Staff Support		B. Do the following people from your organization support submission of this application for CDC recognition?				
		1. Leadership/management				
		2. Program Coordinator (if already hired)				
		3. Lifestyle Coach(es) (if already hired)				
Staff	Guidelines for Staff Eligibility, Skills and Roles, and Sample Job Descriptions	C. Does your organization have or plan to hire the following staff (at minimum) with the knowledge, skills, and abilities listed in Guidelines for Staff Eligibility, Skills and Roles, and Sample Job Descriptions of the DPRP Standards?				
		1. A Diabetes Prevention Coordinator responsible for submitting data to CDC and receiving all programmatic and data-related correspondence about the organization's recognition status				
		2. A Lifestyle Coach responsible for implementing the yearlong CDC-approved curriculum and providing support and guidance to participants in the program				
Staff Training		D. Does your organization have a plan for Program Coordinator(s) and Lifestyle Coach(es) to offer or attend the following?				

		1. A training on delivery of a CDC-approved curriculum that includes the required content listed within the DPRP Standards (If outside training is needed, please see a list of training entities that hold Memorandums of Understanding with CDC here: https://www.cdc.gov/diabetes/prevention/lifestyle-program/staffing-training.html.)				
		2. For organizations offering online only or combination programs, training on the specific technology platform to be used to deliver the online lifestyle change program				
		3. Training on computer skills necessary for data collection and interpretation of participants' outcomes to effectively monitor their progress toward meeting program goals				
		4. CDC-sponsored webinar trainings on specialized topics such as program delivery ("Welcome to the DPRP") and data submission ("Submit for Success")				
		5. Training to comply with federal, Health Insurance Portability and Accountability Act (HIPAA), state, and or local laws governing Personally Identifiable Information (PII), including laws related to data collection, storage, use, and disclosure (CDC does not permit the transmission of PII.)				
		6. Additional refresher training or training to develop new skills needed to effectively manage and deliver the yearlong lifestyle change program				
DPRP Evaluation Data Collection and Submission	Submitting Evaluation Data to the DPRP	E. Does your organization have staff with the knowledge, skills, and tools needed to collect, enter, and submit the required DPRP evaluation data elements using a comma separated value (CSV) format to the CDC DPRP every 6 months?				
		1. If you answered "Yes" to question E. above, has your organization designated a staff member who will be responsible for collecting, entering, and submitting the required DPRP evaluation data elements to CDC every 6 months?				

		2. If you answered "No" or "Unsure" to question E. above, does your organization have a plan for training a designated staff member who will be responsible for collecting, entering, and submitting the required DPRP evaluation data elements to CDC every 6 months?				
		3. If you answered "No" or "Unsure" to question E. above, does your organization have a plan to contract with an external organization (i.e., a third party data administrator) with the knowledge, skills, and tools needed to collect, enter, and submit the required DPRP evaluation data elements on behalf of your organization to the CDC DPRP every 6 months?				
Organization Infrastructure: in-person only	Location and Delivery Mode	F. For organizations offering in-person only programs:				
		1. Does your organization have any designated space in which to conduct the yearlong lifestyle change program?				
		2. Does your organization provide private settings in which participants can be weighed and monitored by a Lifestyle Coach?				
Organization Infrastructure: online only, distance learning, or combination programs	Location and Delivery Mode	G. For organizations offering online only, distance learning, or combination programs:				
		1. Does your organization have any designated space in which to conduct **the in-person portion** of your combination yearlong lifestyle change program?				
		2. Does your organization have an appropriate technology platform to deliver the online version of the yearlong lifestyle change program?				
		3. Does your organization have an appropriate technology platform to allow participants to interact with a Lifestyle Coach over the yearlong lifestyle change program?				
		4. Does your organization have the ability to obtain weights via digital technology such as Bluetooth-enabled scales?				

Eligible Participants	Participant Eligibility	H. Does your organization have access to a large number of individuals at high risk for type 2 diabetes that meet the eligibility requirements listed with the DPRP Standards?				
Recruitment and Enrollment	Participant Eligibility	l. a. Does your organization have the ability to recruit and enroll a sufficient number of eligible participants (i.e., via marketing and media outreach, partnership engagement, health fairs, etc.) to maintain an adequate number of classes over time? b. Does your organization have the capacity to offer at least one class every 12 months? c. Have you made connections with health care providers, insurers, or employee wellness programs to help ensure referrals to your program?				
Sustainability		J. Does your organization have a plan to sustain the yearlong lifestyle change program long-term without federal, state, or local government or other nongovernmental grant funds?				
Tools and Resources		K. Has your organization reviewed the following downloadable tools and resources on CDC's National Diabetes Prevention Program web site available at https://www.cdc.gov/diabetes/prevention/lifestyle-program/resources/index.html?				
		1. Resources for Recruiting Participants available at https://www.cdc.gov/diabetes/prevention/lifestyle-program/resources/participants.html				
		2. Resources for Health Care Professionals available at https://www.cdc.gov/diabetes/prevention/lifestyle-program/resources/professionals.html				
		3. Resources for Employers and Insurers available at https://www.cdc.gov/diabetes/prevention/lifestyle-program/resources/employers.html				
		4. Resources to Encourage Participant Retention available at https://www.cdc.gov/diabetes/prevention/lifestyle-program/resources/retention.html				
		5. Spread the Word available at https://www.cdc.gov/diabetes/prevention/lifestyle-program/resources/spreadtheword.html				
		Total number of boxes check for each				

Appendix B. CDC Prediabetes Screening Test

Prediabetes: You Could Be at Risk

Prediabetes means blood glucose (sugar) levels are higher than normal but not high enough to be diagnostic for type 2 diabetes. Diabetes is a serious disease that can cause heart attack, stroke, blindness, kidney failure, or loss of toes, feet, or legs. Type 2 diabetes can be delayed or prevented in people with prediabetes through effective lifestyle change programs. It is important for people to take the first step by identifying their risk for type 2 diabetes.[1]

- An online link to the CDC's sponsored screening test can be found at https://www.cdc.gov/diabetes/prevention/pdf/prediabetestest.pdf. The screening test can be given on paper using the document on the following page.
- An American Diabetes Association (ADA) screening test is also acceptable and can be found here http://www.diabetes.org/are-you-at-risk/diabetes-risk-test/.

DO YOU HAVE PREDIABETES?

Prediabetes Risk Test

1. **How old are you?**
   - Less than 40 years (0 points)
   - 40—49 years (1 point)
   - 50—59 years (2 points)
   - 60 years or older (3 points)

2. **Are you a man or a woman?**
   - Man (1 point)
   - Woman (0 points)

3. **If you are a woman, have you ever been diagnosed with gestational diabetes?**
   - Yes (1 point)
   - No (0 points)

4. **Do you have a mother, father, sister, or brother with diabetes?**
   - Yes (1 point)
   - No (0 points)

5. **Have you ever been diagnosed with high blood pressure?**
   - Yes (1 point)
   - No (0 points)

6. **Are you physically active?**
   - Yes (0 points)
   - No (1 point)

7. **What is your weight status? (see chart at right)**

Write your score in the box. ☐

Add up your score. ☐

Height	Weight (lbs.)		
4' 10"	119-142	143-190	191+
4' 11"	124-147	148-197	198+
5' 0"	128-152	153-203	204+
5' 1"	132-157	158-210	211+
5' 2"	136-163	164-217	218+
5' 3"	141-168	169-224	225+
5' 4"	145-173	174-231	232+
5' 5"	150-179	180-239	240+
5' 6"	155-185	186-246	247+
5' 7"	159-190	191-254	255+
5' 8"	164-196	197-261	262+
5' 9"	169-202	203-269	270+
5' 10"	174-208	209-277	278+
5' 11"	179-214	215-285	286+
6' 0"	184-220	221-293	294+
6' 1"	189-226	227-301	302+
6' 2"	194-232	233-310	311+
6' 3"	200-239	240-318	319+
6' 4"	205-245	246-327	328+
	(1 Point)	(2 Points)	(3 Points)
	You weigh less than the amount in the left column (0 points)		

Adapted from Bang et al., Ann Intern Med 151:775-783, 2009.
Original algorithm was validated without gestational diabetes as part of the model.

If you scored 5 or higher:

You're likely to have prediabetes and are at high risk for type 2 diabetes. However, only your doctor can tell for sure if you do have type 2 diabetes or prediabetes (a condition that precedes type 2 diabetes in which blood glucose levels are higher than normal). Talk to your doctor to see if additional testing is needed.

Type 2 diabetes is more common in African Americans, Hispanic/Latinos, American Indians, Asian Americans and Pacific Islanders.

Higher body weights increase diabetes risk for everyone. Asian Americans are at increased diabetes risk at lower body weights than the rest of the general public (about 15 pounds lower).

LOWER YOUR RISK

Here's the good news: it is possible with small steps to reverse prediabetes - and these measures can help you live a longer and healthier life.

If you are at high risk, the best thing to do is contact your doctor to see if additional testing is needed.

Visit DoIHavePrediabetes.org for more information on how to make small lifestyle changes to help lower your risk.

For more information, visit us at

DoIHavePrediabetes.org

Ad Council · American Diabetes Association. · AMA · CDC

Appendix C. Guidelines for Staff Eligibility, Roles, and Responsibilities; and Sample Position Descriptions

Use of Lifestyle Coaches, Training, and Eligibility

CDC-recognized organizations are responsible for ensuring that an adequate and well-trained workforce is available prior to launching the first class of their type 2 diabetes prevention lifestyle change programs. People who are eligible to be Lifestyle Coaches must have been formally trained to a CDC-approved curriculum for a minimum of 12 hours, or approximately two days, by one of the following: 1) a training entity listed on the CDC website, 2) a private organization with a national network of CDC-recognized program sites, 3) a CDC-recognized virtual organization with national reach, or 4) a Master Trainer, as designated by the CDC-recognized program, who has delivered the lifestyle change program for at least one year and has completed a Master Trainer program offered by a training entity on the CDC website.

Additional training on group facilitation, motivational interviewing, and data collection and interpretation are also essential to effectively carry out Lifestyle Coach responsibilities. While Lifestyle Coaches may have credentials (e.g., RD, RN), credentials are not required. Community Health Workers and lay people can be effective coaches as well.

Recognized organizations are responsible for the ongoing support and continued training of Lifestyle Coaches. Organizations should provide new Lifestyle Coaches with an opportunity to attend CDC-sponsored webinar trainings on specialized topics such as program delivery and data submission. Additional refresher or new skill training for experienced Coaches is not required but is highly recommended and has been shown to have a positive impact on participant outcomes.

Recognized organizations should allocate sufficient time for Lifestyle Coaches to effectively carry out their core responsibilities for delivery of the lifestyle change program. A minimum of 3-5 hours of staff time should be allocated to deliver a one-hour class session. Decisions about the number of Lifestyle Coaches hired and time allocations for program delivery will vary based on the delivery modality (i.e. in-person, online, or combination), the experience of the Lifestyle Coaches, the number of classes and locations served at one time, and whether the organization is in a start-up or expansion phase of program delivery.

Additional time outside of class is typically needed for:

- planning and reviewing class session content;
- reviewing food and physical activity trackers and providing feedback to individual participants;
- arranging and adapting session plans to meet unique participant needs such as language, cultural or dietary restrictions, or hearing or sight impairments;

- preparing and monitoring data to support quality improvement; and
- interacting with participants between classes to support retention (such as using social media, sending phone call, e-mail, or text reminders, or engaging in online communities).

Position Description- Lifestyle Coach

Role of the Lifestyle Coach: Lifestyle Coaches implement a CDC-approved curriculum designed for effective lifestyle change for preventing or delaying type 2 diabetes, and provide support and guidance to participants in the program.

Responsibilities of the Lifestyle Coach:

a. Delivering the lifestyle change program and adhering to a CDC-approved curriculum with the required intensity and duration (per the Diabetes Prevention Recognition Program Standards and Operating Procedures, i.e., DPRP Standards) to class participants in an effective, meaningful, and compelling way

b. Encouraging group or individual participation and interaction through the use of open-ended questions and facilitating commitment to activities for effective lifestyle change

c. Motivating participants and creating a friendly and interactive environment for group discussion or interactive learning, whether in-person or online

d. Making learning a shared objective and encouraging peer-to-peer learning

e. Preparing for each class by reviewing the lesson plan and class content, reviewing data, making reminder calls or sending text messages to participants, and reviewing participants' food and activity trackers

f. Being accessible to participants both before and after sessions to answer questions

g. In collaboration with the Program Coordinator and/or Data Preparer, recording, entering, and submitting session data elements for each participant as noted in **Table 2** within the DPRP Standards (i.e., attendance, body weight, total weekly minutes of physical activity, etc.)

h. When make-up sessions are needed, following up with participants outside of class if they were unable to attend a session that week (during months 1-6) or month (during months 7-12) to offer a make-up session (make-up sessions should consist of a one hour, in-person discussion or can be delivered via phone, video conference, or virtual session)

i. Supporting and encouraging goal setting and problem solving

j. Collaborating with the Program Coordinator and others involved in data preparation to regularly monitor participant progress and address any issues to improve participant outcomes

k. Complying with all applicable laws and regulations, including those governing participant privacy and data security (e.g., the Health Insurance Portability and Accountability Act [HIPAA])

l. Completing the required organizational trainings, refresher or new skills trainings, and trainings offered by CDC, such as DPRP-related webinars

m. For organizations seeking reimbursement for delivery to Medicare beneficiaries, Lifestyle Coaches will need to obtain a National Provider Identifier (NPI) number from the Centers for Medicare & Medicaid Services. (Not all Lifestyle Coaches need NPI numbers, only those who teach classes with Medicare beneficiaries in which Medicare is the payer.)

Use of a Program Coordinator, Training, and Eligibility

An organization seeking CDC recognition by participating in the DPRP must designate an individual to serve in the role of Program Coordinator at the time its application is submitted. Because of the important role the Program Coordinator plays in hiring, guiding, and supervising Lifestyle Coaches, it is highly recommended that a Program Coordinator have at least one year of experience working as a Lifestyle Coach. Like Lifestyle Coaches, it is recommended that Program Coordinators have at least 12 hours, or approximately two days, of Lifestyle Coach training aligned to a CDC-approved curriculum.

A Program Coordinator is also responsible for data submission to CDC and receives all programmatic and data-related correspondence from CDC regarding the organization's recognition status. They are CDC's point of contact. When an organization has a Program Coordinator staffing change, CDC must be notified of the new point of contact immediately via an email to DPRPAsk@cdc.gov. If a CDC-recognized organization serves a large number of participants at any one time, multiple Program Coordinators may be required. Similarly, if a CDC-recognized organization serves a small number of participants at any one time, it may be appropriate for a Program Coordinator to serve simultaneously in the role of the Lifestyle Coach, provided the proper Lifestyle Coach training has been completed.

Position Description- Program Coordinator

Roles of the Program Coordinator:

- Program Coordinators serve as the institutional experts for implementing the lifestyle change program consistent with Diabetes Prevention Recognition Program Standards and Operating Procedures, i.e., DPRP Standards.
- They supervise daily operations related to the lifestyle change program and provide guidance and support to Lifestyle Coaches.
- Program Coordinators understand program data submitted to CDC's DPRP and facilitate actions to monitor data and support or mentor Lifestyle Coaches toward quality performance outcomes.
- They disseminate information sent from CDC's DPRP to others in the organization pertaining to training, technical assistance, and an organization's performance and CDC recognition status.
- Program Coordinators may engage in other key functions such as publicity and marketing of the lifestyle change program, which may require assistance from senior leadership in the DPRP organization.

Responsibilities of the Program Coordinator:

1. **Responsibilities to CDC include:**
   a. Serving as the direct link between their organization and the CDC and as the lead for distributing DPRP information to relevant staff (i.e., Lifestyle Coaches and data preparers, if applicable)
   b. Participating in technical assistance opportunities offered by CDC's DPRP and in quality assurance assessments offered by CDC
   c. Notifying the DPRP of changes to organizational information listed on the CDC website in the "*Registry of Recognized Organizations"* available at https://nccd.cdc.gov/DDT_DPRP/Registry.aspx and class locator "*Find a Program Near You"* map available at https://nccd.cdc.gov/DDT_DPRP/Programs.aspx
   d. Notifying CDC's DPRP of any changes to the CDC-approved curriculum used by the organization following the initial application for recognition

2. **Responsibilities to the CDC-recognized organization include:**
   a. Hiring and supervising Lifestyle Coaches
   b. Organizing Lifestyle Coach training to a CDC-approved curriculum and ongoing training and skill-building opportunities
   c. Supporting Lifestyle Coaches in implementing the lifestyle change program
   d. Monitoring and evaluating the quality of support that Lifestyle Coaches provide to lifestyle change program participants
   e. Recruiting, screening, and registering eligible participants for the lifestyle change program
   f. Organizing a master schedule of the lifestyle change program classes offered by the CDC-recognized organization
   g. Ensuring adequate publicity for and marketing of the lifestyle change program (Some Program Coordinators have additional responsibility for establishing community partnerships that drive enrollment, referrals, and reimbursement.)
   h. Engaging with payers to bill for program participation, as appropriate
   i. Assisting Lifestyle Coaches with launching each yearlong class (i.e., a set of participants that entered the lifestyle change program with the same start date) and evaluating the cohort based on the goals of the lifestyle change program, realigning program delivery where needed
   j. Assisting in ensuring commitment and retention of lifestyle change program participants
   k. Facilitating a review of program data with Lifestyle Coaches and other relevant staff, including a data preparer as needed, to regularly monitor and strategize how to improve participant performance
   l. Providing class coverage in the absence of a Lifestyle Coach
   m. Complying with all applicable laws and regulations, including those governing participant privacy and data security (e.g., HIPAA)
   n. Completing the required organizational trainings, refresher or new skills trainings, and trainings offered by CDC (e.g., DPRP webinars), and facilitating completion of these trainings by Lifestyle Coaches

o. For organizations seeking reimbursement for delivery to Medicare beneficiaries, Program Coordinators filling in as Lifestyle Coaches will need to obtain a National Provider Identifier (NPI) number from the Centers for Medicare & Medicaid Services through their CDC-recognized organization. (Not all Lifestyle Coaches need NPI numbers, only those who teach classes with Medicare beneficiaries in which Medicare is the payer.)

Skills, Knowledge, and Abilities of the Lifestyle Coach and Program Coordinator:

Skills, Knowledge, and Abilities	Lifestyle Coach	Program Coordinator
a. Ability to deliver the yearlong lifestyle change program with adherence to a CDC-approved curriculum and DPRP Standards	√	√
b. Ability to facilitate groups to optimize social interaction, shared learning, and group cohesion appropriate for in–person and/or virtual delivery modes	√	√
c. Strong interpersonal and communication skills	√	√
d. Knowledge of the principles of behavior change, including motivational interviewing techniques	√	√
e. Attention to detail and strong computer (i.e., word processing, working with Excel spreadsheets) and data skills (i.e., data collection, entry, reporting, and interpretation)	√	√
f. Ability to understand and oversee participant safety-related issues with respect to program delivery and ensuring participant privacy and confidentiality	√	√
g. Ability to guide behavior change efforts in others without prescribing personal actions or solutions, so that participants increase their self-confidence and capacity to make and sustain positive lifestyle changes	√	√
h. Ability to communicate empathically to participants, who will likely experience difficulty and frustration at times when trying to adopt and sustain healthy lifestyle behavior changes	√	√
i. Ability to build strong relationships with individuals and build community within a group, including virtual groups where applicable	√	√
j. Knowledge of the basic health, nutrition, healthy lifestyle, and fitness principles contained in the CDC-approved curriculum	√	√

k. Ability to work with people from different backgrounds and cultures; cultural competency related to participants served	√	√
l. Ability to administer all aspects of delivering the lifestyle change program, provide quality assurance for program delivery, and build a network of referral partners		√
m. Ability to supervise and evaluate Lifestyle Coaches' performance according to the CDC DPRP Standards and mentor and provide opportunities for ongoing improvement		√
n. Ability to work collaboratively and flexibly and serve as a liaison and advocate for the lifestyle change program with internal and external stakeholders (participants, organizational leaders, physicians/health care providers, public health communities, and public and private employers and insurers and other payers that purchase benefits for people with prediabetes)		√
o. Ability to act as a resource for Lifestyle Coaches by answering questions and providing evidence-based information in a timely manner		√
p. Ability to ensure adequate publicity for and marketing of the lifestyle change program		√
q. Ability to engage with payers to bill for program participation, as appropriate. For Medicare programs, ability to navigate Centers for Medicare & Medicaid Services systems and data requirements that are in addition to CDC's DPRP Standards requirements.		√

Appendix D. Description of the Data Submission and Evaluation Timeline with Examples

Data submission and evaluation for organizations applying on or after January 1, 2018. Please note that for transitioning organizations, there will be a 6-month grace period.

a. When an application for recognition is approved, the organization will have pending recognition status and may begin offering classes on or after the application approval date. CDC will also assign an "effective date" for the purposes of data submission and evaluation. The effective date will be the first day of the month following approval.

   For example, if the application is received on February 20, 2018 and approved by CDC on March 7, 2018, the effective date will be April 1, 2018. The organization will have pending recognition status beginning on the approval date, March 7, 2018.

b. Classes and data collection may begin on or after the approval date and must begin within 6 months following the effective date.

   For example, if the approval date is March 7, 2018 and the effective date is April 1, 2018, the first class session must take place during the period of March 7, 2018 through September 30, 2018. If the applicant will not be able to start classes within 6 months, the organization should defer submitting an application until it is better prepared to begin offering classes.

c. Data are to be submitted to CDC every 6 months starting at 6 months after the effective date.

   For example, if the effective date is April 1, 2018, the first data submission to CDC must occur during October 2018.

d. The 6 month data submission must include one record for each session attended by each participant during the preceding 6 months. The first data submission must also include records for any sessions attended between the approval date and the effective date.

   For example, if the approval date is March 7, 2018 and the effective date is April 1, 2018, the first data submission must include all sessions attended during the period of March 7, 2018 through September 30, 2018, and must be submitted to CDC in October 2018. The second data submission must include all sessions attended during the period October 1, 2018 through March 31, 2019, and must be submitted to CDC in April, 2019.

e. After the first 6 month data submission, CDC will provide the organization with an interim Progress Report (PR). The organization will continue in pending recognition status.

f. Once a full 12 months of data are available, CDC will prepare the first Evaluation Report (ER) that assesses whether the organization has met the requirements for preliminary or full recognition. The evaluation will be based on data from participants who attended their first session at least one year but not more than 18 months before the submission due date.

   For example, if the approval date is March 7, 2018 and the effective date is April 1, 2018, the first ER (in October 2019) will be based on data from participants who attended their first sessions during the period of March 7, 2018 through September 30, 2018.

g. If the organization does not meet the requirements for preliminary or full recognition after the first ER, it will remain in pending status and be reevaluated every 6 months. If, at the end of the third year (after 36 months) of pending recognition, the organization still does not meet the requirements for preliminary or full recognition, it will receive notice of Loss of Recognition (LOR) and must wait 6 months before reapplying for pending recognition.

h. All organizations, including those that have achieved full recognition, are required to submit data every 6 months. An organization must start at least one 12-month class per year in order to have a data submission every 6 months. After each data submission, CDC will prepare a PR or ER (depending on whether data on a full 12-month participant cohort have been submitted at the time of evaluation) and assess whether the organization has met or maintained the requirements for preliminary or full recognition.

i. Once an organization has achieved preliminary recognition, it may remain in preliminary recognition status for four consecutive 6-month data submission periods (i.e., two years), provided it continues to meet the requirement for preliminary recognition at the 12 month mark. Organizations that do not maintain preliminary recognition at 12 months, or fail to achieve full recognition at the 24 month mark, will lose recognition and will need to wait 6 months before reapplying. Loss of preliminary recognition will preclude an organization from participation as a Medicare DPP supplier until preliminary recognition is reachieved.

j. If an organization has achieved full recognition, it may remain in full recognition status for four consecutive 6-month data submission periods (i.e., two years). If the organization does not continue to meet full recognition at 24 months, but does meet the requirements for preliminary recognition, it can stay in full recognition on a Corrective Action Plan for an additional 12 months. Organizations that do not re-achieve full recognition at 36 months will lose recognition and will need to wait 6 months before reapplying. Loss of full recognition will preclude an organization from participation as a Medicare DPP supplier until either preliminary or full recognition is reachieved.

k. If an organization does not submit complete and acceptable data within the month that it is due, the organization will receive notice of LOR and will be required to wait 6 months before reapplying for recognition.

Data submission and evaluation for organizations already in the DPRP by January 1, 2018

a. Data are to be submitted to CDC every 6 months starting 6 months after the last submission prior to January 1, 2018.

   For example, if the last submission was made in October 2017, then the next 6 month submission will be in April 2018.

b. The first evaluation after January 1, 2018 will be based on data from participants who attended their first session at least one year but not more than 18 months before the submission due date.

c. See items g. – k. in the **Data Submission and Evaluation for Organizations Applying on or after January 1, 2018** section above for remaining procedures.

Appendix E. Using Data for Evaluation

Organization requirements for evaluation of data.

In order to have data evaluated, the organization must meet the following criteria:

- The organization must have been delivering the program for 12 months, and
- The organization must have 5+ participants who have completed 9+ full months in the program and 3+ sessions in months 1-6.

Participant requirements for inclusion in the calculation of outcome measures for Requirements 5-9 found in Table XX "Requirements for Recognition".

In order to be included in the analysis, participants must meet the following criteria:

- All participants included in the analysis must be eligible based on a blood test history of GDM, or a risk test;
- All participants included in the analysis must have attended 3+ sessions in months 1-6; and
- All participants must have completed 9+ full months in the program.

Sample data for a recognized organization with 6 participants.

Participant	Prediabetes Determination	Number of days in the program	Number of sessions attended during months 1-6	Number of sessions attended during months 7-12	First recorded weight (lbs.) during months 1-12	Last recorded weight (lbs.) during months 1-12	Percentage weight loss at the last recorded weight
1	Blood test	275	9	3	200	182	9%
2*	Ineligible	180	7	0	175	166	not used in calculations*
3	Risk test	330	12	5	305	288	5.6%
4	Blood test	360	13	6	181	175	3.3%
5	History of GDM	300	16	4	250	231	7.6%
6	Blood test	275	8	3	150	145	3.3%
7**	Risk test	150	4	0	200	190	not used in calculations**

* Participant 2 is not included in the analysis, because he/she was deemed ineligible based on Prediabetes Determination.

** Participant 7 is not included in the analysis, because he/she was not in the program for 9+ months.

Calculation of recognition requirements using example table above:

Organization requirements for evaluation of data:

- The organization in this example has been delivering the program for 12+ months, and
- This organization has 5+ participants who have completed 9+ full months in the program and 3+ sessions in months 1-6.

Participant requirements for inclusion in the analysis:

- Of the 7 participants for whom data were submitted, 6 were eligible based on a blood test, history of GDM, or a risk test.
- All of the eligible participants attended 3+ sessions in months 1-6, and
- Of the 6 eligible participants, 5 completed 9+ full months in the program.

Requirement 5 (Requirement for Preliminary Recognition):

The percent of participants who attend 9+ sessions in months 1-6 must be at least 60% *and* the percent of participants who attend 3+ sessions in months 7-12 must be at least 60%.

This requirement has two parts. The first part **(the percent of eligible participants who attend 9+ sessions in months 1-6 must be at least 60%)** is based on participants who had been in the program 9+ months. The second part **(the percent of participants who attend 3+ sessions in months 7-12 must be at least 60%)** is based on participants who had been in the program 9+ months.

Percent of participants who attend 9+ sessions in months 1-6

$$= \frac{\text{Number of evaluated participants who attended 9+ sessions in months 1-6}}{\text{Number eligible to be evaluated}}$$

= 4/5

= 80%

> 60% (Meets the first part of the requirement)

Percent of participants who attend 3+ sessions in months 7-12

$$= \frac{\text{Number of evaluated participants who attended 3+ sessions in months 7-12}}{\text{Number eligible to be evaluated}}$$

= 5/5

= 100%

> 60% (Meets the second part of the requirement)

Organization achieves Preliminary Recognition

Requirement 8 (Requirement for Full Recognition):

2018 CDC Diabetes Prevention Recognition Program

The average weight loss (mean percentage weight loss) achieved over the entire intervention period must be a minimum of 5% of starting body weight.

Average per-participant percentage weight loss at the end of month 12

= Average per-participant percentage weight loss at the end of month 12 among participants eligible to be evaluated

= [**Sum** (1-(last weight/first weight))] / Number of evaluated participants

= [(1 - (182/200)) + (1 - (288/305)) + (1 - (175/181)) + (1-(231/250)) + (1 – (145/150))] / 5

= 5.8%

> 5% (Meets the requirement)

Organization achieves weight loss requirement for Full Recognition

Note on calculations: Timelines are specific to the individual participant. If a participant attends their first session on March 5, then on April 4, he/she will have been in the program for one full month. His/her first 6-month timeline will run from March 5 through September 4 and the second 6-month timeline will run from September 5 through March 4. The participant will be included in the evaluation if they attend at least 3 sessions in the first 6 months and if time from first session to last session is least 9 complete months. For this participant, the 9 month point would be reached at December 4.

Appendix F. DPRP Recommended Procedures for Measuring Weight

1. Place scale on a firm, flat surface.
2. Make sure the participant removes any coats, heavy sweaters, shoes, keys, or heavy pocket contents. Participants should be advised to wear light clothing.
3. Each participant should stand in the middle of the scale's platform with his/her body weight equally distributed on both feet, placing hands at sides, looking straight ahead prior to reading weight.
4. Weight should be reported to the nearest pound (0.5-0.9 rounds up to the nearest pound, 0.1-0.4 rounds down to the nearest pound).
5. The same scale should be used to measure weights at each session.
6. Weights should be measured under similar circumstances at each session and in the same way the initial measurement was taken (e.g., participants wearing similar clothing, measurements taken at the same time of day).
7. Weight may be measured by the Lifestyle Coach at sessions conducted in-person or by the participant at sessions conducted in-person or virtually.
8. Organizations using Bluetooth-enabled scales should record only one weight per session date. The closest weight to the recorded session date is the one to be used for each participant. The lowest weight taken during the weekly or monthly session can also be used as long as only one weight is recorded per session date. Bluetooth-enabled refers to scales that transmit weights securely via wireless or cellular transmission.
9. For participants attending in-person classes who weigh more than once a week, the closest weight to the recorded session date is the one to be used.

Appendix G. Key Terms and Definitions

Application approval date = The date CDC approves an organization's application for participation in the CDC DPRP. An organization may begin offering classes immediately after receiving its application approval date.

Applicant organization (organization) = An organization that offers the National DPP lifestyle change program and is in the process of applying for pending recognition from the CDC DPRP.

CDC-recognized organization (recognized organization) = An organization that offers the National DPP lifestyle change program and has received pending, preliminary, or full recognition from the CDC DPRP.

Cohort = A completed cohort is a set of participants that entered into a lifestyle change program that has a fixed first and last session and runs for 12 months. An organization can have multiple cohorts running at the same time.

DPP Lifestyle Intervention (lifestyle intervention) = The intervention used during the 2002 DPP research study or replicated during further efficacy and implementation studies.

Data collection period = For the first data submission, the data collection period would include data from sessions held between the application approval date and the data submission due date 6 months later. For subsequent submissions, the data collection period would include data from sessions between the previous due date and the data submission due date 6 months later.

Diabetes Prevention Program (DPP) = The original research study, led by the National Institutes of Health, which showed that making modest behavior changes helped participants lose 5% to 7% of their body weight and reduced the risk of developing type 2 diabetes by 58% in adults with prediabetes (71% for people over 60 years old).

Effective date = The first day of the month following an organization's application approval date.

Eligible participant (for inclusion in evaluation) = A participant who meets the requirements for age, BMI, and prediabetes/risk determination. The participant cannot be pregnant or diagnosed with type 1 or type 2 diabetes at the time of enrollment. If a participant becomes pregnant or is diagnosed with type 2 diabetes during the program, they may continue participation, but their data will not be included in the evaluation.

Evaluated participant = Eligible participants who attended their first session at least one year but not more than 18 months before the submission due date. These participants must have attended at least 3 sessions in the first 6 months and have a total time from first session to last session of the lifestyle change program of at least 9 months.

Full recognition = The CDC recognition status that, like preliminary (see below), allows organizations to become Medicare DPP suppliers and to begin billing Medicare. Full recognition is required to remain a Medicare DPP supplier after the 24 months of preliminary recognition expires. Organizations will be awarded full recognition when they meet the following criteria:

1. The requirements for pending recognition.
2. A minimum of 5 evaluated participants.
3. Among participants meeting the criteria in #2, the requirements for preliminary recognition.
4. Among participants meeting the criteria in #2, the requirements for documentation of body weight, documentation of physical activity minutes, weight loss achieved at 12 months, and the program eligibility requirement as defined in the DPRP Standards and Operating Procedures.

National Diabetes Prevention Program (National DPP) = A partnership of public and private organizations working collectively to establish, scale, and sustain an evidence-based lifestyle change program for people with prediabetes to prevent or delay onset of type 2 diabetes.

Pending Recognition = The CDC recognition status granted to all applicant organizations once an initial application is approved.

Preliminary Recognition = The CDC recognition status that allows organizations to become Medicare DPP suppliers and to begin billing Medicare. Organizations will be awarded preliminary recognition when they meet the following criteria:

1. The requirements for pending recognition.
2. A minimum of 5 evaluated participants.
3. Among participants meeting the criteria in #2, at least 60% attended at least 9 sessions in months 1-6, and at least 60% attended at least 3 sessions in months 7-12.

The CDC Diabetes Prevention Recognition Program (DPRP) = The quality assurance arm of the National DPP charged with evaluating organizations' performance in effectively delivering the lifestyle change program with quality and fidelity. The DPRP awards CDC recognition to organizations that are following a CDC-approved curriculum and achieving meaningful results with participants based on established evidence-based national standards.

The National DPP lifestyle change program (lifestyle change program) = the translated adaptation of the DPP lifestyle intervention which:

- is a yearlong structured program (in-person, online, combination, or other as defined in the DPRP Standards and Operating Procedures) consisting of:
  - an initial 6-month phase offering at least 16 sessions over 16–26 weeks and
  - a second 6-month phase offering at least one session a month (at least 6 sessions).
- is facilitated by a trained Lifestyle Coach.
- uses a CDC-approved curriculum.
- includes regular opportunities for direct interaction between the Lifestyle Coach and participants.
- focuses on behavior modification, managing stress, and social support.

Coverage of Developmental Diagnoses

Question: Should coverage of developmental delay diagnoses be modified?

Question source: OHA, school-based health systems

Issue:
School-based health systems bill Medicaid for medical services offered in schools related to developmental diagnoses (e.g. developmental delay requiring speech or occupational therapy). Since a change in the DMAP file types and transitions to ICD-10 in 2015, there are a number of code pairings that previously were used by the schools to get medical services for children paid for by OHP that are being denied. Some of these are exclusively issues related to fee-for-service rather than CCOs. However, rectifying the policy issue will also have impacts on CCOs in terms of accessing appropriate community-based interventions for children with developmental delay.

In the IDEA (Individuals with Disabilities Education Act) program, schools are obligated to start providing services even if a diagnosis has not been established. The Individualized Education Program (IEP) program and/or Individualized Family Services Plan (IFSP) serves as the overseeing body and provides the prescription for the referrals. Schools are not able to discontinue these services or charge parents for the services.

The most common codes that are being denied are:

R62.0 Delayed milestone in childhood
R62.50 Unspecified lack of expected normal physiological development in childhood
R62.59 Other lack of expected normal physiological development in childhood

Other examples of denied codes include:

a. F80.9 Developmental disorder of speech and language, unspecified
b. F81.89 Other developmental disorders of scholastic skills
c. G72.9 Myopathy, unspecified
d. G93.9 Disorder of brain, unspecified
e. G96.9 Disorder of central nervous system, unspecified
f. Q24.9 Congenital malformation of heart, unspecified

In the last few years, there have been concerns raised by a variety of CCO medical directors that there are some generic codes that have been subjected to excessive use and a series of coding changes have been made. Pertinent history of these and other changes from HSC/HERC are excerpted below.

From Linda Williams, OHA:
EI eligibility requirements for Developmental Delay under **581-015-2780 EI Eligibility** states: (c) Developmental delay: The child experiences a developmental delay and as a result needs EI services. Developmental delay means two standard deviations or more

below the mean in one or more of the following developmental areas, or 1.5 standard deviations below the mean in two or more of the developmental areas:

(A) Cognitive development;

(B) Physical development;

(C) Communication development;

(D) Social or emotional development;

(E) Adaptive development.

(4) The multidisciplinary team must prepare an evaluation report and a written statement of eligibility.

F82 is used by PT and OTs signs and symptoms within the scope of OT and PT and when no diagnosis has been made
F82 Specific developmental disorder of motor-function:

- Clumsy Child syndrome
- Developmental coordination disorder
- Developmental dyspraxia

Expert input

From Katie Zuckerman, Associate Professor Pediatrics, OHSU
It seems like R62.0, R62.5, and F80.9 are used both by pediatric providers and also by EI on a fairly regular basis. Pediatric providers use it when a child has failed a screening test or when they have a clinical concern but have not given a diagnosis yet. Some people may not be aware that habilitative services will be denied with this code. EI uses it as a "provisional diagnosis" mostly in the 0-3 age range when they want to bill Medicaid. I went to a talk this year that showed that many of the kids given this type of diagnosis do not subsequently qualify for Early Childhood Special Ed (because it is not a qualifying diagnosis for ECSE), and then re-enter the SpEd system in elementary. So, it may be a red flag.

F88 is sometimes billed for a lot of things, including "global developmental delay," "delayed social skills" and "sensory integration disorder." I'd be a little hesitant about covering that one since it is so vague and sensory integration therapy is not recommended by the AAP (https://www.aap.org/en-us/about-the-aap/aap-press-room/pages/AAP-Recommends-Careful-Approach-to-Using-Sensory-Based-Therapies.aspx) . F80.9 seems to more narrowly pertain to speech disorders, which seems reasonable. F81.89 pertains to nonverbal learning disorders, which also may be reasonable.

Some of these others, e.g., G72.9, G93.9, G96.9, Q24.9, are so vague that it's hard to know what people are billing them for.

Re: your question
"Delayed milestones" probably has some physiologic sense until about age 8. At that point a child is more accurately labeled "intellectual disability." However, I can tell you that many parents do not like their child labeled ID, I think because developmental delay makes it sound more hopeful like they are going to catch up. So, my guess is that some providers use R62.0 and R62.5 up to higher ages than that.

I think the practical implication of these coding changes will be that more children, particularly those who do not meet the qualification threshold for Early Intervention, those with delay in only one area, and those with certain speech or learning disorders, will be eligible for services under OHP. This may be helpful, especially in the 0-3 age range, because our EI eligibility is one of the strictest in the country and many children who could use the help get turned away from EI.

From Sondra Marshall, PhD, Pediatric neuropsychologist, St Charles Health Care

Children are referred to us for evaluation, with no previous evaluation but struggling in numerous functional domains, who are over the age of 8 and have hx of prematurity, congenital heart disorder or in utero exposure (among other things). Or perhaps they just have an educational classification of a learning disorder but no medical dx. If we are precluded from using R62.0 or R62.5 due to age, what would be the best code?

How is it that in the DSM V, F88 is defined as Specified Neurodevelopment Disorder but in ICD 10 world F88 is attached to many different disorders, such as sensory integration disorder which....well do not get me started! My point being F88 from DSM world really captures the overall gestalt of the referral and allows us to specify associated possible etiology. That is why it works for us, especially with the "in utero exposure, congenital heart disorder and prematurity" population.

<u>HSC/HERC history</u>

HOSC Minutes August 24, 1995

Deatherage presented the recommendation of the Task Force on Developmental Delay. She explained the process that had been followed and how consensus had been reached. The Task Force's recommendation was that 315.4X be added to the Posture and Movement line with criteria specifying that for age 3 and under it is an appropriate diagnosis and for ages greater than 3, the use is diagnostic and should be time limited. The Task Force also recommended a prior authorization protocol be adopted requiring documentation of expected outcomes after a specific period

of treatment for 3 and under and for those over three, that authorization be for no more than 120 days. These recommendations were adopted by the Subcommittee.

September 23, 2004 HOSC Minutes
VII. Coordination Disorder Guideline
Dr. Little explained that the guideline for Line 336 (in packet), had been attached to that line for many years, and that she queried Dr. Kitchen about its origin, who did not recall. The diagnosis, 315.4, is also known as developmental coordination disorder, clumsiness syndrome, dyspraxia syndrome and specific motor development disorder. The current guideline for physical therapy is in conflict with this guideline. Delete the Coordination Disorder guideline from Line 336.

HOSC Minutes August 12, 2010
Dyspraxia
Smits introduced a summary document regarding dyspraxia. The discussion centered around whether there was effective treatments for dyspraxia syndrome (315.4), and the decision was there were not, and that the diagnosis was hard to define. However, the group felt that dyspraxia (781.3) should be kept on the Signs and Symptoms list to allow work up for a cause. There are no treatments included for diagnoses on the signs and symptoms list.

1) Advise DMAP to keep dyspraxia (781.3) on the Signs and Symptoms List.
2) Remove dyspraxia syndrome (315.4) from line 317 Neurological Dysfunction In Posture And Movement Caused By Chronic Conditions. Advise DMAP to place dyspraxia syndrome (315.4) on the Never Covered List.

2011 ICD 10 review
The Mental Health and Chemical Dependency Subcommittee reviewed several of the F80 codes and place them all on the DMAP Excluded File (now “Undefined”)

November 2014 VBBS Minutes
DMAP/HSC Code Clean Up
Smits introduced an Excel spreadsheet with recommendations for placement of CPT codes which currently are duplicated on several lists or are otherwise in need of revision. The supplemental issues Word document was also reviewed. There was no discussion; the subcommittee accepted the recommendations as presented.

ICD-9	Diagnosis Description	Current file	Recommended Placement
315.4	Developmental coordination disorder	EXCLUDED FILE	297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 381 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
315.5	Mixed development disorder	EXCLUDED FILE	297,381
315.8	Other specified delays in development	EXCLUDED FILE	297,381
315.9	Unspecified delay in development	EXCLUDED FILE	297,381

May 2015

Remove ICD-9 315.4 (developmental coordination disorder, clumsiness syndrome, dyspraxia syndrome, or specific motor development disorder) and ICD-10 F82 (Specific developmental disorder of motor function) from lines 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS and 381 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION. Place ICD-9 315.4 and ICD-10 F82 on the DMAP "Undefined Conditions File"

Remove ICD-9 315.9 (Unspecified delay in development) from lines 297 and 381 and place on Undefined List.

Remove ICD-9 348.9 (Unspecified condition of brain) from the dysfunction lines. Place ICD-9 348.9 on the DMAP "Undefined" List

Current Prioritized List Status

Code	Code Description	Current Prioritized List Placement
R62.0	Delayed milestone in childhood	Diagnostic Workup File (DWF)
R62.50	Unspecified lack of expected normal physiological development in childhood	Diagnostic Workup File (DWF)
R62.59	Other lack of expected normal physiological development in childhood	Diagnostic Workup File (DWF)

Code	Code Description	Current Prioritized List Placement
F70.	Mild intellectual disabilities	345,377
F71.	Moderate intellectual disabilities	71,292,345,377

Coverage of Developmental Diagnoses

Code	Code Description	Current Prioritized List Placement
F72.	Severe intellectual disabilities	71,292,345,377
F73.	Profound intellectual disabilities	71,292,345,377
F78.	Other intellectual disabilities	71,292,345,377
F79.	Unspecified intellectual disabilities	71,292,345,377
F80.0	Phonological disorder	345
F80.1	Expressive language disorder	345
F80.2	Mixed receptive-expressive language disorder	345
F80.4	Speech and language development delay due to hearing loss	345
F80.81	Childhood onset fluency disorder	345
F80.82	Social pragmatic communication disorder	345
F80.89	Other developmental disorders of speech and language	345
F80.9	Developmental disorder of speech and language, unspecified	Undefined Diagnosis File
F81.0	Specific reading disorder	Undefined Diagnosis File
F81.2	Mathematics disorder	Undefined Diagnosis File
F81.81	Disorder of written expression	Undefined Diagnosis File
F81.89	Other developmental disorders of scholastic skills	Undefined Diagnosis File
F81.9	Developmental disorder of scholastic skills, unspecified	Undefined Diagnosis File
F82.	Specific developmental disorder of motor function	Undefined Diagnosis File
F84.0	Autistic disorder	71,193,292,345,377
F84.2	Rett's syndrome	71,292,345,377
F84.3	Other childhood disintegrative disorder	71,193,292,345,377
F84.5	Asperger's syndrome	193 AUTISM SPECTRUM DISORDERS
F84.8	Other pervasive developmental disorders	71,193,292,345,377
F84.9	Pervasive developmental disorder, unspecified	193 AUTISM SPECTRUM DISORDERS
F88.	Other disorders of psychological development	Undefined Diagnosis File
F89.	Unspecified disorder of psychological development	Undefined Diagnosis File

Line: 71
Condition: NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES (See Coding Specification Below) (See Guideline Notes 6,64,65,129,170)
Treatment: MEDICAL AND SURGICAL TREATMENT (E.G., G-TUBES, J-TUBES, RESPIRATORS, TRACHEOSTOMY, UROLOGICAL PROCEDURES)

Line: 193
Condition: AUTISM SPECTRUM DISORDERS (See Guideline Notes 65,75)
Treatment: MEDICAL THERAPY/BEHAVIORAL MODIFICATION INCLUDING APPLIED BEHAVIOR ANALYSIS
ICD-10: F84.0,F84.3-F84.9
CPT: 0359T-0374T,90785,90832-90840,90846-90849,90882,90887,93792,93793, 96118,98966-98969,99051,99060,99201-99215,99224-99226,99324-99355, 99366,99415,99416,99441-99449,99487-99490,99495-99498
HCPCS: G0176,G0177,G0248-G0250,G0406-G0408,G0425-G0427,G0459,G0463-G0467,G0469,G0470,G0511,G0513,G0514,H0004,H0023,H0032,H0034, H0038,H2010,H2014,H2027,H2032,S9484

Line: 292
Condition: NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS (See Coding Specification Below) (See Guideline Notes 6,64,65,170)
Treatment: MEDICAL AND SURGICAL TREATMENT (E.G., DURABLE MEDICAL EQUIPMENT AND ORTHOPEDIC PROCEDURE)

Line: 345
Condition: NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS (See Guideline Notes 6,64,65,90)
Treatment: MEDICAL THERAPY

Line: 377
Condition: DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION (See Guideline Notes 6,38,64,65,90)
Treatment: MEDICAL THERAPY (SHORT TERM REHABILITATION WITH DEFINED GOALS)

Coverage of Developmental Diagnoses

HERC Staff Summary:

Schools are facing a number of rejected claims while providing services for children with developmental delay. Some of this can be ameliorated by education around using more appropriate codes. However, some of the codes, such as "Delayed milestone in childhood" may be the most appropriate code to receive some interventions, particularly under the age of 8. Depending on how these lists are implemented, the placement of these codes in the diagnostic file rather than on the Prioritized List is resulting in denial of therapies for some children. A solution would need to allow for treatment to be offered without necessarily a more specific diagnosis, but still subject to appropriate limitations and meeting medical necessity requirements.

HERC Staff Recommendations:

Code	Code Description	Current Prioritized List Placement	Recommended Changes
R62.0	Delayed milestone in childhood – includes late talker, late walker, delayed attainment of expected physiological developmental stage	Diagnostic Workup File (DWF)	**Remove from Diagnostic Workup File. Add to 3 dysfunction lines. Subject to Guideline Note 6.**
R62.50	Unspecified lack of expected normal physiological development in childhood	Diagnostic Workup File (DWF)	Quite vague, no change.
R62.59	Other lack of expected normal physiological development in childhood – Approximate Synonyms Constitutional delay of growth and puberty Constitutional delayed growth and puberty	Diagnostic Workup File (DWF)	No change

Code	Code Description	Current Prioritized List Placement	
F80.9	Developmental disorder of speech and language,	Undefined	**Remove from**

Code	Code Description	Current Prioritized List Placement	
	unspecified – Communication disorder NOS, Language disorder NOS	Diagnosis File	**Undefined Diagnosis File. Add to dysfunction line for communication.**
F81.0	Specific reading disorder – "backward reading" Developmental dyslexia, specific learning disorder, with impairment in reading, specific reading retardation. Def: Serious impairment of reading skills unexplained in relation to general intelligence and teaching processes.	Undefined Diagnosis File	School purview
F81.2	Mathematics disorder – Developmental acalculia, Developmental arithmetical disorder	Undefined Diagnosis File	School purview
F81.81	Disorder of written expression – Specific learning disorder, with impairment in written expression, specific spelling disorder	Undefined Diagnosis File	School purview
F81.89	Other developmental disorders of scholastic skills	Undefined Diagnosis File	School purview
F81.9	Developmental disorder of scholastic skills, unspecified – Knowledge acquisition disability NOS, Learning disability NOS, Learning disorder NOS	Undefined Diagnosis File	School purview
F82.	Specific developmental disorder of motor function – clumsy child syndrome, developmental coordination disorder, developmental dyspraxia	Undefined Diagnosis File	Reviewed at May 2015 VbBS/HERC and removed from 2 dysfunction lines. **Place on Line 659,** MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS

Code	Code Description	Current Prioritized List Placement	
			OR NO TREATMENT NECESSARY.
F88.	Other disorders of psychological development – Developmental agnosia, Global developmental delay, other specific neurodevelopmental disorder	Undefined Diagnosis File	**Discuss adding this to dysfunction lines with a coding specification**
F89.	Unspecified disorder of psychological development	Undefined Diagnosis File	No change

Code	Description	Current Prioritized List Placement	Recommended change
T1018	School-based individualized education program (IEP) services, bundled	Ancillary	No change
T1024	Evaluation and treatment by an integrated, specialty team contracted to provide coordinated care to multiple or severely handicapped children, per encounter	Ancillary	No change

1) **Add R62.0 *Delayed milestone in childhood* to dysfunction lines: 292, 345, and 377.**
    a. Guideline Note 6 will apply
    b. It does not need to be added to dysfunction line 71 because a more specific diagnosis can be used (e.g. urinary incontinence, fecal incontinence)
    c. Add a coding specification

R62.0 is included on lines 292, 345, and 377 for children 8 and under.

i. Rationale: This matches eligibility criteria for special education under Individualized Education Program (IEP) program and/or Individualized Family Services Plan (IFSP) and is clinically consistent.

2) **Add F80.9 *Developmental disorder of speech and language, unspecified* to dysfunction line 345.**
   a. This is a mental health diagnosis so parity rules apply to Guideline Note 6

3) **Consider adding F88** Other disorders of psychological development **to lines 292, 345, and 377.** This code is broad but useful when underlying diagnoses are not known and children may be older than 8.

   Applicable To
   - Developmental agnosia
   - Global developmental delay
   - Other specified neurodevelopmental disorder

   Approximate Synonyms
   - Borderline cognitive developmental delay
   - Cognitive development, borderline
   - Cognitive developmental delay
   - Developmental delay, cognitive
   - Developmental delay, global
   - Developmental disorder, mixed
   - Developmental disorder, specific
   - Developmental neurologic disorder
   - Global developmental delay
   - Mixed developmental disorder
   - Neurodevelopmental disorder
   - Neurodevelopmental disorder, other specified
   - Sensory integration disorder
   - Specific developmental disorder

   Sensory integration disorder has been reviewed and is intended not to be covered on the Prioritized List. If this code is added, a coding specification is necessary.

   Coding specification: F88 is included on these lines for developmental delay. When it is used to indicate sensory integration disorder or sensory processing disorder, it is included on Line 659.

4) **HSD staff to work with schools to help with identifying appropriate diagnoses**

5) **Place F82** *Specific developmental disorder of motor function* **on Line 659 rather than Undefined File.**
   a. It is “specific” and so seems contradictory to have it in an “undefined” file

Breast Reconstruction Revision

Question: Should revisions to breast reconstruction after mastectomy be limited to non-cosmetic cases?

Question source: Alison Little, CCO medical director

Issue: The current guideline regarding breast reconstruction after mastectomy does not have any wording to limit revisions to previously done reconstruction. Dr. Little received a request for a revision of a breast reconstruction solely for cosmetic purposes (i.e. the patient wanted larger breasts). The gender dysphoria guideline note has wording clarifying when a revision to a reconstruction is covered.

HERC staff recommendation:

1) Revise GN79 as shown below.
    a. The added wording is from the gender dysphoria guideline

GUIDELINE NOTE 79, BREAST RECONSTRUCTION

Line 191

Breast reconstruction is only covered after mastectomy as a treatment for breast cancer or as prophylactic treatment for the prevention of breast cancer in a woman who qualifies under Guideline Note 3, and must be completed within 5 years of initial mastectomy. Revision of previous reconstruction are only covered in cases where the revision is required to address complications of the surgery (wound dehiscence, fistula, chronic pain directly related to the surgery, etc.). Revisions are not covered solely for cosmetic issues.

Breast reconstruction may include contralateral reduction mammoplasty (CPT 19318) or contralateral mastopexy (CPT 19316). Mastopexy is only to be covered when contralateral reduction mammaplasty is inappropriate for breast reconstruction and mastopexy will accomplish the desired reconstruction result.

Cardiac MRI for Indications other than Congenital Heart Disease

Question: Should cardiac MRI be included for indications other than evaluation of congenital cardiac disease?

Question source: Primary Health; HERC staff

Issue: Cardiac MRI CPT codes were new codes in 2007. Placement was debated over several meetings in 2007 and 2008. Ultimately, it was decided to put cardiac MRI codes only on the congenital heart disease lines. It was felt that other indications had less expensive imaging modalities available, such as ECHO. There was also concern that the test had not been proven as a valuable test in many areas.

Cardiac MRI has become a more common and accepted test over the past decade. CMS recently changed their guidelines regarding determination of ejection fraction (EF) for qualifying for an implantable cardiac defibrillator and included cardiac MRI as one modality for determining EF. Most private insurers cover cardiac MRI for evaluation of cardiomyopathy, and for determination of EF, although some restrict to when ECHO is non-diagnostic. CCO's are increasingly getting requests for cardiac MRIs for evaluation of cardiomyopathy. Echocardiography, in particular trans-esophageal echocardiogram (TEE), remains the generally accepted modality for the evaluation of cardiac anatomy and function most of the time by most practitioners. However, there are patients who cannot be adequately imaged with ECHO.

Expert Guidelines

THE NICE 2015 (https://www.nice.org.uk/guidance/qs99/resources/secondary-prevention-after-a-myocardial-infarction-pdf-2098977438661) guideline on Secondary Prevention after MI states that **"**Left ventricular function can be assessed using a variety of methods, including echocardiography, cardiac magnetic resonance imaging (MRI), angiography and nuclear imaging. [Expert opinion]." The NICE 2010 (https://www.nice.org.uk/guidance/cg108/resources/chronic-heart-failure-in-adults-management-pdf-35109335688901) guideline on management of congestive heart failure states "Consider alternative methods of imaging the heart (for example, radionuclide angiography, cardiac magnetic resonance imaging or transoesophageal Doppler 2D echocardiography) when a poor image is produced by transthoracic Doppler 2D echocardiography. [2003]."

The ACCF/ACR/AHA/NASCI/SCMR 2010 Expert Consensus Document on Cardiovascular Magnetic Resonance (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3042771/pdf/nihms268875.pdf) stated that "CMR may be used for assessment of LV and RV size and morphology, systolic and diastolic function, and for characterizing myocardial tissue for the purpose of understanding the etiology of LV systolic or diastolic dysfunction." Additionally, "CMR may be useful for identifying coronary artery anomalies and aneurysms, and for determining coronary artery patency."

Expert input

Dr. Eric Stecker:

> My feeling is CMR is unlikely to be abused or overused since it is probably a money loser for cardiologists and health systems. Labor intensive by tech's and cardiologists to protocol and conduct it. It is not used as first line for EF assessment – echo is. Rarely it's used when echo images or precision of estimate of EF are insufficient. CMR is essential to evaluate for a non-ischemic etiology of cardiomoypathies, myocardial viability when needed to guide whether to

revascularize or not, and evaluating for risk of sudden cardiac death among patients with unexplained arrhythmias (heart block, VT, VF) or family history of a genetic disorder predisposing to hypertrophic cardiomyopathy, fibrosis or cardiomyopathy. So I think it should just be covered as a standard diagnostic test and encourage echo first line when possible. Can look later to see if people are overusing it.

Current Prioritized List Placement

CPT	Code Description	Current Lines
75557	Cardiac magnetic resonance imaging for morphology and function without contrast material;	Congenital heart disease lines: 44,67,70,85,86,89,90,105,106, 111, 128, 130, 138, 176, 186, 188, 224, 233,258, 264, 651
75559	With stress imaging	Same as above
75561	Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences;	Same as above
75563	with stress imaging	Same as above
75565	Cardiac magnetic resonance imaging for velocity flow mapping	Same as above

HERC staff summary

Cardiac MRI (CMR) has become a standard imaging modality for a variety of cardiac indications. It does not appear to have potential for overuse according to our cardiology expert.

HERC staff recommendations:

1) Remove CMR from all current lines on the Prioritized List and add to the Diagnostic Procedures File
    a. CPT 75557-75565 (Cardiac magnetic resonance imaging)
2) Consider adopting a new diagnostic guideline as shown below

DIAGNOSTIC GUIDELINE DX CARDIAC MAGNETIC RESONANCE IMAGING

Cardiac magnetic resonance imaging (CMR) is covered only after it has been determined that echocardiogram and Doppler studies are inconclusive or expected to be nondiagnostic.

Postpartum Depression Screening

Question: How should coverage of postpartum depression screening be clarified on the Prioritized List?

Question source: Dana Hargunani, CMO; HSD

Issue: Postpartum depression has major impacts on child and maternal health. Currently, it is not clear that postpartum depression screening is explicitly intended to be covered on the Prioritized List. Also, there is a lack of clarity about the coverage of this screening when provided during the child's appointment rather than during the mother's visit.

Perinatal depression (encompassing pregnancy and 12 months postpartum) or postpartum depression (typically up to 6 weeks postpartum) are both underassessed and treated.

The American Academy of Pediatrics (AAP) developed a new CPT code to allow reporting of the administration of a caregiver-focused health risk assessment (eg, maternal depression inventory) for the benefit of the patient.

Metrics and Scoring have approved a postpartum visit metric for 2019-2020 with a future plan to include quality measures such as postpartum depression screening in 2021.

Prioritized List Status

Code	Code Description	Current List Placement	Fee Schedule
Z13.32	Encounter for screening for maternal depression	New ICD 10 code, Just reviewed by BHAP, recommended placement on Line 3	
96127	Brief emotional/behavioral assessment (eg, depression inventory, attention-deficit/hyperactivity disorder [ADHD] scale), with scoring and documentation, per standardized instrument	Diagnostic Procedures File	$4.42
96150	Health and behavior assessment (eg, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; initial assessment	1,3,4,5,8,9,10,12 and 184 other lines.	$15.04-17.23
96151	Health and behavior assessment (eg, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; re-assessment	1,3,4,5,8,9,10,12 and 184 other lines.	$14.53-16.68
96152	Health and behavior intervention, each 15 minutes, face-to-face; individual	1,3,4,5,8,9,10,12 and 184 other lines.	$13.77-15.85
96153	Health and behavior intervention, each 15 minutes,	1,3,4,5,8,9,10,12 and 184	$2.98-

Code	Code Description	Current List Placement	Fee Schedule
	face-to-face; group (2 or more patients)	other lines.	3.52
96154	Health and behavior intervention, each 15 minutes, face-to-face; family (with the patient present)	1,3,4,5,8,9,10,11 and 194 other lines.	$13.27-15.81
96155	Health and behavior intervention, each 15 minutes, face-to-face; family (without the patient present)	1,3,4,5,8,9,10,11 and 194 other lines.	$15.95-17.42
96160	Administration of patient-focused health risk assessment instrument (eg, health hazard appraisal) with scoring and documentation, per standardized instrument	Diagnostic Procedures File	$3.23
96161	Administration of caregiver-focused health risk assessment instrument (eg, depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument	Diagnostic Procedures File	$3.23
G8431	Screening for depression is documented as being positive and a follow-up plan is documented	Ancillary Procedures File	
G8432	Depression screening not documented, reason not given	Ancillary Procedures File	
G8433	Screening for depression not completed, documented reason	Ancillary Procedures File	
G8510	Screening for depression is documented as negative, a follow-up plan is not required	Ancillary Procedures File	
G8511	Screening for depression documented as positive, follow-up plan not documented, reason not given	Ancillary Procedures File	

Evidence Summary

USPSTF, 2016

https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/depression-in-adults-screening1

The USPSTF recommends screening for depression in the general adult population, including pregnant and postpartum women. Screening should be implemented with adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up.

- "B" Recommendation

O'Connor, 2016

https://jamanetwork.com/journals/jama/fullarticle/2484344

- Systematic review for USPSTF
- Pregnant and postpartum women 18 years and older
- 6 trials (n = 11 869) showed 18% to 59% relative reductions with screening programs, or 2.1% to 9.1% absolute reductions, in the risk of depression at follow-up (3-5 months) after participation in programs involving depression screening, with or without additional treatment components, compared with usual care.
- Based on 23 studies (n = 5398), a cutoff of 13 on the English-language Edinburgh Postnatal Depression Scale demonstrated sensitivity ranging from 0.67 (95% CI, 0.18-

0.96) to 1.00 (95% CI, 0.67-1.00) and specificity consistently 0.87 or higher. Data were sparse for Patient Health Questionnaire instruments.
- Pooled results for the benefit of CBT for pregnant and postpartum women with screen-detected depression showed an increase in the likelihood of remission (pooled relative risk, 1.34 [95% CI, 1.19-1.50]; with absolute increases ranging from 6.2% to 34.6%.
- Author conclusions: Direct and indirect evidence suggested that screening pregnant and postpartum women for depression may reduce depressive symptoms in women with depression and reduce the prevalence of depression in a given population.

MED, 2016

- Policy brief on screening for postpartum depression and linkage to care
    - *Some states allow only PHQ-9, EPDS, or Beck, and others allow any validated screen*

Table 2. *Test Characteristics of Postpartum Depression Screening Tools*

Screening Test	Sensitivity (95% CI)	Specificity (95% CI)	Strength of Evidence[3]
Antenatal Risk Questionnaire	78.1% (65.0 to 88.7%)	47.1% (40.3 to 59.9%)	Low
BDI	80% to 90%[1]	80% to 90%[1]	Low
BDI-II	75% to 90%[1]	80% to 90%[1]	Low
EPDS	80% to 90%[1]	80% to 90%[1]	Moderate
HRSD-17	80% to 85%[2]	80% to 85%[2]	Low
HRSD-21	80% to 85%[2]	75% to 80%[2]	Low
Leverton Questionnaire	95.2% (90.4 to 98.1%)	91.3% (88.4 to 93.7%)	Low
PDSS	80% to 90%[1]	80% to 90%[1]	Moderate
PHQ-9	75% to 89%[2]	83% to 91%[2]	Low
Two-Question Screen	100% (2 studies; sensitivity 100% in both)	44.3% and 65.7%	Moderate

BDI = Beck Depression Inventory, EPDS= Edinburgh Postpartum Severity Score, HRSD = Hamilton Rating Scale for Depression, PDSS = Postpartum Depression Screening Scale, PHQ = Patient Health Questionnaire

Source: AHRQ (Myers et al., 2013)

[1] Approximate range at most commonly used thresholds

[2] Approximate range at varying thresholds

[3] Based on four domains: risk of bias, consistency, directness, and precision

-
    - Some allow for billing on mom's or child's Medicaid ID (Colorado, Illinois), others only on mom (New York) or only child (Minnesota)
    - Several states used 99420 which has been replaced with 96160
    - Key issues identified in the MED report – resources need to be available for screening tools, referral pathways need to be in place, provider and telephonic support can be important.

Other state strategies

Minnesota

- Developed clinical pathways for postpartum depression screening and follow up
- Postpartum depression screening is covered in well child checks, up to 3 times in the first 12 months of life
- Recommended 99420 which was reimbursed in 2015 at $8.67

New York

- Reimburses for screening for postpartum depression
- When done during the infant visit, it is billed to the mother's Medicaid number
- Up to 3 screens in the 12 months postpartum are covered
- Providers are instructed to have a plan in place to address positive screens
- 99420 is to be used, reimbursement $15.60

Illinois

- Created metrics around prenatal and postpartum depression screening
- 96127, with the HD modifier (96127 HD) for postpartum depression screening, up to a year after the infant's birth; may be billed on the infant's recipient number, if infant is the patient.
- The University created a phone consultation service to connect providers to psychiatrists for advice about diagnosis, management, and medications
- The creation of a hotline, staffed by mental health experts, for women to call for advice or resources
- Provider education efforts across the state

Colorado

- Any screen is acceptable but encourage PHQ9 and EPDS
- Recently replaced 99420 with G8431- positive screen, G8510- negative screen
- Reimbursement $10.28, yearly

National Guidance

CMS, 2015

CMS Core Set of Children's Health Care Quality Measures includes a maternity care behavioral risk assessment at the initial prenatal visit with depression screening listed along with alcohol, tobacco, drug use, and intimate partner violence screening

CMS, 2016 Informational Bulletin on Postpartum Depression

- Maternal depression screening during the well-child visit is considered a pediatric best practice and is a simple way to identify mothers who may be suffering from depression and may lead to treatment for the child or referral for mothers to other appropriate treatment.
- States and managed care plans can promote uptake by:
    - Posting information about maternal depression screening on provider websites and publishing information in provider newsletters.
    - Delivering provider trainings to promote the use of maternal depression screening tools and proper billing codes.
    - Conducting in-person visits to clinics to train providers on how to implement screenings, help practices modify clinic flow, and discuss referral strategies.
    - Offering practitioners continuing medical education (CME) credits for participation.
- States may cover maternal depression screening for non-Medicaid eligible mothers during the well-child visit. States may also cover treatment for the mother when both

the child and the mother are present, treatment focuses on the effects of the mother's condition on the child, and services are for the direct benefit of the child.

Recommendations from professional associations

AAP Bright Futures https://www.aap.org/en-us/Documents/periodicity_schedule.pdf

- Maternal depression screening is recommended during well child checks by 1 month, 2 months, 4 months, and 6 months

ACOG, 2015 https://www.acog.org/-/media/Committee-Opinions/Committee-on-Obstetric-Practice/co630.pdf?dmc=1&ts=20180710T0405387857

- ACOG recommends screening at least once during the perinatal period for depression and anxiety symptoms using a standardized, validated tool
- Screening by itself is insufficient. It must be coupled with appropriate follow up and treatment
- Systems should be in place to ensure follow up for diagnosis and treatment

Postpartum Depression Screening

HERC Staff Summary

Screening for postpartum depression is recommended by the USPSTF and is intended to be covered on the Prioritized List, during mom's or a child's visit, and clarity is needed.

The American Academy of Pediatrics has specifically been advocating for the use of the 96161 to be used during the child's visit for maternal depression screening so clarifying this code is appropriate would be in alignment with national efforts.

The claim for maternal depression screening can be appropriately billed to mom when she is the patient, or to the infant when they are the patient.

HERC Staff Recommendations:

1. Add Z13.32 Encounter for screening for maternal depression to Line 3 (per BHAP recommendations), although pairing with this would not be necessary, any well child or postpartum visit would be appropriate pairing.
2. Add 96160, 96161, and 96127 to Line 3 (and continue to have them be Diagnostic as well)
3. Add a Guideline
   GUIDELINE NOTE XXX POSTPARTUM DEPRESSION SCREENING
   Line 3
   Postpartum depression screening using a validated instrument (e.g. Edinburgh Postpartum Severity Score, PHQ-9) is included on this line during the child's visit (CPT 96161) or during the mother's visit (CPT 96160, 96127) when there is a plan in place to address positive depression screens.
4. HSD may need to clarify that this code can be billed in addition to other screens such as developmental screening
5. Recommend to HSD to review the reimbursement rate for these codes. Other states are reimbursing between $8.67 and $15.60. The current reimbursement rates for FFS are $3.23.
6. Other parts of OHA will need to work with partners on promoting the uptake of postpartum depression screening and additional resources to ensure adequacy of follow-up and access to appropriate treatment. There are excellent examples from other states.



Clinical Guidelines for Implementing Universal Postpartum Depression Screening in Well Child Checks

Minnesota Department of Health

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Clinical Guidelines for Implementing Universal Postpartum Depression Screening in Well Child Checks

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Disclaimer: The information included in this document is for informational and educational purposes only. Users of the guidelines should not substitute information contained herein for professional judgment, nor should they rely solely on the information provided. Furthermore, this document does not reflect the optimal medical practice for all circumstances. Users are advised to seek professional counsel on the issues raised by consulting with medical staff for matters involving clinical practice.

Why screen for postpartum depression during well child checks?

Maternal postpartum depression (PPD) can have serious adverse effects on the mother and child relationship, resulting in an environment that can disrupt the infant's development. Infants who live in a neglectful or depressed setting are likely to show delays in development and impaired social interaction.

In a new clinical report by the American Academy of Pediatrics (AAP), "Incorporating Recognition and Management of Perinatal and Postpartum Depression Into Pediatric Practice," published in the November print issue of Pediatrics (published online Oct. 25), pediatric practices are encouraged to screen mothers for postpartum depression, to use community resources for the treatment and referral of the depressed mother, and to provide support for the mother-child relationship.

Estimated rates of depression among pregnant and postpartum women can range between 5 percent and 25 percent. A family history of depression, alcohol abuse and a personal history of depression increase the risk of perinatal depression. A prenatal visit in the pediatric medical home is an excellent opportunity to establish a relationship with the parents, assess for risk of depression and supports, and initiate preventive strategies. Postpartum depression can lead to increased medical costs, inappropriate medical care, discontinuation of breastfeeding and child abuse and neglect.

Screening is recommended by Bright Futures and the AAP Mental Health Task Force, and is a best practice in caring for infants and their families. (American Academy of Pediatricians, 2015).

Many mothers are screened for postpartum depression at their 6 week postpartum visit, as is recommended by the American College of Obstetricians and Gynecologists (American College of Obstetricians and Gynecologists, 2015). However, providers who deliver well child checks are likely to see the mothers more often and have an opportunity to screen for PPD during a wider range of dates. In addition, an infant is more likely to receive a 2 month well child check - 92% in Minnesota's Medicaid population in 2012 (Minnesota Department of Health, 2014) - than a mother is likely to receive a postpartum visit.

Nationally, 64% of mothers covered by a Medicaid health plan receive a postpartum care visit, compared with 82% covered by commercial health plans (Onstad, 2014).

Effective, free, relatively quick, validated screening tools exist to identify mothers at risk for postpartum depression. Treatments exist and are accessible, with great variability depending on location and insurance, for mothers to treat postpartum depression. Untreated, postpartum depression can have a negative impact on a baby's overall health and development.

Providers administering well child checks are in a key position to interact with the baby's primary caretaker and to universally screen for postpartum depression, as part of the care they provide for the child.

The consequences of maternal depression on child development

(Canadian Paediatirc Society, 2004)

- Prenatal
  - Inadequate prenatal care, poor nutrition, higher preterm birth, low birth weight, pre-eclampsia and spontaneous abortion.
- Infant
  - Behavioral: Anger and protective style of coping, passivity, withdrawal, self-regulatory behavior, and dysregulated attention and arousal
  - Cognitive: Lower cognitive performance
- Toddler
  - Behavioral: Passive noncompliance, less mature expressions of autonomy, internalizing and externalizing problems, and lower interaction
  - Cognitive: Less creative play and lower cognitive performance
- School Age
  - Behavioral: Impaired adaptive functioning, internalizing and externalizing problems, affective disorders, anxiety disorders and conduct disorders
  - Academic: Attention deficit/hyperactivity disorder and lower IQ scores
- Adolescent
  - Behavioral: Affective disorders (depression), anxiety disorders, phobias, panic disorders, conduct disorders, substance abuse and alcohol dependence
  - Academic: Attention deficit/hyperactivity disorder and learning disorders

Basic Implementation

Work Flow

In developing a work flow for implementing the PPD screen in well child checks, the key components are:

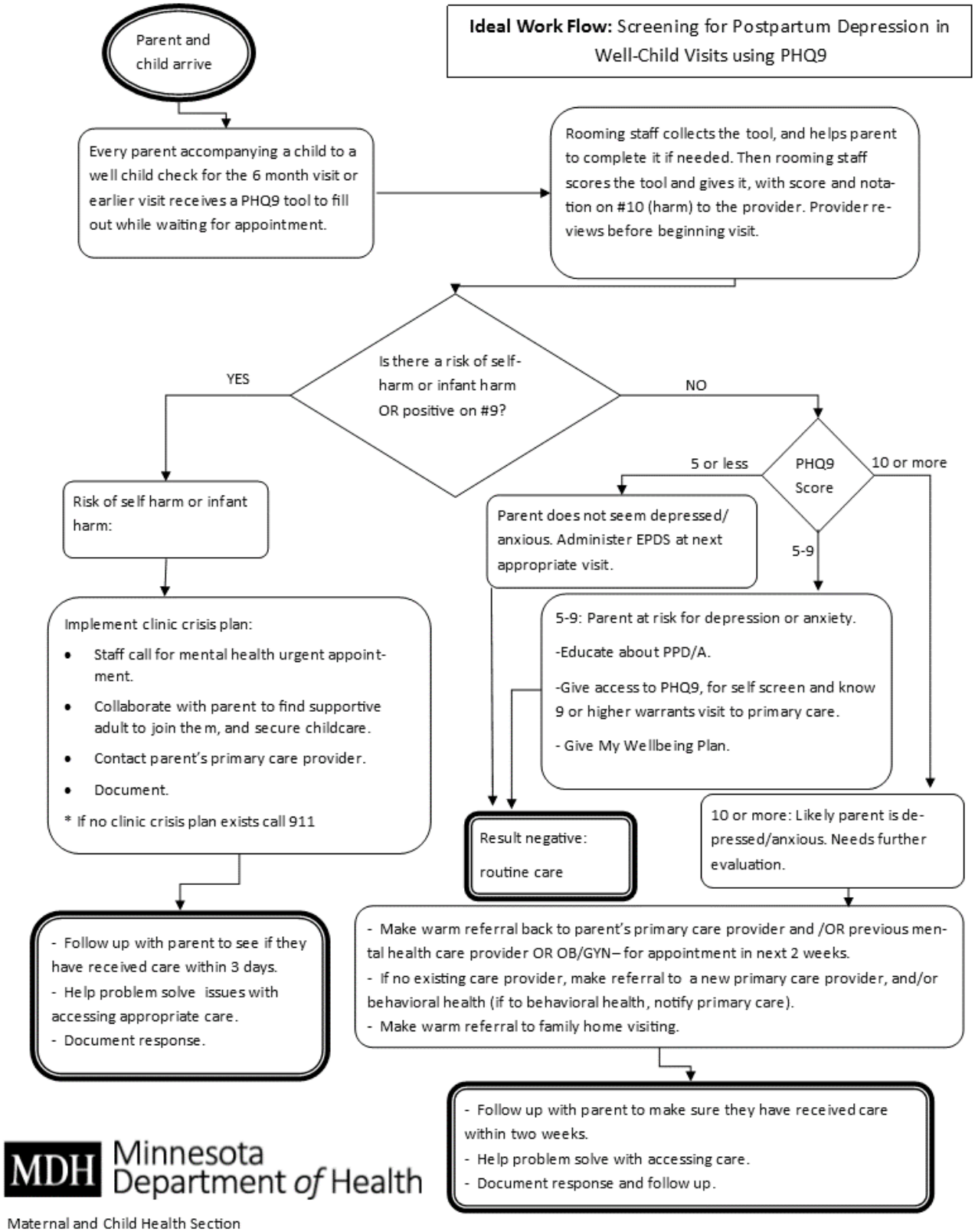
- Introduction and completion of the screen
- Provider review of score and identification of next steps
- Discussion of score and any necessary next steps with parent
- Documentation and any necessary follow up

Potential interventions that would be appropriate, depending on the score on the screening tool are:

- Very low score: Basic education regarding postpartum depression and maintaining positive mental health – Maternal Wellbeing Plan (found at http://www.health.state.mn.us/divs/cfh/topic/pmad/pmadfs.cfm)
- Mild to moderate score: Warm referral to see a provider regarding the mental health concern. Education regarding postpartum depression. Possibly other community supports.
- High or crisis score: Immediate transfer to a provider for parent. Create a plan for this process before launching universal screening.

The community resources and other interventions offered to a parent could be developed by clinic staff. They may include local public health, family home visiting, early childhood family education, and other social service supports.

Ideal Work Flow: Screening for Postpartum Depression in Well-Child Visits using PHQ9



MDH Minnesota Department *of* Health

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Oct 2015

Documenting and Charting for Postpartum Depression in Well Child Checks

When screening for postpartum depression in well child checks, the most essential documentation practices are:

- Have the results of the screen available, in the child's chart, to the child's provider.
- Document the follow up that occurs following a positive score on the screen.

Finding the right way to accomplish these two essentials can be tricky. It may be done very differently in different settings and clinical systems. There is not one "recommended" practice, but the following are ways systems have met these priorities along with HIPAA and their unique clinic/system expectations.

"Provider" refers to child's provider (not parent's).

Options	**Details**	**Advantages**	**Disadvantages**	**Clinic Types**
In the Parent's Record – Parent is in same EMR	1. Completed paper screening tool is scored, then used by provider during the well child check. 2. Well child check in record has a note that a tool was used to complete a screen. 3. Provider opens up parent's record, puts score and follow up activities in parent's record only (not child's). 4. Tool may be scanned into parent's record. 5. Internal message may be sent to parent's provider to ask them to complete necessary follow up.	• All information only in parents file, only parent and parent's provider have access. • Parent's provider can do follow up. • May get easier as technology improves.	• Parent may not have a file in system, may not pop up at future well child checks. • May take more care coordination time.	Systems where parent sees a provider in the same system, especially when provider is same for parent and baby.
In the Child's Record	1. Completed paper screening tool is scored, then used by provider during the well child check. 2. Provider/support puts information about the tool being completed, score of tool, and follow up activities into child's record. 3. Encounters in child's record are used to track follow up.	• Information regarding the child's health is readily accessible to child's provider but is not clear to all readers (i.e. using "pass" or other coded words).	Mental health information on parent is available from child's record.	Systems where parent sees a provider in the same system.

Options	Details	Advantages	Disadvantages	Clinic Types
In the Child's Record (cont.)	4. Parent's provider, if in system, can be notified through internal messaging. 5. Tool may be scanned into child's record.	• Tracking follow up from pediatric visit is easier.		
In a stand-alone file	1. Completed paper screening tool is scored, then used by provider during the well child check. 2. WCC has a note that a tool was used to complete a screen. 3. Care coordination staff put score and parent information, and follow up, into separate, stand-alone file—like Excel spread sheet. 4. Tool may be scanned into unattached folder on protected drive.	• Information on parent is not connected to child's record. • Information is available, if you know where to look.	Difficult (maybe impossible) to do flagging, reporting.	Systems where the parent is not a patient.
Send to parent's provider	1. Screening tool comes with a consent form for information to be shared with parent's provider, and spot to fill in provider information. 2. Completed paper screening tool is scored, then used by provider during the well child check. 3. WCC has a note that a tool was used to complete a screen. 4. Care coordination staff forward screen information and recommendation for follow up care to parent's provider.	• Information on parent is not connected to child's record. • Information is available, if you know where to look. • Parent will (if it works) receive follow up care from own provider.	Difficult (maybe impossible) to do flagging, reporting.	Systems where parent is not a patient.

Other interesting options include:

- Obtaining consent from the parent to put the score into the child's record.
- Upload actual screening tool into parent's chart.
- Keep parent and baby linked in medical record (may expire after a certain amount of time after birth).
- Only record if screen is high.

Scripts for Screening and Referral for PPD

Training may be helpful for all of the staff involved in administering the postpartum depression screen and needed follow up. Here are scripts that could be used. These are scripts to be used as a guide by staff and providers to discuss postpartum depression.

These scripts should NOT be given to patients. Segments of it could be adapted into written form if desired. The italics are recommended words to be used when speaking to the parent.

Please review and adapt to the needs of the families in the clinic population.

Handing out the Screen

This block could be printed on the screen:

Congratulations on your new baby! It's a big adjustment and we would like to know how you are feeling. Please check the answer that comes closest to how you have been feeling in the past 7 days, not just how you feel today.

Front desk staff: (The person handing the parent the screening tool.)

Having a baby is a big adjustment and your provider would like to check in with you and find out how you are feeling. Please fill this out, thinking about how you have been feeling over the past week. Your (nurse/medical assistant) will collect it from you in the room.

Introducing the Screen to Patients:

- PROVIDER: *As your child's provider, I'm concerned about the wellbeing of your child and so I'm also concerned about the wellbeing of the people who take care of your child. I'd like to know how you are feeling and how you have been coping. Please take a few minutes to fill out this short survey.* (OR – *Thank you for filling this out.)*

Response to a positive PPD screen:

- PROVIDER: *This is a screen for depression. I'm concerned because you have a high score. Have you been feeling down, depressed, or anxious lately?*
    - PROVIDER: *Would you be willing to see someone for help?*
        - PROVIDER: *Do you have someone you feel comfortable talking with, such as your clinician, doctor, midwife, or a therapist you already see?*

- Yes: PROVIDER: *Can we help you make an appointment?*
- No: PROVIDER: *Let's talk about who you would like to talk with.*
    - PROVIDER: *Can we help you identify a provider or connect you to a therapist?*

Follow Up Plan:

If the screen was high:

- A follow up phone call within hours or days after the initial screen was high
    - clinic should decide who will be the staff member who makes this call consistently use this staff member
- A follow up appointment with the parent's provider or therapist should take place within a week.

Follow-up Call:

- PROVIDER: *I wanted to follow up with you about the discussion we had when you were in last week. Have you been able to connect with your provider or therapist?*
    - Yes: PROVIDER: *How did everything go?*
        - Things went well: PROVIDER: *I am glad to hear that, please let us know if you need any additional information or referrals.*
        - Things did not go well: PROVIDER: *Can I help connect you to a different provider?*
    - No: PROVIDER: *What has prevented you from connecting with the referral?*
        - Try to problem solve with the parent—if wait time is long provide second referral, if require childcare/transportation provide additional information.

How to Respond to High Positive Screen:

- PROVIDER: *This is a screen for depression. Based upon your response(s) and/or our discussion, I'm worried about your wellbeing. I believe you need to see someone today. I can help you set something up right now.*
    - PROVIDER: *Let's talk about how this process will go.*
        - Discuss how clinic handles crisis- walk parent through the process, and physically have a staff member get them to emergency room, OR bring in behavioral health OR find transportation for them to emergency room.
        - It's very important that the clinic has a plan for the child while the parent receives care. Possible options in Minnesota include:
            - Clinic is connected to behavioral health/emergency room and can make arrangements for child care with family.
            - Clinic works with mom to contact Mother-Baby Program at Hennepin County Medical Center (612)873-6262, to create plan for family.

- The place where parent is being transferred does not have child care: ask parent if they have someone they can call to come and be with them, who can also watch child (mother, sister, partner)

- Help parent manage any additional responsibilities (Childcare, eldercare etc.)

If the parent says they do not want to see someone today:

- PROVDIER: *Is there a reason why you are hesitating?*
  - Listen to parent, try to help parent deal with issues around why they don't want to see someone. Try NOT to be confrontational, rather gently work with parent to help them feel safe visiting additional resources.
  - PROVIDER: *Can I call someone to be with you? (Such as your mom, partner, sister, friend etc.)*
  - If a parent absolutely refuses to seek further care today, work as hard as you can to have someone come meet them.

Follow up for High Positive Screen:
Make a follow up call to high positive screens within days or hours. Child's clinic will make call to see if the mother has connected to care. It would be best to have mother make an appointment for herself within 1 week.

If a patient refused further care, call them within 24 hours and continue trying to follow up call until reached. If having trouble reaching them use emergency contact to try and reach them (without breaking HIPAA-just ask if the emergency contact can help you reach the parent for follow up)

- *I wanted to follow up with you about the referral you received when you were in last week. Have you been able to connect with the referral?*
  - Yes: *Did everything go alright?*
    - Yes: *I am glad to hear that, please let us know if you need any additional information or referrals*
    - No: *Would you like a referral to a different provider?*
  - No: *What has prevented you from connecting with the referral?*
    - Try to problem solve with the parent—if wait time is long provide second referral, if require childcare/transportation provide additional information.

<u>Every clinic should have a Crisis Response Plan prepared. If clinic has no Crisis Resource in place at time of emergency call 911.</u>

Key Issues

Choosing Well-Child Visits for Postpartum Depression Screening

The best option for screening mothers for postpartum depression is to screen at all well child checks within the first year, or at least up to and including the 6 month check. In Minnesota, a maternal depression screen at a well child check in the first 12 months is billable, up to three times in a calendar year. It is a recommended part of a complete Child and Teen Check Up (Minnesota's Early and Periodic Screening, Diagnostic, and Treatment) in visits within the first year.

Some pediatric clinics choose specific well child checks at which to do the PPD screen. This may be useful for clinics who have significant differences between visits (i.e. other screens only done at certain visits) and but may not be helpful for clinics with patients who came for well child checks in a less than regular fashion. A practical suggestion: if you must pick only one visit (*not recommended)* than do it at the 2 month – unless you know all your moms are attending and getting screened at their 6 week postpartum visit, then do it at the 4 month.

Here are some things to consider in deciding which well child visits to do PPD screening at:

Visit	*Advantages*	*Disadvantages*	*Data*
1 or 2 week (new born)	If there is a concern, it is best to catch it as early as possible.	Most parents are still in the middle of major adjustment to the hormonal changes and generally having a baby. Concerns over anxiety or depression are expected and not out of the ordinary.	Psychosis presents itself within two weeks in 65% of all cases of postpartum psychosis. (Heron, 2007), (MGH Center, 2008), (Scotland, 2012).
2 month	• Most important time to catch this with a caregiver. • The initial "baby blues" have passed and this is the point where depression/anxiety will start to have an effect on the child. • Anxious or depressed moms and moms in low-income communities are less likely to attend their 6 week check.	Many mothers will also attend their 6 week postpartum visit, where they will (hopefully) be screened.	Children who are younger when first exposed to their mother's depression may be more vulnerable to the development of psychopathology than children not exposed until later (Goodman, 2011), (AAP, 2010).

Visit	*Advantages*	*Disadvantages*	*Data*
4 or 6 month	• If it hasn't been caught yet, this may be the last good chance to catch it and start to address the effect upon the baby. • No verified differences in screening at 4 or 6 month.	Late, so if screening here, should also be screening earlier.	There is a strong body of research on the impact of a depressed parent on children. Effects include increased risk of mood disorder in children, impaired cognitive functioning, and poor language development (Conroy, 2012) (Grace, 2003) (Zajicek-Farber, 2009) (Scotland 2012), (AAP 2010). One study suggests screening at 6 month is better than 4 (Sheeder, 2008). One study notes no significant difference (Whichman, 2010).
All visits	• Don't have to remember which visit it is. • More chances to find caregivers with concerns.	Caregiver may tire of the screen (no clear research to support this concern)	

Additional Screening Advice:

- Parents with a previous mental health history should be screened at every well-child visit.
- Parents with PPD/ or anxiety symptoms should be screened at every well-child visit.

If the provider suspects PPD/ or anxiety, parent should be screened at every well-child visit (Heron , Robertson Blackmore, McGuinness, Craddock, & Jones, 2007).

Deciding Which Tool to Use

Factors to take into consideration when selecting a validated tool to use for the postpartum depression screen:

- Is the tool specifically designed for pregnant or postpartum mothers? EPDS is, PHQ9 is not.
- Is the tool used within the medical community, outside of OB/GYN, and therefore the score and concern is easily communicated to a provider? PHQ9 is, EPDS is not.
- Are there other providers in the clinic system who have already chosen a tool to use? Is consistency in the system important?
- Is the tool billable within the state Medicaid rules? In Minnesota, the approved tools are the Beck, PHQ9, and EPDS.
- Is the tool free and easily accessible? PHQ9 and EPDS are both free.
- Is the tool available and verified, in other languages spoken in our patient population?
- Is the tool already available for use in the clinic electronic health record?

Billing

This information is from the Minnesota Department of Human Services Child & Teen Checkups Provider Guide, as of 11/30/2015. It will likely be different in other states.

When billing for a maternal depression screening, refer to the following criteria:

- Use CPT code 99420 with modifier UC.
- Use the child's MHCP recipient ID number.
- Bill it on the same claim as the C&TC screening or other pediatric visit.
- May be billed on the same date as a child's developmental screening (96110), and or a social-emotional screening (96127).

When a maternal depression screening is performed using one of the standardized screening instrument during a well-child check, and reported on the claim, that line item on the claim will be paid at our fee schedule rate. The fee schedule rate for the CPT code 99420 is $8.67.

Resources

The Minnesota Department of Health has created an information sheet and a tool for helping plan for maternal wellbeing – the Maternal Wellbeing Plan. These are available online, in 7 languages (Amharic, English, Hmong, Karen, Russian, Somali, and Spanish) at http://www.health.state.mn.us/divs/cfh/topic/pmad/.

For Parents

There are many sources for support and information regarding postpartum depression, including:

For immediate help:

Call 911 or

Crisis Connection at 866-379-6363; TTY 612-379-6377 or
Text "LIFE" to 61222 available in many rural areas.

For resources and support:

Pregnancy Postpartum Support Minnesota
Resource List: www.ppsupportmn.org
PPSM HelpLine call or TEXT to (612) 787-PPSM or PPSMhelpline@gmail.com
Support and information provided by peer volunteers 7days a week.

Mother-Baby HopeLine at Hennepin County Medical Center
(612) 873-HOPE or (612) 873-4673
Mental health support and resources. The HopeLine is not a crisis phone line.
They will call you back within 2 days.

Postpartum Support International
www.postpartum.net

For Providers

Here are a few of the resources available for providers:

Mother-Baby HopeLine at Hennepin County Medical Center:

(612) 873-HOPE or (612) 873-4673

Mental health support and resources. The HopeLine is not a crisis phone line. They will call you back within 2 days. Staffed by trained professionals with experience providing technical assistance to other providers.

Depression in Mothers: More Than the Blues

http://store.samhsa.gov/product/Depression-in-Mothers-More-Than-the-Blues/SMA14-4878

A free toolkit designed for providers who come in contact with mothers experiencing depression. It includes facts about depression, screening tools, referrals, resources and handouts for mothers who are depressed.

Substance Abuse and Mental Health Services Administration: Toolkit for providers.

Support and Training to Enhance Primary Care for Postpartum Depression (Step-PPD)

http://www.step-ppd.com/step-ppd/home.aspx

A free online training course for primary care providers designed to increase understanding of postpartum depression (PPD), and provide education on caring for women with postpartum depression. The course covers basic understanding of PPD, how to assess PPD, and how to treat PPD.

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Colorado Department of Public Health and Environment

Nationwide Initiatives on Pregnancy-Related Depression



A Summary of 16 Key Informant Interviews

June 2013

Colorado Department of Public Health and Environment

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The Colorado Maternal and Child Health Program wishes to thank the key informants nation-wide for their time and information; Marisol Erlacher, Project Consultant, for conducting and summarizing the interviews; and Colorado Department of Public Health and Environment staff members for preparation of this report.

Introduction

Pregnancy-related depression is depression that occurs either during pregnancy or up to one year postpartum. Also known as maternal, postpartum or perinatal depression, pregnancy-related depression can have devastating effects on a mother, her child and her family. The issue is complex and finding adequate support for individuals who suffer from it can be difficult.

Historically, the effects of depression during pregnancy or postpartum, or after a pregnancy loss, have been primarily associated with the mother. However, mounting evidence suggests that depression during this time in the life course also affects the child and other family members, often with delayed effects that impact the child's developmental years. In response to this body of evidence, states working on pregnancy-related depression have moved toward a more comprehensive approach to address screening, referral and treatment barriers, as well as associated stigma. From home visitation to public awareness campaigns, the experiences of these states provide a wealth of information to help others successfully tackle this challenging issue.

Background

Depression is the most common complication of pregnancy for mothers, both in Colorado and nationwide. According to Colorado's Pregnancy Risk Assessment Monitoring System (PRAMS), nearly one in every nine Colorado women who give birth (11.0 percent) will experience signs and symptoms of depression (PRAMS, 2009-2010). The Centers for Disease Control and Prevention have noted that anywhere from 8-19 percent of women nationwide report having postpartum depressive symptoms.[1]

Colorado's 2011-2015 Maternal and Child Health Block Grant needs assessment identified pregnancy-related depression as one of nine priority areas for Colorado's Maternal and Child Health program. The priority focuses on a population-level approach by promoting timely screening, referral and support for pregnancy-related depression through improvements to the health care and mental health systems. This priority also aligns with Colorado's mental health and substance abuse "winnable battle," one of 10 identified public health and environmental priorities Colorado has committed to addressing in the coming years.

The Maternal Wellness team at the Colorado Department of Public Health and Environment coordinates the state's pregnancy-related depression efforts. As a foundation for multi-year program planning, Maternal Wellness staff members identified the need to learn more about other states' experience in addressing the public health issue of pregnancy-related depression.

Method

During the summer of 2012, Colorado's Maternal Wellness team developed and administered an online survey with every state and territorial maternal child health and behavioral/mental health director. Additionally, a handful of community-based support organizations were identified and included in the survey.

[1] Centers for Disease Control and Prevention (2013). Depression among women of reproductive age. Retrieved April 2013 from http://www.cdc.gov/reproductivehealth/Depression/index.htm.

A total of 125 individuals were invited to complete the survey. The survey received 61 individual responses representing 38 separate states and territories. Of those states and territories responding, 28 reported they were implementing, or had recently implemented, initiatives focused on pregnancy-related depression. A copy of the survey can be found **here**.

Results from the survey were then reviewed to prioritize states for key informant interviews. The Pregnancy-Related Depression State Advisory Committee, comprised of experts and key stakeholders from across Colorado, helped identify the 16 most relevant states to interview. Each state was contacted to participate in a brief telephone interview with an independent contractor. Interviews were completed primarily with representatives from state health departments. However, representatives from a community-based organization, insurance provider and mental health department were also included. A list of states and representatives interviewed can be found at the end of this report. Individual state interview summaries can be found by clicking **here** to access an addendum to this report.

For the purpose of this report, the term "pregnancy-related depression" will be used to encompass postpartum depression, perinatal depression and maternal depression. Individual states may have used various terms to describe strategies, but all survey and interview questions were framed using the term pregnancy-related depression.

This report discusses the notable strategies, key themes, challenges and successes identified by states during the interviews.

Notable Strategies

The 16 state representatives interviewed discussed a variety of strategies to strengthen pregnancy-related depression screening and referral systems. Many states worked within existing programs focused on maternal and child populations to implement screening, referral and in some cases treatment, at the service delivery level. The development of cross-sector collaborations, the use of hotlines as referral resources, the training of providers and public awareness campaigns were also common strategies.

Home Visitation

For many states, work in pregnancy-related depression began with the inception of home visitation programming. Recent funding for home visitation programs through the Affordable Care Act's Maternal, Infant and Early Childhood Home Visitation program (MIECHV) expanded access to these services in many communities. States most often focused on the integration of screening and referral protocols into the existing framework. A handful of states integrated treatment into programming for mothers who screen positive for symptoms of depression, and who are receptive to a short intervention delivered by program staff members.

Iowa – This state instituted "listening visits" as part of its home visitation program. Public health nurses are trained to implement the listening visits curriculum when conducting home visits to help a mother identify at least two things causing stress in her life. These nurses then work with the new mother to develop solutions to these issues. The Edinburgh Postnatal Depression Scale is used to determine if a listening visit is indicated for a woman based on how she answered the questions. The intervention's effectiveness has been evaluated using postpartum depression screenings directly after receiving the visit and at a one month follow-up visit. On average, women's scores dropped up to 5 points after receiving the visits and continued to

decrease on future screens.

Louisiana and Massachusetts – These states have interdisciplinary teams that provide mental health support using licensed practitioners or social workers. Both states provide in-home interventions, referral and support for mothers exhibiting symptoms of depression. In Louisiana, infant mental health consultants serve a dual role of providing direct services to program participants and consulting with staff members.

Michigan – The Maternal Infant Health Program (MIHP) works in collaboration with obstetric and pediatric programs to coordinate care for mothers. MIHP is a direct-service, home visitation program that promotes healthy pregnancies to improve birth outcomes and supports the health of infants. It is administered by the Michigan Department of Community Health and available to all pregnant Medicaid beneficiaries and their infants statewide.

Healthy Start

Healthy Start is a national program funded by the Health Resources and Services Administration of the U.S. Department of Health and Human Services. The program focuses on decreasing health disparities and increasing access to health services to improve maternal and child health outcomes. Many states awarded this funding have integrated pregnancy-related depression screening and referral into program benchmarks.

Alaska – Its Healthy Start program operates in the northwest region of the state, largely comprised of Alaskan Natives/American Indians identified as experiencing high rates of perinatal and postpartum depression. The program requires perinatal and postpartum depression screenings as part of its case management and home visitation programs, and also provides community education classes that address depression and other behavioral health issues.

Florida – This state's Healthy Start program operates through 32 coalitions statewide. The program provides universal screening to pregnant women enrolled in the program, using the Edinburgh Postnatal Depression Scale.

Cross-Sector Collaborations

Driven by a lack of targeted, sustainable funding streams, public and private agencies have collaborated to move pregnancy-related depression work forward in many states. Several states organized cross-sector workgroups and collaborations as a result of state-mandated legislation. States have found ways to maximize resources by networking across government agencies, education institutions, hospitals, private practices, health insurance providers, Medicaid providers and mental health agencies. For example, partnerships with local universities allow for collaboration on research and technical assistance programming for providers. This strategy has increased awareness of pregnancy-related depression among providers, and provided a more cohesive vision for state priorities through the inclusion of diverse partners.

Vermont – The Vermont Child Health Improvement Program (VCHIP) has provided a blueprint for cross-sector collaboration. VCHIP is a 10 year-old quality improvement arm operating from the University of Vermont's College of Medicine that institutes protocols for high-quality pregnancy and postpartum care. VCHIP focuses on population-level maternal and child health services research and facilitates cross-functional partnerships between researchers, practitioners, insurers, professional organizations and government. The program empowers providers with the knowledge and skills needed to deliver high quality services and develops educational materials to better inform practitioners on how to integrate best practices into

current systems. VCHIP supports the state's focus on maternal and child health outcomes, including pregnancy-related depression.

Michigan – A group of statewide stakeholders met for several months and developed recommendations to improve access to mental health services for expectant and new mothers.

New Jersey – In 2005, this state formed a work group in collaboration with the Commissioner of Health to plan a statewide postpartum depression project in accordance with newly passed legislation.

Oregon – The Maternal Mental Health Work Group has a legislative mandate to review maternal mental health issues and develop recommendations for the legislature on how to improve statewide maternal and child mental health systems.

Hotlines

Often women and family members seek out information and referral resources in a time of crisis. For this reason, a number of states use hotlines to provide resources on pregnancy-related depression.

Illinois, Iowa, Nebraska and Missouri – These states provide guidance, support and resources to depressed mothers through a hotline staffed by volunteers, including trained mothers or professionals.

Oregon and Missouri – These states either provide specific depression-focused hotlines or work in collaboration with state-run, toll-free Maternal and Child Health information numbers to connect mothers directly with designated support hotlines and other resources.

New Jersey – A state-run, toll-free hotline provides multiple health resources for callers. Staff members screen callers and refer them to appropriate resources. Callers with insurance who desire mental health services are referred within their networks. Callers without insurance are connected to a referral source that serves uninsured clients. Three staff members are dedicated to postpartum depression phone calls.

Provider Education and Trainings

As part of the survey, states were asked to comment on technical assistance and training opportunities for providers, including how these opportunities were implemented and resulting successes. Many states developed comprehensive websites that not only provide accessible information for consumers and providers, but also serve as avenues for training. Providing continuing education credits was a critical element of successful training programs, most likely due to the incentive for the provider to attend.

Florida, Iowa, Massachusetts, Michigan, New Mexico, Nebraska and Ohio – These states use web-based trainings for providers. Florida's webinars address the varying degrees of depression and different levels of intervention available to a mother. The goal is to help providers recognize other effective and available interventions beyond medication. New Mexico has provided interactive webinar trainings on pregnancy-related depression that have reached providers in Illinois, Oklahoma and Texas.

Louisiana – This state provides an introduction to perinatal depression within a comprehensive, 36-hour continuing education program. The program provides an overview of various topics, including segments on recognizing maternal depression, its impact on infants, interventions and other high-risk/co-occurring issues, such as substance abuse and domestic

violence.

Michigan and Nebraska – Both states provide trainings that include continuing education credits. While Michigan offered continuing medical education credits for medical doctors, in addition to nursing and social worker continuing education credits, Nebraska recognized that the audience was largely comprised of nurses and social workers and chose to solely offer continuing nursing education credits. Both states' curriculums are web-based and focus on the topic of depression during and after pregnancy, as well as the importance of screening, referral and treatment. Michigan's training includes a curriculum on motivational interviewing and program intervention theories. Both initiatives measure training utilization through post-course surveys and regular reports identifying the number of users and licensure status.

Public Awareness Campaigns

Many of the states interviewed identify public awareness campaigns or consumer marketing initiatives as part of their efforts to address pregnancy-related depression. Communication channels included specialized websites, social media, informational packets and mass media, including billboards, bus ads, etc. The target audience for most efforts was general, with many states targeting moms who had suffered from pregnancy-related depression as a way to generate awareness.

Oklahoma – The Oklahoma Department of Health partnered with a local advertising agency to develop a public service announcement titled *Quicksand*. The campaign used actors of diverse ethnic backgrounds to create a visual and audio representation of symptoms associated with postpartum depression using language captured from mothers who had experienced the illness.

Nebraska – This state collaborated with local partners and a social marketing firm to develop the *Moms Reach Out Campaign*. This campaign uses a website as its communication outlet and peer stories to engage its audience.

Massachusetts – This state developed a comprehensive public awareness campaign to target providers and new parents. The *New Parent Initiative* uses peer stories from new parents and providers to build empathy, create support and share information about issues new parents may experience. Topics include parenting expectations, child development, maternal depression, substance abuse, premature birth, adoption and family planning.

Key Trends

States with successful pregnancy-related depression initiatives often had policy changes and/or legislation in place to help move the work forward. Reimbursement was also identified as a key factor in improving the uptake of screening efforts among practitioners. Additionally, recommending a screening tool (or tools) and bundling payment for depression screening with other risk factor screenings has improved the success of universal screening efforts either program-wide or system-wide.

Legislation and Policy

Numerous states have successfully leveraged legislation to increase statewide support for and impact of depression initiatives.

Illinois – *Senate Bill 15: Postpartum Mood Disorders Prevention Act,* enacted in 2008, supports the development of policies and procedures to address perinatal depression and calls for the early screening of women by health care workers. The Governor's office each year proclaims May Perinatal Mood Disorders Awareness Month, to increase the public awareness of the impact perinatal mood disorders have on mothers, children and families.

Massachusetts – In 2010, the state enacted *An Act Relative to Postpartum Depression*. This legislation developed from the Perinatal Connections Program, a grant-funded program implemented to address policy implications, programming, data collection, systems and technical assistance for maternal depression. This legislation gave the Massachusetts Department of Public Health authority to improve the screening and treatment of perinatal depression. This authority allowed the department to develop effectiveness standards for depression screening, as well as regulate data submission by providers and health insurance carriers that conduct depression screenings.

New Jersey – The 2006 *Postpartum Depression Screening Bill* requires all health care professionals who provide prenatal care to educate women about postpartum depression and obtain a history of postpartum depression prior to delivery. Additionally, the law requires facilities and providers delivering postnatal care to screen new mothers for postpartum depression when leaving the birthing facility and at the postpartum check-up. Compliance is tracked through the Electronic Birth Certificate Program.

Oregon – This state successfully used legislative efforts to address stakeholder engagement, public awareness and provider education. *House Bill 2666: Maternal Mental Health Work Group* required the development of a statewide work group on maternal mental health disorders appointed by the Department of Human Services director. The work group was charged with identifying vulnerable populations and developing recommendations for accessible and effective strategies to improve maternal mental health. *House Bill 3625: Maternal Mental Health Month* declares May as Maternal Mental Health Month in Oregon. *House Bill 2235: Maternal Mental Health Patient and Provider Education Program* created a program to deliver provider education to help prevent the associated long-term negative outcomes of depression on women, children and families. Oregon's ability to develop diverse legislation targeting a spectrum of pregnancy-related depression issues has successfully sustained momentum on improving maternal mental health.

Reimbursement for Screening

As part of the initial survey, each respondent was asked whether the state's Medicaid program had an open Current Procedural Terminology (CPT) code or International Statistical Classification of Disease and Related Health Problems (ICD) code for any of the following: postpartum depression screening, adult depression screening or general preventative screening that can include depression. The goal of this question was to identify states that had successfully tied a reimbursement code(s) to screening and further discuss how this effort supported a state's overall depression work.

Many of those surveyed were unclear on whether open reimbursement codes existed. This is likely due to the survey's outreach to public health staff members rather than those in charge of public insurance programs. However, a small sample of states noted their efforts to achieve screening reimbursement codes, and this achievement, in combination with additional state

initiatives, clearly supported the increased use of screening by providers.

Oklahoma – A qualified Medicaid practitioner who provides prenatal care services may be reimbursed for a psychosocial assessment. Any traditional Oklahoma Medicaid member or SoonerCare Choice member (the state's managed care plan) is eligible to receive the screening. The assessment includes two forms: the American Congress of Obstetricians and Gynecologist's Obstetric Medical History Form and the Oklahoma Health Care Authority's Prenatal Psychosocial Assessment Form. Providers have a reimbursement limit of one per pregnancy at a rate of $30. Medicaid members who change providers during pregnancy are limited to reimbursement for two assessments per pregnancy.

Virginia – As part of the BabyCare program, a Medicaid provider can use a universal screening form containing evidence-based questions to screen for interpersonal violence, substance abuse and maternal depression. Providers can use this screen during pregnancy and up to two years after delivery. Providers may screen under either the mother's or infant's plan, with as many as four screenings per pregnant member and four screenings per infant member per year.

Michigan – Women enrolled in the Maternal Infant Health Program, a Medicaid program for eligible pregnant women and women as much as 60 days postpartum, receive a risk identifier tool during pregnancy and immediately postpartum. This risk identifier tool includes the Edinburgh Postnatal Depression Scale and is reimbursable as part of the program.

Illinois – While not referenced on the survey, any physician or other provider enrolled in the state's Medicaid program may complete a perinatal depression screening during a prenatal, postpartum, infant well-child or episodic visit. Reimbursement is available for this screening; it is classified as a "risk assessment" at $14.60. If a mother is no longer covered under Medicaid, a provider may bill the child's Medicaid number.

Recommending Specific Screening Tools

Many of the states interviewed have conducted reviews of screening tools to improve screening standardization and increase use of evidence-based practices. The screening tool most commonly used by the states interviewed was the Edinburgh Postnatal Depression Scale.

Oklahoma and Vermont – Both states have completed studies evaluating the efficacy and relevance of the Edinburgh Postnatal Depression Scale. Vermont had a study published in the *Journal of Women's Health* illustrating that, while the professional understanding of the importance of screening has increased over time, confidence in delivering the screening has not. The article recommended training as a way to build confidence among practitioners[2].

Oklahoma – An Oklahoma work group completed a five-month pilot project using the Edinburgh Postnatal Depression Scale in clinical settings. The goal of the pilot project was to determine the efficacy and logistics of using this screening tool in clinic settings statewide. The pilot project determined that the Edinburgh Postnatal Depression Scale was the most appropriate tool due to ease of use and accessibility.

Massachusetts – The Massachusetts Department of Public Health developed the Postpartum Depression Screening Grid to help providers determine the most effective screening tool for their purposes. The grid provides a listing of appropriate screening tools for postpartum depression and includes administration, completion time, validity and electronic availability for each tool.

[2] Price, SK. et al. (2012). Perinatal depression screening and intervention: enhancing health provider involvement. *Journal of Women's Health*, 21(4), 447-455.

Bundling of Screening Assessments

Many states have been forward-thinking in the use of screening assessments by bundling depression screening with other associated risk screens. The two most notable pairings include substance abuse and domestic violence screening. Many states that bundled screening assessments were successful in obtaining reimbursement.

Louisiana – The state's Birth Outcomes Initiative is developing a screening tool entitled La HART (Louisiana Health Assessment, Referral and Treatment). This screening tool currently focuses on substance use and domestic violence, but plans are underway to add depression screening and resources.

Michigan – All Medicaid-eligible women in Michigan's Maternal Infant Health Program are administered the Edinburgh Postnatal Depression Scale, Perceived Stress Scale and T-ACE Substance Abuse Screen. These screens are embedded within the program's risk identifier tools. The results of each screening are entered into a state database and a score is generated based on an algorithm. If a woman scores moderate or high risk, a set of interventions are provided by program staff.

Virginia – The Virginia Department of Health worked with an expert panel to effectively bundle screenings. This panel was part of a grant funding requirement and included Medicaid representation. It focused on screening and referral, and determined that a triad of issues commonly co-existed with mothers: interpersonal violence, substance abuse and depression. After three years of work, the panel was able to bundle screenings and seek reimbursement for this package.

Challenges and Key Lessons Learned

As part of the interview process, key informants were asked to share challenges encountered and recommendations for addressing those challenges. The most frequent barriers noted by states in effectively addressing the issue of pregnancy-related depression were related to health care providers incorporating the issue into their practice and the stigma associated with a mental health diagnosis.

Many states noted that health care providers have not been able to appropriately assist patients suffering from pregnancy-related depression, often due to a lack of awareness and skills to support women who express symptoms. In most cases, providers respond within their professional limitations or the limitations of their respective institutions or agencies. As previously described, many states have worked diligently to provide direct educational support through face-to-face trainings or web-based curriculum. Other states have invited health care providers to join collaborative efforts to continue to disseminate information through their professional channels. Ultimately, it appears that affecting cultural change among providers may mean legislation or policy mandating screening or screening reimbursement for health care providers who work with mothers of childbearing age.

The stigma associated with mental health diagnoses is a common national theme. The stigma of mental health is even greater among postpartum women due to the pressures and expectations associated with motherhood. This stigma, along with many other existing cultural norms and expectations, has made it difficult for mothers to accept a diagnosis and follow through with treatment — a common barrier noted by many of the interviewed states. Efforts to provide varying levels of intervention allow mothers with low to moderate depression to find

relief without the need for a referral to additional mental health services. This strategy addresses both stigma and lack of referral sources.

Conclusion

A great deal of innovative work in pregnancy-related depression is taking place around the country. Work groups and collaborations have helped move the work forward, pooling resources and talents to further initiatives in creative ways. Technology has become a cost-effective and accessible way to provide information to mothers and providers in the community. Many states use websites with peer stories to reach consumers. Others have developed web-based provider training modules, including continuing education credits, to provide incentives to attend. Partnerships with state Medicaid programs and administrators have proven successful as well. Whether combined with legislation or as an individual connection, these collaborations have been key to furthering universal and standardized screening, reimbursement and data collection efforts. Despite many of the stated successes, more work needs to be done to evaluate these strategies to ensure future efforts focus on those approaches with the greatest potential to improve the rates of pregnancy-related depression among new mothers.

Addressing maternal mental health is complex, but the various examples highlighted here demonstrate a critical role for public health in bringing awareness to the issue at the population level and promoting standard screening and referral throughout health systems. Successfully addressing pregnancy-related depression today is key to improving the health and mental health of women, children and their families tomorrow.

Appendix A: List of State Interview Participants

Alaska Debra Golden	Perinatal Nurse Consultant	Alaska Department of Health and Social Services
Florida Susan Potts	Infant, Maternal and Reproductive Health	Florida Department of Health
Illinois Sarah Allen, D Clin Pysch	Founding Director and Clinical Advisor	Postpartum Depression Alliance of Illinois
Iowa Stephanie Trusty	Coordinator of Maternal Health Title V Grant	Iowa Department of Mental Health
Louisiana Paula Zeanah, PhD	Clinical Director of LA Nurse Family Partnerships (NFP)	Louisiana Office of Public Health Maternal Child Health Program
Massachusetts Karin Downs	Assistant Clinical Director MPH Director for Title V Program	Bureau of Family Health and Nutrition
Michigan Joni Detwiler, BS, SW	Public Health Consultant Maternal Infant Health	Michigan Department of Community Health
Missouri Sharmini Rogers, MPH, MBBS	Chief of Bureau of Genetics Senior and Healthy Childhood	Department of Health Services
Nebraska Kathy Karsting, RN, MPH	Program Manager	Maternal Child Adolescent Health DHHS-Division of Public Health
New Jersey Elizabeth Dahms	Public Health Consultant	NJ Department of Health
New Mexico Sharen Kimmet, RN, BSN, CCM	Nurse Case Manager	Blue Salud
Ohio Maria Himmeger	Office of Children and Families and Prevention	Ohio Department of Mental Health
Oklahoma Julie Dillard	Public Health Social Work Coordinator	Oklahoma State Department of Health
Oregon Nurit Fischler, MS	MCH Systems and Policy Specialist, Maternal and Child Health Section	Center for Prevention and Health Promotion, Oregon Health Authority
Vermont Dr. Breena Holmes	Maternal and Child Health Director	Vermont Department of Health
Virginia Joan Corder-Mabe	Program Manager for Reproductive Health Unit	Virginia Department of Health

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CMCS Informational Bulletin

DATE: May 11, 2016

FROM: Vikki Wachino, Director
Center for Medicaid and CHIP Services

SUBJECT: **Maternal Depression Screening and Treatment: A Critical Role for Medicaid in the Care of Mothers and Children**

Introduction

This Informational Bulletin discusses the importance of early screening for maternal depression and clarifies the pivotal role Medicaid can play in identifying children with mothers who experience depression and its consequences, and connecting mothers and children to the help they need. State Medicaid agencies may cover maternal depression screening as part of a well-child visit. In addition, states must cover any medically necessary treatment for the child as part of the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit.

Prevalence and Impact of Maternal Depression

Maternal depression is a serious and widespread condition that not only affects the mother, but may have a lasting, detrimental impact on the child's health. Maternal depression presents a significant early risk to proper child development, the mother-infant bond, and the family. Maternal depression screening and treatment is an important tool to protect the child from the potential adverse physical and developmental effects of maternal depression. According to the American Academy of Pediatrics (AAP), screening mothers for maternal depression is a best practice for primary care pediatricians caring for infants and their families[1] and can be integrated into the well-child care schedule, as well as included in the prenatal visit.

Maternal depression is characterized by a spectrum of severity: the common "maternity blues" or "baby blues" are usually gone after a few days or one to two weeks and are helped with reassurance and support for the mother. This is distinct from postpartum depression and post-partum psychosis (the most serious condition), which meet specific diagnostic criteria.[2] According to AAP, it has been estimated that 5 percent to 25 percent of all pregnant, postpartum and parenting women have some type of depression depending on the population surveyed. "Maternal depression" in this guidance encompasses the full spectrum of severity, not only the most severe diagnoses. Mothers who have low incomes are more likely to experience some form of depression than the general population of mothers. For low-income women, rates of depressive symptoms are reported to be between 40 percent and 60 percent.[3] There are estimates that 11 percent of infants in families with incomes below the federal poverty level live with a mother who has severe depression and that more than half (55 percent) of all infants living in poverty are being raised by mothers with some form of depression.[4]

In light of recent evidence that children living with mothers with depression may be at risk for long-term physical and behavioral health consequences, the importance of screening and treating

maternal depression is clear. As Harvard University's Center on the Developing Child indicated in 2009, children raised by a clinically depressed mothers may perform lower on cognitive, emotional, and behavioral assessments than children of non-depressed caregivers, and are at risk for later mental health problems, social adjustment difficulties, and difficulties in school.[5] The risk to the child may depend on the severity of the maternal depression, but timely screening and appropriate treatment can reduce maternal depression and its consequences.

According to the AAP, "If the maternal depression persists untreated and there is not intervention for the mother and the dyadic relationship, the developmental issues for the infant also persist and are likely to be less responsive to intervention over time." [6] Recent research shows promising results for intensive interventions that focus specifically on mother-child interactions, suggesting that treatments designed to improve child well-being must attend both to relieving the mothers' depression and focus on interactions with the child as central dimensions of the interventions. [7]

Medicaid's Role in Maternal Depression Screening and Treatment

Screening

Maternal depression screening is endorsed by several independent expert medical panels that impact services provided to Medicaid eligible children and adults. For example:

The AAP-endorsed Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents ™ is used by many states to implement their EPSDT well-child visits. Bright Futures includes recommendations for well-child visits at one week and one and two months of age, including a recommendation for "Parental (maternal) well-being," which includes a postpartum checkup, with depression and substance abuse screening. Any suggestion of depression should trigger screening questions and providers furnishing these services as part of a well-child visit are guided to refer the mother to her obstetrician or other health care professional and appropriate community-based mental health services. In terms of Medicaid coverage, covering Bright Futures recommended services as part of the preventive benefit strengthens access to these services.

In addition, the United States Preventive Services Task Force (USPSTF) recently published recommendations for screening for depression in the general adult population, including pregnant and postpartum women. [8] The recommendation was given a B grade, based on the quality and strength of the evidence about potential benefits and harm for screening for this purpose. For state Medicaid agencies, section 4106 of the Affordable Care Act (ACA) established a one percentage point increase in the Medicaid federal medical assistance percentage (FMAP) applied to expenditures for preventive services to states that cover <u>all</u> USPSTF grade A and B preventive services and the Advisory Committee on Immunization Practices (ACIP) recommended vaccines.

The EPSDT benefit is Medicaid's comprehensive child health benefit. Under the EPSDT benefit, eligible individuals under age 21 must be provided periodic screening services (well child exams).[9] One required element of this screening is a comprehensive health and developmental history, including assessment of physical and mental health development.

A maternal depression screening can be considered an integral part of a risk assessment for the child, in light of the evidence that maternal depression can place children at risk of adverse health consequences. There are several validated screening tools for depression which are simple to administer and can help identify maternal depression and potential risk to the child.[10] Some of these screening tools are specific to postpartum women and some are more general.

Some states cover maternal depression screening as part of a Medicaid well-child visit. These states may instruct providers to claim for this activity either as a service for the child or for the mother, depending on the mother's Medicaid eligibility. The Centers for Medicare & Medicaid Services (CMS) wishes to clarify that, since the maternal depression screening is for the direct benefit of the child, state Medicaid agencies may allow such screenings to be claimed as a service for the child as part of the EPSDT benefit. State Medicaid agencies have discretion to determine reimbursement approaches available to the pediatric provider for furnishing the maternal depression screening.

In keeping with the expert recommendations, several state Medicaid agencies have recognized the importance of the maternal depression screening and are allowing providers to perform and bill for this screening as part of the EPSDT well-child visit:

- *Colorado:* The Colorado Department of Health Care Policy and Financing issued Provider Bulletins with guidance on maternal depression screening. Starting January 2014, postpartum depression screening is covered as an annual depression screening and Medicaid primary care providers are encouraged to screen new mothers at a well-child visit using the mother's Medicaid ID number. To facilitate screening in more settings, providers seeing an infant for a well-baby visit are alternatively allowed to bill for the service using the Medicaid ID of the infant.[11]
- *Illinois:* The Illinois Department of Healthcare and Family Services (HFS) covers perinatal depression screening when an approved screening instrument is used. If the postpartum depression screening (for the woman) occurs during a well-child visit or episodic visit for an infant (under age one) covered by HFS' Medical Programs, the screening may be billed as a "risk assessment" under the infant's Medicaid identification number. Alternatively, if the woman is postpartum and covered by HFS' Medical Programs, the postpartum depression screening may be billed under the woman's identification number.[12]
- *North Dakota:* North Dakota Medicaid covers maternal depression screening as a separate service when performed in conjunction with a Health Tracks (EPSDT) screening or any other pediatric visit, and is considered a risk assessment for the child. Up to three maternal depression screenings are allowed for a child under the age of one. Providers are instructed to bill only when one of the standardized screening tools is used and to bill using the child's North Dakota Medicaid ID Number.[13]
- *Virginia:* Virginia covers the Behavioral Health Risks Screening Tool developed for pregnant and non-pregnant women of child-bearing age through the Maternal, Infant, and Early Childhood Home Visiting Program. The state provided information to practitioners on how to bill Medicaid for using the screening tool as well as what treatment services are available to women who screen positive. The Edinburgh Postnatal Depression Anxiety Subscale is used to address depressive symptoms and risk of co-occurring anxiety. Pregnant women are eligible for additional services, including case management

during pregnancy and up to the end of the month following their 60th day post-partum. Infants are eligible for case management services up to their second birthday.[14]

Diagnostic and Treatment Services

If a problem is identified as a result of an EPSDT screen, states have an obligation to arrange for medically necessary diagnostic and treatment services to address the child's needs.[15] Diagnostic and treatment services directed solely at the mother would be coverable under the Medicaid program only if the mother is Medicaid eligible. Mothers who are not Medicaid eligible may receive some benefit from diagnostic and treatment services directed at treating the health and well-being of the child (such as family therapy services) to reduce or treat the effects of the mother's condition on the child. Consistent with current policy regarding services provided for the "direct benefit of the child," such diagnostic and treatment services must actively involve the child, be directly related to the needs of the child and such treatment must be delivered to the child and mother together, but can be claimed as a direct service for the child. Such services also must be coverable under one or more section 1905(a) benefit categories such as rehabilitative services or other licensed practitioner services.

State Medicaid agencies should encourage the child's provider to refer mothers for other appropriate care, including diagnosis, therapy and/or medication. Mothers who are Medicaid eligible should be referred to their primary care providers or other appropriate providers. Mothers who are ineligible for Medicaid, or lose their eligibility 60 days postpartum, can be referred to community resources that offer appropriate mental health services, such as community mental health programs, federally qualified health centers or other programs that may exist in the community. For example, the Substance Abuse and Mental Health Services Administration (SAMHSA) offers a behavioral health treatment service locater at https://findtreatment.samhsa.gov/. Eligibility levels for parents in state Medicaid programs vary; in states that have taken up Medicaid's expansion of eligibility to low income adults, significantly greater number of low income mothers will be eligible and can receive comprehensive coverage than in states that have not.

The Health Resources and Services Administration (HRSA) in partnership with the Administration for Children and Families (ACF), funds states, territories and tribal entities to create home visiting evidence-based programs that improve maternal and child health, prevent child abuse and neglect, encourage positive parenting, and promote child development and school readiness. Medicaid coverage authorities offer states the flexibility to provide services in the home, which may improve care and service delivery for eligible pregnant women, parents, and young children. The majority of evidenced-based home visiting programs deliver services such as screening, case management, family support, counseling, and skills training for pregnant women and parents with young children and many of these services are also Medicaid-coverable. CMS issued an Information bulletin on March 2, 2016 describing the intersection between home visiting models and Medicaid[16].

Promoting Maternal Depression Screening Under Medicaid

Generally, experience in states has shown that there is broad agreement that communication to providers about screening tools, Medicaid billing codes, referral options and other information is

central for successful uptake and continued use.[17] States and managed care plans use a variety of approaches to promote maternal depression screening among providers, including:

- Posting information about maternal depression screening on provider websites and publishing information in provider newsletters.
- Delivering provider trainings to promote the use of maternal depression screening tools and proper billing codes.
- Conducting in-person visits to clinics to train providers on how to implement screenings, help practices modify clinic flow, and discuss referral strategies.
- Offering practitioners continuing medical education (CME) credits for participation.

States that elect to cover this service utilizing a managed care delivery system must ensure that the service is appropriately reflected in the managed care plans' contract, and can include performance standards to ensure that the service is widely performed. Activities designed to promote maternal depression screenings among Medicaid providers and to train them on how to incorporate maternal depression screening and treatment into the EPSDT well-child visit are generally eligible for Medicaid administrative matching funds.

Conclusion

Maternal depression can take a substantial toll on the health and well-being of both mothers and children, and can increase related health costs, impede the development of the child, and create negative social consequences. Maternal depression screening during the well-child visit is considered a pediatric best practice and is a simple way to identify mothers who may be suffering from depression and may lead to treatment for the child or referral for mothers to other appropriate treatment. In addition to covering this screening for Medicaid eligible mothers, states may cover maternal depression screening for non-Medicaid eligible mothers during the well-child visit. States may also cover treatment for the mother when both the child and the mother are present, treatment focuses on the effects of the mother's condition on the child, and services are for the direct benefit of the child.

States interested in learning more on this topic and to request technical assistance may contact Kirsten Jensen, Director, Division of Benefits and Coverage at Kirsten.jensen2@cms.hhs.gov.

Endnotes

[1] *Managing Maternal Depression Before and After Birth*, American Academy of Pediatrics, October 25, 2010 Managing Maternal Depression Before and After Birth, American Academy of Pediatrics, October 25, 2010 http://pediatrics.aappublications.org/cgi/reprint/peds.2010-2348v1
[2] Earls, Marian, MD. *Clinical Report – Incorporating Recognition and Management of Perinatal and Postpartum Depression into Pediatric Practice*, American Academy of Pediatrics, 2010 http://pediatrics.aappublications.org/content/early/2010/10/25/peds.2010-2348
[3] Earls, 2010
[4] Veriker, Tracey, Jennifer Macomber, and Olivia Golden, *Infants of Depressed Mothers Living in Poverty: Opportunities to Identify and Serve*, The Urban Institute. August 2010
[5] Maternal Depression Can Undermine the Development of Young Children, Working Paper 8, Center on the Developing Child, Harvard University, December 2009. http://www.developingchild.harvard.edu.

[6] Earls, 2010
[7] Center on the Developing Child, Harvard University, December 2009
[8] http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/depression-in-adults-screening1#discussion1
[9] Section 1905(r) of the Social Security Act.
[10] *Identifying and Treating Maternal Depression: Strategies and Considerations for Health Plans*, National Institute for Health Care Management Foundation, June 2010. See Table 4. http://www.nihcm.org/pdf/FINAL_MaternalDepression6-7.pdf Tools like the Edinburgh Postpartum Depression Scale and Postpartum Depression Screening Scale have been developed specifically to measure postpartum depression. As part of their recommendation to screen adults for depression in primary care settings, the USPSTF concluded that asking two simple questions, such as those included in the Patient Health Questionnaire-2, may be as effective as more formal instruments.
[11] Colorado Department of Health care Policy and Financing, Provider Bulletins: *Postpartum Depression Screenings and Payment in the Pediatric Primary Care Office* (March 2014) and *Supplement* (August 2014).
[12] *Handbook for Providers of Healthy Kids Services: Policies and Procedures for Healthcare for Children*, Illinois Department of Healthcare and Family Services, January 2015. http://hfs.illinois.gov/html/010915n.html
[13] North Dakota Department of Human Services, Medical Services Division, Medicaid Coding Guideline, effective July 1, 2011, revised June 11, 2013. https://www.nd.gov/dhs
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[15] EPSDT – *A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents*, Center for Medicaid and CHIP Services, CMS, June 2014 https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/downloads/epsdt_coverage_guide.pdf
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[17] *Reimbursement Efforts to Address Depression Among Pregnant and Postpartum Women*, Colorado Department of Public Health and the Environment, November 2013. https://www.colorado.gov/pacific/sites/default/files/PF_Reimbursement-Efforts-to-Address-Depression-Among-Pregnant-and-Postpartum-Women.pdf

MATERNAL DEPRESSION SCREENING

MEDICAID AND EPSDT COVERAGE

Overview

- On May 11, 2016, the Centers for Medicare and Medicaid Services (CMS) issued an informational bulletin on maternal depression screening and treatment, emphasizing the importance of early screening for maternal depression and clarifying the pivotal role Medicaid can play in identifying children with mothers who experience depression and its consequences, and connecting mothers and children to the help they need.

- State Medicaid agencies may cover maternal depression screening as part of a well-child visit.

- In addition to screenings, states must also cover any medically necessary treatment for the child as part of the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit. Additionally, treatment for maternal depression that includes both the child and the parent, such as family counseling, may also be paid for under EPSDT.

- While Medicaid programs are permitted to pay for these services, states must affirmatively act to implement coverage. States also have discretion regarding the procedures used to pay pediatricians for providing maternal depression screening services.

Why Should AAP Chapters Take Action?

- Maternal depression can have a lasting impact on a child's health and well-being if left untreated. When parents are depressed it can negatively impact a child's development, impede their ability to learn, and have effects that can last into adulthood.

- The Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents, 3rd Edition, recommends a postpartum checkup as part of well-child visits, including depression and substance use disorder screenings and maternal depression screenings as a best practice for pediatricians.

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- While CMS authorization to cover maternal depression screenings under EPSDT was in place prior to issuance of the bulletin, most states have not moved forward with paying pediatricians and other physicians for this service. The bulletin serves to remind states of this option while also providing stakeholders (like AAP chapters) with needed support for related advocacy work with state Medicaid programs.

What Can States Do?

- Currently, 13 state Medicaid programs (CO, DE, IA, IL, MA, MN, ND, NV, NY, OH, SC, VA, WA) already provided coverage of maternal depression screenings. While state Medicaid agencies are not required to cover maternal depression screenings, the bulletin reiterates their ability to do so. States must affirmatively act (ie, adopt policy or rules) to provide coverage of maternal depression screenings.

- States have discretion to determine the procedures used for paying pediatricians for maternal depression screenings. For example:
    - **North Dakota** Medicaid considers maternal depression screenings a risk assessment for the child and covers it as a separate service when provided in conjunction with an EPSDT screening or any other pediatric visit. Pediatricians are instructed to bill under the child's Medicaid ID.
    - Medicaid primary care physicians in **Colorado** are "encouraged" to screen new mothers at a well-child visit using the parent's Medicaid ID number, but are allowed to use the child's in instances where the mother is not enrolled;

- States are permitted to require that a specific screening tool be used in order for pediatricians to be paid. They can also limit the number of screenings allowed.

What Should Pediatric Practices Know About Providing Maternal Depression Screenings?

- As currently noted in the AAP Bright Futures and Preventive Medicine Coding Fact Sheet, CPT code 99420: administration and interpretation of health risk assessment instrument (eg, health hazard appraisal), can be used for a postpartum screening administered to a mother as part of a routine newborn check and can be billed under the child's name.

- Beginning **January 1, 2017**, 99420 will be revised and an additional new code will become effective. The AAP developed a new CPT code to allow reporting of the administration of a caregiver-focused health risk assessment (eg, maternal depression inventory) for the benefit of the patient.

- The **October 2016** issue of the AAP Coding Newsletter will include member education on appropriate reporting of the new codes.

- Because state laws, managed care contracts, and liability coverage policies vary, pediatricians are encouraged to explore any potential concerns with care offered to adults in the context of delivery of care to a pediatric patient.

What Can AAP Chapters Do?

- AAP chapters can reach out to state Medicaid programs and/or policy makers to advocate for maternal depression screening coverage and payment as part of EPSDT when provided during a child's well-visit. Implementation of coverage of depression screenings should include a plan for Medicaid agencies to communicate with physicians regarding screening tools, how to bill, options for patient referrals, etc.

- Work with state medical and specialty societies, parent and family advocates, and other stakeholders in your state to support increasing access to maternal depression screenings.

- Be aware of existing community resources to help refer parents to appropriate mental health services when necessary. This will be especially important in instances when the parent is ineligible for Medicaid coverage.

Additional Resources

- AAP Clinical Report: Incorporating Recognition and Management of Perinatal and Postpartum Depression Into Pediatric Practice
- CMS: Medicaid: Keeping Mom Healthy
- Bright Futures
- Center for Law and Social Policy: Seizing New Policy Opportunities to Help Low-Income Mothers with Depression
- AAP Division of State Government Affairs

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November 28, 2016

Dear Medical Director:

The American Academy of Pediatrics (AAP), representing over 66,000 pediatricians, pediatric medical sub-specialists and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents and young adults, is advocating for coverage and payment for new CPT codes and modifiers that are effective January 1, 2017.The AAP urges all payers to pay for health risk assessments as a separately reported service as well as live audio and video visits between the patient and the pediatrician as the same level as payment for in person office visits.

Since the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires that the "version of the medical data code sets specified in the implementation specifications must be the version that is valid at the time the health care is furnished," covered entities must incorporate the new codes into their claims processing systems by January 1, 2017. We want to inform you of these new codes and ascertain how your claims systems and payment edits will pay on claims reporting the following:

Health Risk Assessment: There will be new codes on Jan. 1 for reporting administration and scoring of a patient-centered health risk assessment and a caregiver-focused health risk assessment. Following is additional information on the new health risk assessment CPT codes:

●**96160** *Administration of patient-focused health risk assessment instrument (e.g., health hazard appraisal) with scoring and documentation, per standardized instrument.*

Code 96160 replaces code 99420 (administration and interpretation of health risk assessment instrument, e.g., health hazard appraisal) for administration of a patient-focused health risk assessment.

●**96161** *Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument*.
Code 96161 is new for 2017 and used to report use of a standardized instrument to screen for health risks in the caregiver for the *benefit* of the patient. It is intended that code 96161 will be reported to the patient's health plan as it is a service for the benefit of the patient.

In 2017 RBRVS, CMS published both codes as status 'A' (Active), with the RUC-recommended RVUs as follows:

CPT	Status	Work RVUs	Non-Facility PE RVUs	Facility PE RVUs	Mal-Practice RVUs	Total Non-Facility RVUs	Total Facility RVUs	Global
96160	A	0.00	0.13	NA	0.00	0.13	NA	ZZZ
96161	A	0.00	0.13	NA	0.00	0.13	NA	ZZZ

CMS also designated both codes as 'add on' codes (i.e., ZZZ global period), meaning that the resources expended in providing these services is not presently accounted for in the base code (i.e., E/M code) and, therefore, should be reported separately.

A common scenario in pediatrics is the administration and scoring of a caregiver-focused health risk assessment, such as a recommended routine maternal depression screen conducted for the benefit of the infant and, as of 1/1/2017 would be reported with CPT code 96161. CMS is on record of encouraging state Medicaid agencies to allow such screenings to be claimed as a service for the child as part of the EPSDT benefit. As per the attached CMS Informational Bulletin dated May 11, 2016, state Medicaid agencies have discretion to determine reimbursement approaches available to the pediatric provider for furnishing the maternal depression screening. "In keeping with the expert recommendations, several state Medicaid agencies have recognized the importance of the maternal depression screening and are allowing providers to perform and bill for this screening as part of the EPSDT well-child visit." The AAP calls upon private carriers to pay separately for CPT codes 96160 and 96161.

Moderate Sedation: There are a number of changes to the moderate sedation codes, their guidelines and relative values. These revisions accommodate a change in the practice of medicine and provide instruction regarding report of moderate sedation services to reflect clarification regarding how time is reported for these services. The changes include: 1) the deletion of the existing moderate sedation codes that identify one hour or thirty-minute sedation periods (99143, 99144, 99145, 99148, 99149, and 99150); 2) the addition of six new codes to identify thirty or fifteen-minute increments for sedation (99151, 99152, 99153, 99155, 99156, 99157); 3) revision of the accompanying guidelines (including time requirements) and parentheticals associated with the moderate sedation codes and 4) published relative values for moderate sedation.

The Academy urges all payers to provide appropriate payment for reported moderate sedation codes that reflect the total relative value of the service as shown in the table below.

2017 CMS National Physician Fee Schedule Relative Value for Moderate Sedation Codes

CPT code	Short Descrptn	Work RVUs	Non-Facility PE RVUs	Facility PE RVUs	Mal-Practice RVUs	Total Non-Facility RVUs	Total Facility RVUs	Global
99151	Mod sed same phys/qhp <5 yrs	0.50	1.63	0.12	0.05	2.18	0.67	XXX
99152	Mod sed same phys/qhp 5/>yrs	0.25	1.18	0.08	0.02	1.45	0.35	XXX
99153	Mod sed same phys/qhp ea	0.00	0.30	0.30	0.01	0.31	0.31	ZZZ
99155	Mod sed oth phys/qhp <5 yrs	1.90	0.56	0.56	0.17	2.63	2.63	XXX
99156	Mod sed oth phys/qhp 5/>yrs	1.65	0.35	0.35	0.15	2.15	2.15	XXX
99157	Mod sed other phys/qhp ea	1.25	0.27	0.27	0.11	1.63	1.63	ZZZ

Modifier 95: CPT 2017 introduces a new modifier used to indicate that services represented by specific CPT codes were provided via synchronous (real-time) communication using audio and video telecommunications. The telemedicine modifier 95 is appended only to specific CPT codes included in the new CPT Appendix P. Appendix P includes codes for services commonly performed by pediatricians, including

■■ New and established patient office or other outpatient evaluation and management services (**99201–99205**, **99212–99215**)
■■ Subsequent hospital care (**99231–99233**)
■■ Inpatient and outpatient consultations (**99241–99245**, **99251–99255**)
■■ Subsequent nursing facility care (**99307–99310**)
■■ Prolonged services in the office or outpatient setting (**99354**, **99355**)
■■ Individual behavior change interventions (**99406–99409**)
■■ Transitional care management services (**99495**, **99496**)
■■ Remote real-time interactive video-conferenced critical care codes (**0188T**, **0189T**)

The Academy encourages all payers to provide coverage benefits and pay appropriately for these new codes as separately reported services, apart from the evaluation and management service. In addition, carriers are urged to pay for services reported with Modifier 95 at the same level of payment as in person office visits. ***We request your coverage and payment policy for the above listed CPT codes and modifier.***

We look forward to your response on your coverage and payment policy for these new CPT codes. If you have questions or need additional information, please contact Lou Terranova, Senior Health Policy Analyst at lterranova@aap.org or 847-434-7633.

Sincerely,

/S/

Benard P. Dreyer, MD, FAAP
President

BPD/lt

Attachment: CMSC Informational Bulletin (May 11, 2016) *Maternal Depression Screening and Treatment: A Critical Role for Medicaid in the Care of Mothers and Children*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, MD 21244-1850

CMCS Informational Bulletin

DATE: May 11, 2016

FROM: Vikki Wachino, Director
Center for Medicaid and CHIP Services

SUBJECT: **Maternal Depression Screening and Treatment: A Critical Role for Medicaid in the Care of Mothers and Children**

Introduction

This Informational Bulletin discusses the importance of early screening for maternal depression and clarifies the pivotal role Medicaid can play in identifying children with mothers who experience depression and its consequences, and connecting mothers and children to the help they need. State Medicaid agencies may cover maternal depression screening as part of a well-child visit. In addition, states must cover any medically necessary treatment for the child as part of the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit.

Prevalence and Impact of Maternal Depression

Maternal depression is a serious and widespread condition that not only affects the mother, but may have a lasting, detrimental impact on the child's health. Maternal depression presents a significant early risk to proper child development, the mother-infant bond, and the family. Maternal depression screening and treatment is an important tool to protect the child from the potential adverse physical and developmental effects of maternal depression. According to the American Academy of Pediatrics (AAP), screening mothers for maternal depression is a best practice for primary care pediatricians caring for infants and their families[1] and can be integrated into the well-child care schedule, as well as included in the prenatal visit.

Maternal depression is characterized by a spectrum of severity: the common "maternity blues" or "baby blues" are usually gone after a few days or one to two weeks and are helped with reassurance and support for the mother. This is distinct from postpartum depression and post-partum psychosis (the most serious condition), which meet specific diagnostic criteria.[2] According to AAP, it has been estimated that 5 percent to 25 percent of all pregnant, postpartum and parenting women have some type of depression depending on the population surveyed. "Maternal depression" in this guidance encompasses the full spectrum of severity, not only the most severe diagnoses. Mothers who have low incomes are more likely to experience some form of depression than the general population of mothers. For low-income women, rates of depressive symptoms are reported to be between 40 percent and 60 percent.[3] There are estimates that 11 percent of infants in families with incomes below the federal poverty level live with a mother who has severe depression and that more than half (55 percent) of all infants living in poverty are being raised by mothers with some form of depression.[4]

In light of recent evidence that children living with mothers with depression may be at risk for long-term physical and behavioral health consequences, the importance of screening and treating

maternal depression is clear. As Harvard University's Center on the Developing Child indicated in 2009, children raised by a clinically depressed mothers may perform lower on cognitive, emotional, and behavioral assessments than children of non-depressed caregivers, and are at risk for later mental health problems, social adjustment difficulties, and difficulties in school.[5] The risk to the child may depend on the severity of the maternal depression, but timely screening and appropriate treatment can reduce maternal depression and its consequences.

According to the AAP, "If the maternal depression persists untreated and there is not intervention for the mother and the dyadic relationship, the developmental issues for the infant also persist and are likely to be less responsive to intervention over time." [6] Recent research shows promising results for intensive interventions that focus specifically on mother-child interactions, suggesting that treatments designed to improve child well-being must attend both to relieving the mothers' depression and focus on interactions with the child as central dimensions of the interventions. [7]

Medicaid's Role in Maternal Depression Screening and Treatment

Screening

Maternal depression screening is endorsed by several independent expert medical panels that impact services provided to Medicaid eligible children and adults. For example:

The AAP-endorsed Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents ™ is used by many states to implement their EPSDT well-child visits. Bright Futures includes recommendations for well-child visits at one week and one and two months of age, including a recommendation for "Parental (maternal) well-being," which includes a postpartum checkup, with depression and substance abuse screening. Any suggestion of depression should trigger screening questions and providers furnishing these services as part of a well-child visit are guided to refer the mother to her obstetrician or other health care professional and appropriate community-based mental health services. In terms of Medicaid coverage, covering Bright Futures recommended services as part of the preventive benefit strengthens access to these services.

In addition, the United States Preventive Services Task Force (USPSTF) recently published recommendations for screening for depression in the general adult population, including pregnant and postpartum women. [8] The recommendation was given a B grade, based on the quality and strength of the evidence about potential benefits and harm for screening for this purpose. For state Medicaid agencies, section 4106 of the Affordable Care Act (ACA) established a one percentage point increase in the Medicaid federal medical assistance percentage (FMAP) applied to expenditures for preventive services to states that cover <u>all</u> USPSTF grade A and B preventive services and the Advisory Committee on Immunization Practices (ACIP) recommended vaccines.

The EPSDT benefit is Medicaid's comprehensive child health benefit. Under the EPSDT benefit, eligible individuals under age 21 must be provided periodic screening services (well child exams).[9] One required element of this screening is a comprehensive health and developmental history, including assessment of physical and mental health development.

A maternal depression screening can be considered an integral part of a risk assessment for the child, in light of the evidence that maternal depression can place children at risk of adverse health consequences. There are several validated screening tools for depression which are simple to administer and can help identify maternal depression and potential risk to the child.[10] Some of these screening tools are specific to postpartum women and some are more general.

Some states cover maternal depression screening as part of a Medicaid well-child visit. These states may instruct providers to claim for this activity either as a service for the child or for the mother, depending on the mother's Medicaid eligibility. The Centers for Medicare & Medicaid Services (CMS) wishes to clarify that, since the maternal depression screening is for the direct benefit of the child, state Medicaid agencies may allow such screenings to be claimed as a service for the child as part of the EPSDT benefit. State Medicaid agencies have discretion to determine reimbursement approaches available to the pediatric provider for furnishing the maternal depression screening.

In keeping with the expert recommendations, several state Medicaid agencies have recognized the importance of the maternal depression screening and are allowing providers to perform and bill for this screening as part of the EPSDT well-child visit:

- *Colorado:* The Colorado Department of Health Care Policy and Financing issued Provider Bulletins with guidance on maternal depression screening. Starting January 2014, postpartum depression screening is covered as an annual depression screening and Medicaid primary care providers are encouraged to screen new mothers at a well-child visit using the mother's Medicaid ID number. To facilitate screening in more settings, providers seeing an infant for a well-baby visit are alternatively allowed to bill for the service using the Medicaid ID of the infant.[11]
- *Illinois:* The Illinois Department of Healthcare and Family Services (HFS) covers perinatal depression screening when an approved screening instrument is used. If the postpartum depression screening (for the woman) occurs during a well-child visit or episodic visit for an infant (under age one) covered by HFS' Medical Programs, the screening may be billed as a "risk assessment" under the infant's Medicaid identification number. Alternatively, if the woman is postpartum and covered by HFS' Medical Programs, the postpartum depression screening may be billed under the woman's identification number.[12]
- *North Dakota:* North Dakota Medicaid covers maternal depression screening as a separate service when performed in conjunction with a Health Tracks (EPSDT) screening or any other pediatric visit, and is considered a risk assessment for the child. Up to three maternal depression screenings are allowed for a child under the age of one. Providers are instructed to bill only when one of the standardized screening tools is used and to bill using the child's North Dakota Medicaid ID Number.[13]
- *Virginia:* Virginia covers the Behavioral Health Risks Screening Tool developed for pregnant and non-pregnant women of child-bearing age through the Maternal, Infant, and Early Childhood Home Visiting Program. The state provided information to practitioners on how to bill Medicaid for using the screening tool as well as what treatment services are available to women who screen positive. The Edinburgh Postnatal Depression Anxiety Subscale is used to address depressive symptoms and risk of co-occurring anxiety. Pregnant women are eligible for additional services, including case management

during pregnancy and up to the end of the month following their 60th day post-partum. Infants are eligible for case management services up to their second birthday.[14]

Diagnostic and Treatment Services

If a problem is identified as a result of an EPSDT screen, states have an obligation to arrange for medically necessary diagnostic and treatment services to address the child's needs.[15] Diagnostic and treatment services directed solely at the mother would be coverable under the Medicaid program only if the mother is Medicaid eligible. Mothers who are not Medicaid eligible may receive some benefit from diagnostic and treatment services directed at treating the health and well-being of the child (such as family therapy services) to reduce or treat the effects of the mother's condition on the child. Consistent with current policy regarding services provided for the "direct benefit of the child," such diagnostic and treatment services must actively involve the child, be directly related to the needs of the child and such treatment must be delivered to the child and mother together, but can be claimed as a direct service for the child. Such services also must be coverable under one or more section 1905(a) benefit categories such as rehabilitative services or other licensed practitioner services.

State Medicaid agencies should encourage the child's provider to refer mothers for other appropriate care, including diagnosis, therapy and/or medication. Mothers who are Medicaid eligible should be referred to their primary care providers or other appropriate providers. Mothers who are ineligible for Medicaid, or lose their eligibility 60 days postpartum, can be referred to community resources that offer appropriate mental health services, such as community mental health programs, federally qualified health centers or other programs that may exist in the community. For example, the Substance Abuse and Mental Health Services Administration (SAMHSA) offers a behavioral health treatment service locater at https://findtreatment.samhsa.gov/. Eligibility levels for parents in state Medicaid programs vary; in states that have taken up Medicaid's expansion of eligibility to low income adults, significantly greater number of low income mothers will be eligible and can receive comprehensive coverage than in states that have not.

The Health Resources and Services Administration (HRSA) in partnership with the Administration for Children and Families (ACF), funds states, territories and tribal entities to create home visiting evidence-based programs that improve maternal and child health, prevent child abuse and neglect, encourage positive parenting, and promote child development and school readiness. Medicaid coverage authorities offer states the flexibility to provide services in the home, which may improve care and service delivery for eligible pregnant women, parents, and young children. The majority of evidenced-based home visiting programs deliver services such as screening, case management, family support, counseling, and skills training for pregnant women and parents with young children and many of these services are also Medicaid-coverable. CMS issued an Information bulletin on March 2, 2016 describing the intersection between home visiting models and Medicaid[16].

Promoting Maternal Depression Screening Under Medicaid

Generally, experience in states has shown that there is broad agreement that communication to providers about screening tools, Medicaid billing codes, referral options and other information is

central for successful uptake and continued use.[17] States and managed care plans use a variety of approaches to promote maternal depression screening among providers, including:

- Posting information about maternal depression screening on provider websites and publishing information in provider newsletters.
- Delivering provider trainings to promote the use of maternal depression screening tools and proper billing codes.
- Conducting in-person visits to clinics to train providers on how to implement screenings, help practices modify clinic flow, and discuss referral strategies.
- Offering practitioners continuing medical education (CME) credits for participation.

States that elect to cover this service utilizing a managed care delivery system must ensure that the service is appropriately reflected in the managed care plans' contract, and can include performance standards to ensure that the service is widely performed. Activities designed to promote maternal depression screenings among Medicaid providers and to train them on how to incorporate maternal depression screening and treatment into the EPSDT well-child visit are generally eligible for Medicaid administrative matching funds.

Conclusion

Maternal depression can take a substantial toll on the health and well-being of both mothers and children, and can increase related health costs, impede the development of the child, and create negative social consequences. Maternal depression screening during the well-child visit is considered a pediatric best practice and is a simple way to identify mothers who may be suffering from depression and may lead to treatment for the child or referral for mothers to other appropriate treatment. In addition to covering this screening for Medicaid eligible mothers, states may cover maternal depression screening for non-Medicaid eligible mothers during the well-child visit. States may also cover treatment for the mother when both the child and the mother are present, treatment focuses on the effects of the mother's condition on the child, and services are for the direct benefit of the child.

States interested in learning more on this topic and to request technical assistance may contact Kirsten Jensen, Director, Division of Benefits and Coverage at Kirsten.jensen2@cms.hhs.gov.

Endnotes

[1] *Managing Maternal Depression Before and After Birth*, American Academy of Pediatrics, October 25, 2010 Managing Maternal Depression Before and After Birth, American Academy of Pediatrics, October 25, 2010 http://pediatrics.aappublications.org/cgi/reprint/peds.2010-2348v1
[2] Earls, Marian, MD. *Clinical Report – Incorporating Recognition and Management of Perinatal and Postpartum Depression into Pediatric Practice*, American Academy of Pediatrics, 2010 http://pediatrics.aappublications.org/content/early/2010/10/25/peds.2010-2348
[3] Earls, 2010
[4] Veriker, Tracey, Jennifer Macomber, and Olivia Golden, *Infants of Depressed Mothers Living in Poverty: Opportunities to Identify and Serve*, The Urban Institute. August 2010
[5] Maternal Depression Can Undermine the Development of Young Children, Working Paper 8, Center on the Developing Child, Harvard University, December 2009. http://www.developingchild.harvard.edu.

[6] Earls, 2010
[7] Center on the Developing Child, Harvard University, December 2009
[8] http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/depression-in-adults-screening1#discussion1
[9] Section 1905(r) of the Social Security Act.
[10] *Identifying and Treating Maternal Depression: Strategies and Considerations for Health Plans*, National Institute for Health Care Management Foundation, June 2010. See Table 4. http://www.nihcm.org/pdf/FINAL_MaternalDepression6-7.pdf Tools like the Edinburgh Postpartum Depression Scale and Postpartum Depression Screening Scale have been developed specifically to measure postpartum depression. As part of their recommendation to screen adults for depression in primary care settings, the USPSTF concluded that asking two simple questions, such as those included in the Patient Health Questionnaire-2, may be as effective as more formal instruments.
[11] Colorado Department of Health care Policy and Financing, Provider Bulletins: *Postpartum Depression Screenings and Payment in the Pediatric Primary Care Office* (March 2014) and *Supplement* (August 2014).
[12] *Handbook for Providers of Healthy Kids Services: Policies and Procedures for Healthcare for Children*, Illinois Department of Healthcare and Family Services, January 2015. http://hfs.illinois.gov/html/010915n.html
[13] North Dakota Department of Human Services, Medical Services Division, Medicaid Coding Guideline, effective July 1, 2011, revised June 11, 2013. https://www.nd.gov/dhs
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[15] EPSDT – *A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents*, Center for Medicaid and CHIP Services, CMS, June 2014 https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/downloads/epsdt_coverage_guide.pdf
[16] *Coverage of Maternal, Infant, and Early Childhood Home Visiting Services*. Center for Medicaid and CHIP Services, CMS, March 2016. https://www.medicaid.gov/federal-policy-guidance/downloads/CIB-03-02-16.pdf
[17] *Reimbursement Efforts to Address Depression Among Pregnant and Postpartum Women*, Colorado Department of Public Health and the Environment, November 2013. https://www.colorado.gov/pacific/sites/default/files/PF_Reimbursement-Efforts-to-Address-Depression-Among-Pregnant-and-Postpartum-Women.pdf

Section 10.0

Coverage Guidances

Single Fraction Radiotherapy for Palliation of Bone Metastases

Draft Coverage Guidance for VbBS Consideration

August 9, 2018

Oregon Health Authority

Oregon Health & Science University

Center For Evidence-based Policy

Background

- Cancer that has metastasized to the bones can rarely be cured, but can be treated to slow the cancer's growth and reduce pain
- Effects of bone metastases on patients' quality of life
  - Severe pain
  - Impaired mobility
  - Pathologic fractures
  - Spinal cord compression
  - Bone marrow aplasia
  - Hypercalcemia

Background

- Prostate and breast cancers cause up to 70% of bone metastases because of the high incidence and long clinical course of these cancers
- Treatment decisions for bone metastases based on
  - Type of index cancer
  - Whether bone metastases are localized or widespread
  - Evidence of extraskeletal metastases
  - Treatment history
  - Symptoms
  - Patient's general state of health

Background

- Treatments for bone metastases
  - Bisphosphonates
  - Denosumab
  - Ablation
  - Surgery
  - Radiotherapy
- Radiotherapy is an effective treatment for bone metastases
  - Pain response rate is more than 60%

Background

- Single fraction or multiple fraction radiotherapy can be used as treatment for painful bone metastases
  - More commonly used for uncomplicated bone metastases, (i.e., not at risk for imminent pathologic fracture and not causing neurologic compromise due to spinal cord compression)
- Most common single fraction treatment regimen is 8 Gy
- Common multiple fraction regimens generally deliver 2 Gy to 4 Gy doses with 5 to 10 fractions
  - Total radiation is less with single fraction compared to multiple fraction

Scope Statement

- Populations
  - Patients receiving palliative radiotherapy for painful bone metastases
- Interventions
  - Single fraction radiotherapy
- Comparators
  - Multiple fraction radiotherapy

Scope Statement

- Critical Outcomes
  - Pain
  - Morbidity associated with bone metastases (e.g., pathologic fractures, spinal cord compression)
  - Quality of life
- Important Outcomes
  - Need for retreatment
  - Harms

Evidence Sources

- Systematic reviews:
  - Rich et al. (2018) systematic review and meta-analysis compared single fraction to multiple fraction radiotherapy
  - Chow et al. (2017) systematic review compared single fraction regimens with differing doses
- Additional RCTs:
  - Westhoff et al. (2016) analyzed long-term quality of life outcomes from the Dutch Bone Metastasis Study
  - Chow et al. (2014) multicenter randomized controlled noninferiority trial compared single fraction to multiple fraction radiotherapy
  - Rudzianskiene et al. (2017) single-center RCT compared single fraction to multiple fraction radiotherapy for multiple myeloma

Evidence Review

- Rich et al. (2018) systematic review
  - Fair-quality systematic review that included 29 RCTs comparing single fraction to multiple fraction radiotherapy of uncomplicated painful bone metastases
  - Most studies compared a single treatment of 8 Gy to 30 Gy in 10 fractions, or 20 Gy in 5 fractions
  - Overall response rate
    - No statistically significantly differences between the single fraction and multiple fraction arms (61% vs. 62%, OR 0.98, 95% CI 0.95 to 1.01, p = 0.25)
  - Complete response rate
    - No statistically significant differences between the single fraction and multiple fraction arms (23% vs. 24%, OR 0.97, 95% CI 0.89 to 1.06, p = 0.55)

Evidence Review

- Rich et al. (2018) systematic review
  - Retreatment rates were statistically significantly greater in the single fraction arm compared to the multiple fraction arm (20% vs. 8%, OR 2.42, 95% CI 1.87 to 3.12, $p < 0.01$)
  - Pathologic fractures – No statistically significant differences between the single fraction and multiple fraction arms (3.6% vs. 3.0%, OR 1.21, 95% CI 0.76 to 1.95, $p = 0.08$)
  - Spinal cord compression – No statistically significant differences between the single fraction and multiple fraction arms (2.8% vs. 1.9%, OR 1.44, 95% CI 0.90 to 2.3, $p = 0.13$)

Evidence Review

- Chow et al. (2017) systematic review
  - Fair-quality systematic review comparing single fraction regimens with differing doses
  - 3 studies directly compared single fraction regimens using differing doses
    - 8 Gy single fraction regimens performed better than 4 Gy or 6 Gy single fraction regimens with respect to response rates and need for retreatment
  - The authors concluded that 8 Gy should be the standard dose for most single fraction regimens for painful bone metastases

Evidence Review

- Westhoff et al. (2016) RCT
  - Analyzed long-term quality of life outcomes from the Dutch Bone Metastasis Study
  - Compared 8 Gy single fraction radiotherapy to 6 fractions of 4 Gy in 1,157 patients with painful bone metastases between 1996 and 1998
  - Participants completed quality of life questionnaires weekly for 13 weeks after treatment and then monthly for up to 2 years
  - Comparing single fraction and multiple fraction regimens, the authors mostly found comparable quality of life outcomes
    - There was a temporary worsening of physical domain scores in the multiple fraction group in the first month after treatment that was not regarded as clinically relevant (Cohen's d effect size of 0.12 to 0.17 lower than in the single fraction group)

Evidence Review

- Chow et al. (2014) RCT
  - Multicenter noninferiority trial comparing a single 8 Gy radiotherapy treatment to a 20 Gy multiple fraction regimen for the retreatment of previously irradiated painful bone metastases
  - Overall pain response at 2 months
    - Intention to treat analysis: 28% of the patients in the single fraction arm and 32% of patients in the multiple fraction arm ($p = 0.21$, upper bound of the 95% CI 9.2%, which was within the prespecified noninferiority margin of 10%)
  - No statistically significant differences with respect to in-field pathologic fractures or spinal cord compression
  - Acute toxicities at 14 days (lack of appetite, vomiting, diarrhea, skin redness) were more common in the multiple fraction arm

Evidence Review

- Rudzianskiene et al. (2017) RCT
  - Compared 8 Gy single fraction radiotherapy to 30 Gy in 10 fractions for the treatment of multiple myeloma with painful bone lesions
  - 101 patients enrolled, 43 were randomized to the 8 Gy single fraction and 58 patients were randomized to 30 Gy in 10 fractions
  - No statistically significant differences between the single fraction and multiple fraction arms for overall response (74.4% vs. 84.5%, p = 0.2) or for complete pain response (68.8% vs. 69.4%, p = 0.952)
  - Acute toxicities did not vary between the 2 groups

Evidence Summary

- For the treatment of uncomplicated painful bone metastases, single fraction and multiple fraction treatment regimens result in similar outcomes with respect to pain relief, acute toxicity, pathologic fractures, and spinal cord compression
- Patients treated with single fraction radiotherapy are more likely to require retreatment
- 1 large RCT found no significant differences in quality of life outcomes comparing single fraction and multiple fraction regimens

GRADE Table

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Pain **(Critical outcome)**	Overall response 61% for single fraction vs. 62% for multiple fraction ARD = 1% NNT = 100 OR 0.98 (95% CI 0.95 to 1.01) ●●●● (High confidence, based on 26 RCTs, n = 6,099)

GRADE Table

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Morbidity associated with bone metastases (Critical outcome)	Pathologic fracture occurred in 3.6% of single fraction patients vs. 3.0% of multiple fraction patients ARD = 0.6% NNH = 166 OR 1.21 (95% CI 0.76 to 1.95) ●●●○ (Moderate confidence, based on 12 RCTs, n = 4,437) Spinal cord compression occurred in 2.8% of single fraction patients vs. 1.9% of multiple fraction patients ARD = 0.9% NNH = 111 OR 1.44 (95% CI 0.9 to 2.3) ●●●○ (Moderate confidence, based on 6 RCTs, n = 2,886)

GRADE Table

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Quality of life (Critical outcome)	No significant differences in quality of life ratings at up to 2 years, except for a small temporary decline in physical health domain scores during the first month after treatment for patients receiving multiple fractions (Cohen's d effect size 0.12 to 0.17) ●●●● (High confidence, based on 1 RCT, n = 1,115)
Need for retreatment (Important outcome)	Retreatment rate of 20% for single fraction vs. 8% for multiple fraction ARD = 12% NNH = 8 OR 2.42 (95% CI 1.87 to 3.12) ●●●● (High confidence, based on 16 RCTs, n = 4,950)
Harms (Important outcome)	No significant differences in rates of acute radiation toxicities ●●●◌ (Moderate confidence, based on 26 RCTs, n = 6,099)

Payer Policies

- Washington State Medicaid Program
  - No Washington Medicaid coverage policy was found for single fraction radiotherapy for bone metastases
- Medicare
  - No National Coverage Determinations or Local Coverage Determinations were identified for single fraction radiotherapy for bone metastases
- Private payers
  - Aetna, Cigna, Moda, and Regence: no coverage policies for single fraction radiotherapy for bone metastases were found

Guidelines

- 4 guidelines were identified with recommendations on single fraction radiation for bone metastases:
  - American Society for Radiation Oncology (ASTRO) guidelines on palliative radiotherapy for bone metastases
  - American College of Radiology ACR Appropriateness Criteria® on non-spine bone metastases
  - American College of Chest Physicians guidelines on symptom management for lung cancer patients
  - European Association of Urology guidelines on pain management and palliative care for patients with urologic cancers

Guidelines

- All 4 of these guidelines state
  - Single fraction radiotherapy is equivalent to multiple fraction radiotherapy in relieving pain
  - Retreatment rates are higher for single fraction versus multiple fraction radiotherapy
  - Single fraction radiotherapy is more convenient for patients
- Quality measure from ASTRO:
  - Percentage of patients, regardless of age, with a diagnosis of bone metastases and no history of previous radiation who receive external beam radiotherapy with any of the recommended fractionation schemes (i.e., 30Gy/10fxns, 24Gy/6fxns, 20Gy/5fxns, 8Gy/1fxn)

Discussion

Values and Preferences

Many patients with painful bone metastases (and their caregivers) would highly value the decreased burden of time, travel, and cost that is associated with single fraction radiotherapy. Preference for single dose treatment might be highest for patients with limited life expectancy.

Discussion

Resource Allocation

Single fraction radiotherapy is less costly than multiple fraction treatment. In addition to direct savings in procedure costs, there are potential savings in travel costs (and other costs borne by patients and families). These savings are moderated somewhat by the increased need for retreatment after single dose therapy.

Single fraction radiotherapy is nonetheless an expensive intervention that is a challenge to cover under prevailing hospice care payment methodology.

Discussion

Other Considerations

Professional society guidelines emphasize the comparable efficacy and side effects of single fraction compared to multiple fraction radiotherapy.

European Association of Urology guidelines state that single fraction radiotherapy "remains the treatment of choice for alleviating bone pain." This treatment option might be underutilized in the U.S.

Discussion

Balance of Benefits and Harms

Single fraction radiotherapy has efficacy comparable to multiple fraction treatment, with no significant differences noted in pain relief, quality of life measurements, or morbidity associated with uncomplicated bone metastases. Rates of acute radiation toxicity show no significant differences. Single fraction radiotherapy is associated with a higher need for retreatment (although retreatment with another single fraction is not inferior to retreatment with multiple fraction therapy).

Discussion

Rationale

Our recommendation for coverage of single fraction radiotherapy is based on a substantial body of evidence demonstrating comparable results to multiple fraction treatment. Single dose treatment is less costly and more convenient, making it the preferred option for many patients, and most valued by patients with limited life expectancy. Our recommendation is strong, and utilization of single fraction radiotherapy for painful bone metastases is encouraged.

Draft Coverage Guidance

Single fraction radiotherapy for palliation of bone metastases is recommended for coverage *(strong recommendation).* Single fraction radiotherapy should be given strong consideration for use over multiple fraction radiotherapy when clinically appropriate (e.g., not contraindicated by risk of imminent pathologic fracture, worsening neurologic compromise or radioresistant histologies such as sarcoma, melanoma, and renal cell carcinoma).

Health Evidence Review Commission (HERC)

Coverage Guidance:

Single Fraction Radiotherapy for Palliation of Bone Metastases

DRAFT for VbBS/HERC meetings 8/9/2018

HERC Coverage Guidance

Single fraction radiotherapy for palliation of bone metastases is recommended for coverage *(strong recommendation)*. Single fraction radiotherapy should be given strong consideration for use over multiple fraction radiotherapy when clinically appropriate (e.g., not contraindicated by risk of imminent pathologic fracture, worsening neurologic compromise or radioresistant histologies such as sarcoma, melanoma, and renal cell carcinoma).

Note: Definitions for strength of recommendation are in Appendix A. *GRADE Informed Framework Element Description*.

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Rationale for development of coverage guidances and multisector intervention reports

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as plan administrators seek to improve patient experience of care, population health, and the cost-effectiveness of health care. In the era of public and private sector health system transformation, reaching these goals requires a focus on maximizing the benefits and minimizing the harms and costs of health interventions.

HERC uses the following principles in selecting topics for its reports to guide public and private payers:

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

HERC bases its reports on a review of the best available research applicable to the intervention(s) in question. For coverage guidances, which focus on clinical interventions and modes of care, evidence is evaluated using an adaptation of the GRADE methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat, or manage disease at a population level. In some cases, HERC has reviewed evidence and identified effective interventions, but has not made formal coverage recommendations when these policies are implemented in settings other than traditional health care delivery systems because effectiveness may be dependent on the environment in which the intervention is implemented.

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GRADE-Informed Framework

HERC develops recommendations by using the concepts of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for performing the steps involved in developing recommendations. The table below lists the elements that determine the strength of a recommendation. HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Estimates of effect are derived from the evidence presented in this document. Assessments of confidence are from the published systematic reviews and meta-analyses, where available and judged to be reliable.

In some cases, no systematic reviews or meta-analyses encompass the most current literature. In those cases, HERC may describe the additional evidence or alter the assessments of confidence in light of all available information. Such assessments are informed by clinical epidemiologists from the Center for Evidence-based Policy. Unless otherwise noted, estimated resource allocation, values and preferences, and other considerations are assessments of HERC.

Should single fraction radiotherapy be recommended for coverage for painful bone metastases?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Pain *(Critical outcome)*	Overall response 61% for single fraction vs. 62% for multiple fraction ARD = 1% NNT = 100 OR 0.98 (95% CI 0.95 to 1.01) ●●●● *(High confidence, based on 26 RCTs, n = 6,099)*	Single fraction radiotherapy is less costly than multiple fraction treatment. In addition to direct savings in procedure costs, there are	Many patients with painful bone metastases (and their caregivers) would highly value the decreased burden of time,	Professional society guidelines emphasize the comparable efficacy and side effects of single fraction compared to

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Should single fraction radiotherapy be recommended for coverage for painful bone metastases?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Morbidity associated with bone metastases *(Critical outcome)*	Pathologic fracture occurred in 3.6% of single fraction patients vs. 3.0% of multiple fraction patients ARD = 0.6% NNH = 166 OR 1.21 (95% CI 0.76 to 1.95) ●●●○ *(Moderate confidence, based on 12 RCTs, n = 4,437)* Spinal cord compression occurred in 2.8% of single fraction patients vs. 1.9% of multiple fraction patients ARD = 0.9% NNH = 111 OR 1.44 (95% CI 0.9 to 2.3) ●●●○ *(Moderate confidence, based on 6 RCTs, n = 2,886)*	potential savings in travel costs (and other costs borne by patients and families). These savings are moderated somewhat by the increased need for retreatment after single dose therapy. Single fraction radiotherapy is nonetheless an expensive intervention that is a challenge to cover under prevailing hospice care payment methodology.	travel, and cost that is associated with single fraction radiotherapy. Preference for single dose treatment might be highest for patients with limited life expectancy.	multiple fraction radiotherapy. European Association of Urology guidelines state that single fraction radiotherapy "remains the treatment of choice for alleviating bone pain." This treatment option might be underutilized in the U.S.
Quality of life *(Critical outcome)*	No significant differences in quality of life ratings at up to 2 years, except for a small temporary decline in physical health domain scores during the first month after treatment for patients receiving multiple fractions (Cohen's *d* effect size 0.12 to 0.17) ●●●● *(High confidence, based on 1 RCT, n = 1,115)*			

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Should single fraction radiotherapy be recommended for coverage for painful bone metastases?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Need for retreatment *(Important outcome)*	Retreatment rate of 20% for single fraction vs. 8% for multiple fraction ARD = 12% NNH = 8 OR 2.42 (95% CI 1.87 to 3.12) ●●●● *(High confidence, based on 16 RCTs, n = 4,950)*			
Harms *(Important outcome)*	No significant differences in rates of acute radiation toxicities ●●●○ *(Moderate confidence, based on 26 RCTs, n = 6,099)*			

Balance of benefits and harms: Single fraction radiotherapy has efficacy comparable to multiple fraction treatment, with no significant differences noted in pain relief, quality of life measurements, or morbidity associated with uncomplicated bone metastases. Rates of acute radiation toxicity show no significant differences. Single fraction radiotherapy is associated with a higher need for retreatment (although retreatment with another single fraction is not inferior to retreatment with multiple fraction therapy).
Rationale: Our recommendation for coverage of single fraction radiotherapy is based on a substantial body of evidence demonstrating comparable results to multiple fraction treatment. Single dose treatment is less costly and more convenient, making it the preferred option for many patients, and most valued by patients with limited life expectancy. Our recommendation is strong, and utilization of single fraction radiotherapy for painful bone metastases is encouraged.
Recommendation: Single fraction radiotherapy for palliation of bone metastases is recommended for coverage (strong recommendation). Single fraction radiotherapy should be given strong consideration for use over multiple fraction radiotherapy when clinically appropriate (e.g., not contraindicated by risk of imminent pathologic fracture, worsening neurologic compromise or radioresistant histologies such as sarcoma, melanoma and renal cell carcinoma).

Note: GRADE-informed framework elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.

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Background

When cancer has metastasized to the bones, the cancer can rarely be cured, but often can be treated to slow its growth (Macedo et al., 2017) and reduce pain. Bone metastases can have important effects on a patient's quality of life and are characterized by severe pain, impaired mobility, pathologic fractures, spinal cord compression, bone marrow aplasia, and hypercalcemia (Macedo et al., 2017). Prostate and breast cancers cause up to 70% of bone metastases because of the high incidence and relatively long clinical course of these cancers (Macedo et al., 2017).

Treatment decisions for bone metastases depend on patient and cancer characteristics, such as the type of index cancer, whether bone metastases are localized or widespread, evidence of extraskeletal metastases, treatment history, symptoms, and the patient's general state of health (Macedo et al., 2017). Treatments for bone metastases include bisphosphonates, denosumab, ablation, surgery, and radiotherapy (Macedo et al., 2017). Radiotherapy is an effective treatment for patients with painful bone metastases: the pain response rate is more than 60% (Westhoff et al., 2016).

Indications

Single fraction or multiple fraction radiotherapy is used as a palliative treatment for patients with painful bone metastases. Uncomplicated bone metastases (i.e., not at risk for imminent pathologic fracture and not causing neurologic compromise due to spinal cord compression) can often be treated effectively with radiotherapy (Rich et al., 2018). When radiotherapy is indicated for the treatment of uncomplicated painful bone metastases, the most common single fraction treatment regimen is 8 Gy; common multiple fraction regimens generally deliver 20 to 30 Gy in five to ten fractions.

Technology Description

Single fraction radiotherapy involves one application of external radiation treatment, and multiple fraction radiotherapy involves multiple applications of external radiation treatment over time. Multiple fraction radiotherapy is generally at lower doses than single fraction radiotherapy, although the total radiation dose is higher with multiple fraction versus single fraction radiotherapy.

Evidence Review

Rich et al., 2018

Rich et al. (2018) published a recent fair-quality systematic review and meta-analysis of 29 randomized controlled trials (RCTs) comparing single and multiple fraction radiotherapy regimens for the treatment of uncomplicated painful bone metastases. This article updated a previous systematic review published in 2012 with five additional studies. Studies involving complicated bone metastases and those that used nonconventional radiotherapy modalities were excluded. The authors noted that the majority of patients in the included studies had breast or prostate cancer. Most studies compared a single treatment of 8 Gy to 30 Gy in 10 fractions, or 20 Gy in five fractions. For trials with three arms (i.e., single fraction compared to different multiple fractionation regimens), each comparison to single fraction was considered separately. The primary outcomes of interest for this review were complete response rate and overall response rate (as defined in the individual trials), and secondary outcomes included retreatment rates, pathologic fracture rates, spinal cord compression rates, and acute toxicities. Overall response was commonly defined as a two-point improvement in pain scores; complete

response was commonly defined as complete relief of pain at the treated site. The main limitation of this review is the absence of risk of bias assessments for the included studies.

In the intention-to-treat analysis for the primary outcome of overall response rate, 26 trials with more than 6,000 participants contributed to the meta-analysis. The meta-analytic odds ratio for overall response was not statistically significantly different between the single fraction and multiple fraction arms (61% for single fraction vs. 62% for multiple fraction, OR 0.98, 95% CI 0.95 to 1.01, p = 0.25). Similarly, in the 21 trials with more than 5,000 participants that contributed to the meta-analysis for complete response rate, there were no statistically significant differences between the two arms (23% for single fraction vs. 24% for multiple fraction, OR 0.97, 95% CI 0.89 to 1.06, p = 0.55).

For the secondary outcome of retreatment, 16 trials with approximately 5,000 patients showed that retreatment rates were statistically significantly greater in the single fraction arm compared to the multiple fraction arm (20% vs. 8%, OR 2.42, 95% CI 1.87 to 3.12, p < 0.01). For the 12 studies reporting on pathologic fractures (n = 4,437), there were no statistically significant differences between the two arms (3.6% for single fraction vs. 3.0% for multiple fractions, OR 1.21, 95% CI 0.76 to 1.95, p = 0.08). Similarly, for six studies reporting on spinal cord compression (n = 2,886), there were no statistically significant differences between the two arms (2.8% for single fraction vs. 1.9% for multiple fractions, OR 1.44, 95% CI 0.90 to 2.3, p = 0.13). The authors noted that there were no significant differences between the arms in the rates of acute toxicity, but cautioned that the applicable data were not collected using standardized definitions.

The authors observed that because patients with breast and prostate cancer and longer life expectancy were included in trials with longer-term follow-up, the results are applicable to patients with more favorable prognoses. In the two included trials that followed patients to 26 and 52 weeks, the durability of pain relief was similar between the single fraction and multiple fraction regimens. The authors noted that although some clinicians have expressed concern that single fraction treatment to spinal metastases could result in greater toxicity, such a selected patient population has not been prospectively studied, and the extant data does not corroborate those concerns.

The authors concluded that, consistent with previous systematic reviews on this subject, single fraction regimens produce response rates similar to multiple fraction regimens without an increase in acute toxicity, pathologic fractures, or spinal cord compression, but that patients who received single fraction treatments are more likely to require retreatment.

Chow et al., 2017

The Chow et al. (2017) fair-quality systematic review analyzed studies that compared single fraction regimens with differing doses. The authors did not perform a meta-analysis and noted that the small number of studies that used single fraction doses other than 8 Gy mean that the results must be interpreted cautiously. Only three studies directly compared single fraction regimens using differing doses. In the studies that made direct comparisons, 8 Gy single fraction regimens performed better than 4 Gy or 6 Gy single fraction regimens with respect to response rates and need for retreatment. The authors concluded that 8 Gy should be the standard dose for most single fraction regimens for painful bone metastases.

Westhoff et al., 2016

Westhoff et al. (2016) analyzed long-term quality of life outcomes derived from the Dutch Bone Metastasis Study, an RCT that compared 8 Gy single fraction radiotherapy to six fractions of 4 Gy in 1,157 patients with painful bone metastases between 1996 and 1998. Most patients in this trial had breast, prostate, or lung cancer. Participants completed quality of life questionnaires weekly for 13 weeks after treatment and then monthly for up to two years. The questionnaires were the Rotterdam Symptom Checklist, three questions on side effects of radiation therapy, and two items taken from the European Organisation for Research and Treatment of Cancer Core Quality of Life Questionnaire. Quality of life data were evaluable for 1,115 participants (96%). Components of the various questionnaires were divided into domains of physical, psychosocial, and functional quality of life. When comparing single fraction and multiple fraction regimens, the authors found comparable quality of life outcomes, except for a temporary worsening of physical domain scores in the multiple fraction group in the first month after treatment. However, the magnitude of the difference in the physical domain score (Cohen's *d* effect size of 0.12 to 0.17 lower than in the single fraction group) was not regarded as clinically relevant.

Chow et al., 2014

Chow et al. (2014) conducted a multicenter randomized controlled noninferiority trial comparing a single 8 Gy radiotherapy treatment to a 20 Gy multiple fraction regimen for the retreatment of previously irradiated painful bone metastases. The trial was not blinded. Of the 850 patients randomly assigned (1:1) to treatment groups, only 258 patients in the single fraction arm and 263 patients in the multiple fraction arm received the assigned treatment and had evaluable data at the two month follow-up. Approximately two-thirds of the enrolled patients had previously been treated with a single fraction regimen. The two groups were similar with respect to baseline characteristics. Most patients had breast, prostate, or lung cancer. In the intention-to-treat analysis of overall pain response at two months, 28% of the patients in the single fraction arm and 32% of patients in the multiple fraction arm reported an overall pain response ($p = 0.21$, upper bound of the 95% CI 9.2%, which was within the prespecified noninferiority margin of 10%). In the per-protocol analysis (which was limited to patients with evaluable data), 45% of patients in the single fraction arm and 51% of patients in the multiple fraction arm reported overall pain response ($p = 0.17$, upper bound of the 95% CI 13.2%, which exceeded the prespecified noninferiority margin of 10%). There were not statistically significant differences in quality of life between the two arms as assessed by the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-C30 at up to six months. There were no statistically significant differences between the two arms with respect to in-field pathologic fractures or spinal cord compression. Acute toxicities (lack of appetite, vomiting, diarrhea, skin redness) assessed at 14 days after treatment were more common in patients in the multiple fraction arm, but the only serious adverse event observed in the trial was an episode of myocardial ischemia that occurred in one patient in the single fraction arm 166 days after treatment. In a logistic regression analysis of the per-protocol model, there was no significant interaction between prior treatment fractionation regimen and overall pain response during retreatment.

Rudzianskiene et al., 2017

Rudzianskiene et al. (2017) conducted a single-center RCT comparing 8 Gy single fraction radiotherapy to a 30 Gy 10 fraction regimen for the treatment of multiple myeloma. Eligible patients were over age 18, had a verified diagnosis of multiple myeloma with painful bone lesions, and had a Karnofsky

performance score greater than 40%. Of the 101 patients enrolled, 58 patients were randomized to the control arm (30 Gy in 10 fractions) and 43 were randomized to the experimental arm (8 Gy single fraction). The groups were generally similar at baseline, although there were differences between the groups with respect to age, baseline pain scores, and the anatomic site of the planned treatment. For the primary outcomes of pain relief, there were no statistically significant differences between the arms for overall response (74.4% for single fraction vs. 84.5% for multiple fraction, p = 0.2), or for complete pain response (68.8% for single fraction vs. 69.4% for multiple fraction, p = 0.952). Quality of life indices, as measured by the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-C30, only showed significant improvements over baseline in the multiple fraction arm, but the authors cautioned that the imbalance in patient characteristics at baseline might explain this observation. Acute toxicities did not vary between the two groups.

Evidence Summary

Compared to multiple fraction treatment regimens, single fraction radiotherapy for the treatment of uncomplicated painful bone metastases results in similar outcomes with respect to pain relief, acute toxicity, pathologic fractures, and spinal cord compression. However, patients treated with single fraction radiotherapy are more likely to require retreatment. An analysis from one of the larger RCTs comparing multiple and single fraction regimens found no significant differences in quality of life outcomes.

Policy Landscape

Payer Coverage Policies

Medicaid

No Washington Medicaid coverage policy was found for single fraction radiotherapy for bone metastases.

Medicare

No National Coverage Determinations or Local Coverage Determinations were found for single fraction radiotherapy for bone metastases.

Private Payers

No coverage policies for single fraction radiotherapy for bone metastases were found for Aetna, Cigna, Moda, or Regence.

Recommendations from Others

Four guidelines were identified that include recommendations about the use of single fraction radiation for bone metastases:

- American Society for Radiation Oncology (ASTRO) guidelines on palliative radiotherapy for bone metastases (Lutz et al., 2017)
- American College of Radiology ACR Appropriateness Criteria® on non-spine bone metastases (American College of Radiology, 214)
- American College of Chest Physicians on symptom management for lung cancer patients (Simoff et al., 2013)

- European Association of Urology published on pain management and palliative care for patients with urologic cancers (Paez Borda et al., 2014)

All four of these guidelines state that single fraction radiotherapy is equivalent to multiple fraction radiotherapy in relieving pain, retreatment rates are higher for single fraction versus multiple fraction radiotherapy, and single fraction radiotherapy is more convenient for patients. More details on these guidelines are provided below.

The ASTRO guidelines conclude that:

- An updated review of high-quality data continues to show pain relief equivalency following a single 8 Gy fraction, 20 Gy in 5 fractions, 24 Gy in 6 fractions, and 30 Gy in 10 fractions for patients with previously unirradiated painful bone metastases. Patients should be made aware that single fraction radiotherapy is associated with a higher incidence of retreatment to the same painful site than is fractionated treatment.
- A single 8 Gy fraction provides noninferior pain relief compared with a more prolonged radiotherapy course in painful spinal sites and may therefore be particularly convenient and sensible for patients with limited life expectancy.
- There continues to be no suggestion from available high-quality data that single fraction radiotherapy produces unacceptable rates of long-term side effects that might limit its use for patients with painful bone metastases. The evidence regarding an association between higher risk for pathologic fracture after single fraction radiotherapy versus fractionated therapy remains equivocal.
- The panel reiterates that the use of surgery, radionuclides, bisphosphonates, or kyphoplasty/vertebroplasty does not obviate the need for radiotherapy for patients with painful bone metastases, although 2 recent trials have suggested the potential for similar, albeit less rapid, bone pain relief in prostate cancer patients following an infusion of ibandronate when compared with a single fraction radiotherapy.

The strength of evidence for each of these recommendations from the ASTRO guidelines is either moderate or high, and the strength of recommendation is strong for all of the recommendations.

The American College of Radiology last reviewed the guidelines on non-spine bone metastases in 2014 and concluded that:

- Prospective randomized trials have proven equivalent pain relief with varied fractionation schemes, including 8 Gy in 1 fraction, 20 Gy in 5 fractions, 24 Gy in 6 fractions, or 30 Gy in 10 fractions. Prolonged courses are associated with a lower incidence of retreatment, although shorter courses maximize patient and caregiver convenience by reducing the number of trips to the radiation department.
- Patients who undergo surgical stabilization for impending or completed pathologic fracture of a long bone may be treated with postoperative radiotherapy to 30 Gy in 10 fractions, 24 Gy in 6 fractions, 20 Gy in 5 fractions, or 8 Gy in a single fraction.

The American College of Chest Physicians published guidelines in 2013 that recommended external radiation therapy for lung cancer patients who have pain due to bone metastases. The guidelines concluded that a single fraction of 8 Gy is equally effective for immediate relief of pain as higher fractionated doses of external radiation therapy. In addition, single-fraction radiotherapy is less

expensive than multiple fraction radiotherapy, more cost-effective, and more convenient from the patient's perspective.

The European Association of Urology 2014 guidelines on pain management and palliative care for patients with urologic cancers rated the level of evidence (LE) for recommendations using these categories:

1a: Evidence obtained from meta-analysis of randomized trials
1b: Evidence obtained from at least one randomized trial
2a: Evidence obtained from one well-designed controlled study without randomization
2b: Evidence obtained from at least one other type of well-designed quasi-experimental study
3: Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies, and case reports
4: Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities

The European Association of Urology guidelines include these recommendations on treatment for bone metastases:

- Single-fraction radiotherapy is as effective as multiple fraction radiotherapy in relieving metastatic bone pain (LE: 1a).
- The rates of retreatment and pathologic fractures are significantly higher after single fraction radiotherapy (LE: 1a).
- Single-fraction radiotherapy remains the treatment of choice for alleviating bone pain because of its greater convenience for patients (LE: 1a), faster patient turnover for the radiotherapy unit, and lower costs (LE: 3); the recommended dose is 8 Gy (LE: 1a).
- Pain relief can be achieved with lower doses (LE: 1b), and these lower doses should be borne in mind if a third retreatment is necessary, or if there is concern about radiation tolerance (LE: 2b).

Quality Measures

Two quality measures were identified when searching the National Quality Measures Clearinghouse for single fraction radiotherapy for bone metastases.

In 2017, the American Society of Radiation Oncology developed a quality measure on the use of radiotherapy for bone metastases: the percentage of patients, regardless of age, with a diagnosis of bone metastases and no history of previous radiation who receive external beam radiotherapy with any of the recommended fractionation schemes (i.e., 30Gy/10fxns, 24Gy/6fxns, 20Gy/5fxns, 8Gy/1fxn).

The RAND Corporation quality measure developed in 2010 recommended offering single fraction radiation: percentage of patients with advanced cancer who received radiation treatment for painful bone metastases for whom single fraction radiation was offered, or there was documentation of a contraindication to single fraction treatment.

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Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

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Appendix A. GRADE-Informed Framework Element Descriptions

Element	Description
Balance of benefits and harms	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. An estimate that is not statistically significant or has a confidence interval crossing a predetermined clinical decision threshold will be downgraded.
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed in the absence of likely cost offsets—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted
Other considerations	Other considerations include issues about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.

Strong recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors., but further research or additional information could lead to a different conclusion.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the balance of benefits and harms, cost and resource allocation, and values and preferences, but further research or additional information could lead to a different conclusion.

Confidence in estimate rating across studies for the intervention/outcome

Assessment of confidence in estimate includes factors such as risk of bias, precision, directness, consistency and publication bias.

High: The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

Moderate: The subcommittee is moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical

sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

Low: The subcommittee's confidence in the estimate of effect is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

Very low: The subcommittee has very little confidence in the estimate of effect: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

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Appendix B. GRADE Evidence Profile

Quality Assessment (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Pain							
26	RCT	Unclear[1]	Not serious	Not serious	Not serious		High ●●●●
Morbidity							
12 (pathologic fracture) 6 (spinal cord compression)	RCT	Unclear[1]	Not serious	Not serious	Serious[2]		Moderate ●●●○
Quality of life							
1	RCT	Low	N/A	Not serious	Not serious		High ●●●●
Need for retreatment							
16	RCT	Unclear[1]	Not serious	Not serious	Not serious		High ●●●●
Harms							
26	RCT	Unclear[1]	Not serious	Not serious	Not serious		High ●●●●

[1]The systematic review that informed this estimate did not provide individual or overall risk of bias assessments.

[2]The 95% confidence interval cannot exclude clinically meaningful benefits or harms.

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Appendix C. Methods

Scope Statement

Populations

Patients receiving palliative radiotherapy for painful bone metastases

Population scoping notes: None

Interventions

Single fraction radiotherapy

Intervention exclusions: None

Comparators

Multiple fraction radiotherapy

Outcomes

Critical: Pain, morbidity associated with bone metastases (e.g., pathologic fractures, spinal cord compression), quality of life

Important: Need for retreatment, harms

Considered but not selected for the GRADE table: None

Key Questions

KQ1: What is the comparative effectiveness of single fraction radiotherapy for palliation of painful bone metastases?

KQ2: Does the effectiveness of single fraction radiotherapy for painful bone metastases vary by:

a. Patient characteristics (e.g., expected length of life)
b. Type of cancer
c. Total planned dose of radiotherapy
d. Number of treatment sites
e. Location of sites

KQ3: What are the harms of single fraction radiotherapy for palliation of painful bone metastases?

Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, and technology assessments that met the criteria for the scope described above. Searches of core sources were limited to citations published after 2013.

The following core sources were searched:

Agency for Healthcare Research and Quality (AHRQ)
Canadian Agency for Drugs and Technologies in Health (CADTH)
Cochrane Library (Wiley Online Library)
Institute for Clinical and Economic Review (ICER)
Medicaid Evidence-based Decisions Project (MED)

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National Institute for Health and Care Excellence (NICE)
Tufts Cost-effectiveness Analysis Registry
Veterans Administration Evidence-based Synthesis Program (ESP)
Washington State Health Technology Assessment Program

A MEDLINE® search was also conducted to identify systematic reviews, meta-analyses, and technology assessments, using the search terms for single fraction and bone metastases. The search was limited to publications in English published since 2013. In addition, a MEDLINE® search was conducted for randomized controlled trials published after the search dates of the most recent systematic review selected for each indication.

Searches for clinical practice guidelines were limited to those published since 2013. A search for relevant clinical practice guidelines was also conducted using MEDLINE® and the following sources:

Australian Government National Health and Medical Research Council (NHMRC)
Canadian Agency for Drugs and Technologies in Health (CADTH)
Centers for Disease Control and Prevention (CDC) – Community Preventive Services
National Guidelines Clearinghouse
National Institute for Health and Care Excellence (NICE)
Scottish Intercollegiate Guidelines Network (SIGN)
United States Preventive Services Task Force (USPSTF)
Veterans Administration/Department of Defense (VA/DoD) Clinical Practice Guidelines

Inclusion/Exclusion Criteria

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, randomized controlled trials, or clinical practice guidelines.

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Appendix D. Applicable Codes

CODES	DESCRIPTION
CPT Codes	
77261-77263	Therapeutic radiology treatment planning
77280, 77285, 77290	Therapeutic radiology simulation-aided field setting
77300	Basic radiation dosimetry calculation
77306-77307	Teletherapy isodose plan
77331	Special dosimetry
77332-77334	Treatment devices, design and construction
77336,77370	Medical physics consultation
77401-77416	Radiation treatment delivery
77417	Port verification films/electronic portal imaging for verification
77431	Radiation therapy management, complete course of therapy consisting of one or two fractions
HCPCS Level II Codes	
G6003-G6014	Radiation treatment delivery
ICD-10-PCS Codes	
DP00-DP0C	Beam radiation of bone
ICD-10-CM Codes	
C79.51	Secondary malignant neoplasm of bone
Z51.5	Encounter for palliative care

Note: Inclusion on this list does not guarantee coverage.

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CG: Single Fraction Radiotherapy for Palliation of Bone Metastases

Question: How should the draft Coverage Guidance **Single Fraction Radiotherapy for Palliation of Bone Metastases** be applied to the Prioritized List?

Question source: HERC Staff, HTAS

Issue:
The HTAS approved the following draft "box language":

Single fraction radiotherapy for palliation of bone metastases is recommended for coverage *(strong recommendation)*. Single fraction radiotherapy should be given strong consideration for use over multiple fraction radiotherapy when clinically appropriate (e.g., not contraindicated by risk of imminent pathologic fracture, worsening neurologic compromise or radioresistant histologies such as sarcoma, melanoma, and renal cell carcinoma).

Rationale for Recommendations

Both single fraction and multiple fraction radiotherapy are used as palliative treatments for patients with painful bone metastases. Uncomplicated bone metastases (i.e., not at risk for imminent pathologic fracture and not causing neurologic compromise due to spinal cord compression) can often be treated effectively with radiotherapy.

Single fraction radiotherapy has efficacy comparable to multiple fraction treatment, with no significant differences noted in pain relief, quality of life measurements, or morbidity associated with uncomplicated bone metastases. Rates of acute radiation toxicity show no significant differences. Single fraction radiotherapy is associated with a higher need for retreatment, but retreatment with another single fraction is not inferior to retreatment with multiple fraction therapy.

Our recommendation for coverage of single fraction radiotherapy is based on a substantial body of evidence demonstrating comparable results to multiple fraction treatment. Single dose treatment is less costly and more convenient, making it the preferred option for many patients, and most valued by patients with limited life expectancy. Our recommendation is strong, and utilization of single fraction radiotherapy for painful bone metastases is encouraged.

Current Prioritized List Status: Codes

Applicable diagnostic and procedural codes related to radiation therapy services are found on multiple cancer lines (and on some non-cancer lines, as well). The recommendation in this coverage guidance will not change placement of these codes.

CODES	DESCRIPTION	Current placement
CPT Codes		
77261-77263	Therapeutic radiology treatment planning	Various cancer lines with radiation treatment
77280, 77285, 77290	Therapeutic radiology simulation-aided field setting	Various cancer lines with radiation treatment

77300	Basic radiation dosimetry calculation	Various cancer lines with radiation treatment
77306-77307	Teletherapy isodose plan	Various cancer lines with radiation treatment
77331	Special dosimetry	Various cancer lines with radiation treatment
77332-77334	Treatment devices, design and construction	Various cancer lines with radiation treatment
77336,77370	Medical physics consultation	Various cancer lines with radiation treatment
77401-77416	Radiation treatment delivery	Various cancer lines with radiation treatment
77417	Port verification films/electronic portal imaging for verification	Various cancer lines with radiation treatment
77431	Radiation therapy management, complete course of therapy consisting of one or two fractions	Various cancer lines with radiation treatment
HCPCS Level II Codes		
G6003-G6014	Radiation treatment delivery	Various cancer lines with radiation treatment
ICD-10-PCS Codes		
DP00-DP0C	Beam radiation of bone	
ICD-10-CM Codes		
C79.51	Secondary malignant neoplasm of bone	Line 201 CANCER OF BONES
Z51.5	Encounter for palliative care	Diagnostic Workup File

Current Prioritized List Guidelines:

GUIDELINE NOTE 12, TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT

Lines 93,112-116,125,129,133,135,157,158,163,179,191,200,201,209,211,215,216,218,230, 235,238,239,259-263,271,276,286,287,294,314-316,329,372,396,397,418,433,589,600

Cancer is a complex group of diseases with treatments that vary depending on the specific subtype of cancer and the patient's unique medical and social situation. Goals of appropriate cancer therapy can vary from intent to cure, disease burden reduction, disease stabilization and control of symptoms. Cancer care must always take place in the context of the patient's support systems, overall heath, and core values. Patients should have access to appropriate peer-reviewed clinical trials of cancer therapies. A comprehensive multidisciplinary approach to treatment should be offered including palliative care services (see STATEMENT OF INTENT 1, PALLIATIVE CARE).

Treatment with intent to prolong survival is not a covered service for patients who have progressive metastatic cancer with

A) Severe co-morbidities unrelated to the cancer that result in significant impairment in two or more major organ systems which would affect efficacy and/or toxicity of therapy; OR

B) A continued decline in spite of best available therapy with a non reversible Karnofsky Performance Status or Palliative Performance score of <50% with ECOG performance status of 3 or higher which are not due to a pre-existing disability.

Treatments with intent to relieve symptoms or improve quality of life are covered as defined in STATEMENT OF INTENT 1, PALLIATIVE CARE.
Examples include:

A) Single-dose radiation therapy for painful bone metastases with the intent to relieve pain and improve quality of life.
B) Surgical decompression for malignant bowel obstruction.
C) Medication therapy such as chemotherapy with low toxicity/low side effect agents with the goal to decrease pain from bulky disease or other identified complications. Cost of chemotherapy and alternative medication(s) should also be considered.

To qualify for treatment coverage, the cancer patient must have a documented discussion about treatment goals, treatment prognosis and the side effects, and knowledge of the realistic expectations of treatment efficacy. This discussion may take place with the patient's oncologist, primary care provider, or other health care provider, but preferably in a collaborative interdisciplinary care coordination discussion. Treatment must be provided via evidence-driven pathways (such as NCCN, ASCO, ASH, ASBMT, or NIH Guidelines) when available.

STATEMENT OF INTENT 1: PALLIATIVE CARE

It is the intent of the Commission that palliative care services are covered for patients with a life-threatening or serious progressive illness to alleviate symptoms and improve quality of life.

Palliative care services should include culturally appropriate discussions and medical decision making aligned with patient's personal goals of therapy, assessment of symptom burden, assistance with advance care planning, care coordination, emotional, psychosocial and spiritual support for patients and their families. Palliative care services may be provided concurrently with life prolonging/curative treatments.

Some examples of services associated with an encounter for palliative care (ICD-10 Z51.5) that should be available to patients without regard to Prioritized List line placement:

A) Inpatient palliative care consultations
    1) Hospital Care E&M (CPT 99218-99233)
B) Outpatient palliative care consultations provided in either the office or home setting
    1) E&M Services (CPT 99201-99215)
    2) Transitional Care Management Services (CPT 99495-6)
    3) Advance Care Planning (CPT 99497-8)
    4) Chronic Care Management (CPT 99487-99490)
C) Psychological support and grief counseling (CPT 99201-99215)
D) Medical equipment and supplies for the management of symptomatic complications or support activities of daily living
E) Medications or acupuncture to reduce pain and symptom burden
F) Surgical procedures or therapeutic interventions to relieve pain or symptom burden

Other services associated with palliative care includes:

A) Social Work
B) Clinical Chaplain/ Spiritual Care
C) Care Coordination

It is NOT the intent of the Commission that coverage for palliative care encompasses those treatments that seek to prolong life despite substantial burdens of treatment and limited chance of benefit. See Guideline Note 12 TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT.

HERC Staff Recommendations:

1) Revise Guideline Note 12, as follows:

GUIDELINE NOTE 12, PATIENT-CENTERED CARE OF ADVANCED CANCER ~~TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT~~

Cancer is a complex group of diseases with treatments that vary depending on the specific subtype of cancer and the patient's unique medical and social situation. Goals of appropriate cancer therapy can vary from intent to cure, disease burden reduction, disease stabilization and control of symptoms. Cancer care must always take place in the context of the patient's support systems, overall heath, and core values. Patients should have access to appropriate peer-reviewed clinical trials of cancer therapies. A comprehensive multidisciplinary approach to treatment should be offered including palliative care services (see STATEMENT OF INTENT 1, PALLIATIVE CARE).

Treatment with intent to prolong survival is not a covered service for patients who have progressive metastatic cancer with

A) Severe co-morbidities unrelated to the cancer that result in significant impairment in two or more major organ systems which would affect efficacy and/or toxicity of therapy; OR

B) A continued decline in spite of best available therapy with a non-reversible Karnofsky Performance Status or Palliative Performance score of <50% with ECOG performance status of 3 or higher which are not due to a pre-existing disability.

Treatments with intent to relieve symptoms or improve quality of life are covered as defined in STATEMENT OF INTENT 1, PALLIATIVE CARE.
Examples include:

A) Single-dose radiation therapy for painful bone metastases with the intent to relieve pain and improve quality of life. Single fraction radiotherapy should be given strong consideration for use over multiple fraction radiotherapy when clinically appropriate (e.g., not contraindicated by risk of imminent pathologic fracture, worsening neurologic compromise or radioresistant histologies such as sarcoma, melanoma, and renal cell carcinoma).

B) Surgical decompression for malignant bowel obstruction.

C) Medication therapy such as chemotherapy with low toxicity/low side effect agents with the goal to decrease pain from bulky disease or other identified complications. Cost of chemotherapy and alternative medication(s) should also be considered.

To qualify for treatment coverage, the cancer patient must have a documented discussion about treatment goals, treatment prognosis and the side effects, and knowledge of the realistic expectations of treatment efficacy. This discussion may take place with the patient's oncologist, primary care provider, or other health care provider, but preferably in a collaborative interdisciplinary care coordination discussion. Treatment must be provided via evidence-driven pathways (such as NCCN, ASCO, ASH, ASBMT, or NIH Guidelines) when available.

The development of the single fraction radiotherapy portion of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx.

2) Revise Statement of Intent 1, as follows:

STATEMENT OF INTENT 1: PALLIATIVE CARE

It is the intent of the Commission that palliative care services are covered for patients with a life-threatening or serious progressive illness to alleviate symptoms and improve quality of life.

Palliative care services should include culturally appropriate discussions and medical decision making aligned with patient's personal goals of therapy, assessment of symptom burden, assistance with advance care planning, care coordination, emotional, psychosocial and spiritual support for patients and their families. Palliative care services may be provided concurrently with life prolonging/curative treatments.

Some examples of services associated with an encounter for palliative care (ICD-10 Z51.5) that should be available to patients without regard to Prioritized List line placement:

G) Inpatient palliative care consultations
   1) Hospital Care E&M (CPT 99218-99233)
H) Outpatient palliative care consultations provided in either the office or home setting
   1) E&M Services (CPT 99201-99215)
   2) Transitional Care Management Services (CPT 99495-6)
   3) Advance Care Planning (CPT 99497-8)
   4) Chronic Care Management (CPT 99487-99490)
I) Psychological support and grief counseling (CPT 99201-99215)
J) Medical equipment and supplies for the management of symptomatic complications or support activities of daily living
K) Medications or acupuncture to reduce pain and symptom burden
L) Surgical procedures or therapeutic interventions (for example, palliative radiation therapy) to relieve pain or symptom burden

Other services associated with palliative care includes:

D) Social Work
E) Clinical Chaplain/ Spiritual Care
F) Care Coordination

It is NOT the intent of the Commission that coverage for palliative care encompasses those treatments that seek to prolong life despite substantial burdens of treatment and limited chance of benefit. See Guideline Note 12 PATIENT-CENTERED CARE OF ADVANCED CANCER. ~~TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT~~.

3) No change in Prioritized List placement of radiation therapy services is recommended based on this coverage guidance.

HERC Coverage Guidance: Single Fraction Radiotherapy for Palliation of Bone Metastases
Disposition of Public Comments

Commenters

Identification	Stakeholder
	No public comments were received

DRAFT

Health Evidence Review Commission (HERC)

Coverage Guidance:

Urine Drug Testing

DRAFT for VbBS/HERC meeting materials 8/9/2018

HERC Coverage Guidance

Urine drug testing (UDT) using presumptive testing is recommended for coverage (*weak recommendation*) when the results will affect treatment planning.

Definitive testing is recommended for coverage as a confirmatory test only when the result of the presumptive testing is inconsistent with the patient's history, presentation, or current prescribed medication plan, and the results would change management.

Definitive testing other than to confirm the results of a presumptive test as specified above is not recommended for coverage (*weak recommendation*), unless the clinician suspects use of a substance that is inadequately detected by presumptive UDT (e.g., fentanyl).

Definitive testing is recommended for coverage for no more than seven substances per day.

In patients receiving treatment for a substance use disorder, random UDT is recommended for coverage (*weak recommendation*). Up to 36 presumptive tests and 12 definitive tests are recommended per year. These limits must be applied in accordance with mental health parity law.

In patients receiving chronic opioid therapy for chronic pain, random UDT is recommended for coverage (*weak recommendation*), with frequency of testing depending on the patient's risk level (using a validated opioid risk assessment tool). Definitive testing should be conducted only for confirmatory purposes as described above and should not exceed 12 tests per year:

- Low Risk: Random presumptive testing up to two times per year
- Moderate Risk: Random presumptive testing up to four times per year
- High Risk: Random presumptive testing up to 12 times per year

In patients with unexplained alteration of mental status and when knowledge of drug use is necessary for medical management (e.g., emergency department evaluation for altered mental status), UDT (presumptive and confirmatory definitive testing, if indicated) is recommended for coverage not subject to the above limitations (*weak recommendation*).

Note: Definitions for strength of recommendation are in Appendix A. *GRADE Table Element Description*.

Rationales for each recommendation appear below in the GRADE table.

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Rationale for development of coverage guidances and multisector intervention reports

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as plan administrators seek to improve patient experience of care, population health, and the cost-effectiveness of health care. In the era of public and private sector health system transformation, reaching these goals requires a focus on maximizing the benefits and minimizing the harms and costs of health interventions.

HERC uses the following principles in selecting topics for its reports to guide public and private payers:

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

HERC bases its reports on a review of the best available research applicable to the intervention(s) in question. For coverage guidances, which focus on diagnostic and clinical interventions, evidence is evaluated using an adaptation of the GRADE methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat, or manage disease at a population level. In some cases, HERC has reviewed evidence and identified effective interventions, but has not made formal coverage recommendations when these policies are implemented in settings other than traditional health care delivery systems because effectiveness may be dependent on the environment in which the intervention is implemented.

GRADE Table

HERC develops recommendations by using the concepts of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for performing the steps involved in developing recommendations. The table below lists the elements that determine the strength of a recommendation. HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Estimates of effect are derived from the evidence presented in this document. Assessments of confidence are from the published systematic reviews and meta-analyses, where available and judged to be reliable.

In some cases, no systematic reviews or meta-analyses encompass the most current literature. In those cases, HERC may describe the additional evidence or alter the assessments of confidence in light of all available information. Such assessments are informed by clinical epidemiologists from the Center for Evidence-based Policy. Unless otherwise noted, statements regarding resource allocation, values and preferences, and other considerations are the assessments of HERC, as informed by the evidence reviewed, public testimony, and subcommittee discussion.

Recommendations for coverage are based on the balance of benefit and harms, resource allocation, values and preferences and other considerations. See Appendix A for more details about the factors that constitute the GRADE table.

GRADE Table

Should urine drug testing be recommended in the management of patients receiving opioid prescriptions for chronic pain?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Overdose and death *(Critical outcome)*	Insufficient evidence	Point-of-care presumptive (qualitative testing) is much less expensive than definitive (quantitative) confirmatory testing. Routinely performing definitive testing adds significant cost, especially when testing for a large number of substances. A strategy of using definitive testing as confirmatory after unexpected presumptive test results could optimize resource allocation. Frequency of testing also affects overall cost.	Patients who are prescribed opioids would likely want to be treated in a way that maximizes benefit and reduces harm. Some patients would prefer not to have UDT because it could be seen as questioning their behavior, undermine the perceived validity of opioids as chronic pain treatment, and result in unplanned changes in management that a patient could feel are unwarranted. Patients would generally prefer accurate tests, so false-positive and false-negative results would not lead to an unplanned change in management. From a societal values perspective, society would	UDT can provide critical information about diversion (i.e., a negative UDT result for a patient being prescribed an opioid). This has important public safety implications, and therefore understanding the societal values and preferences related to UDT is important. UDT also provides information about concomitant use of other medications/ substances that is necessary for clinicians to know about to ensure safe and appropriate prescribing; information that patients might not provide and is otherwise difficult to verify.
Identification of diversion *(Critical outcome)*	Insufficient evidence			

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Should urine drug testing be recommended in the management of patients receiving opioid prescriptions for chronic pain?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Identification of other substance use disorders *(Critical outcome)*	Insufficient evidence		want to ensure that patients are not being prescribed medications that increase their risk of death, overdose, or addiction, or that are contributing to street availability of controlled substances.	If UDT suggests evidence of a substance use disorder, there is a need for additional assessment and a potential opportunity for treatment.
Test performance characteristics *(Important outcome)*	Limited evidence from single-center diagnostic accuracy studies comparing point-of-care immunoassays to a reference standard (liquid chromatography or mass spectroscopy) suggests low to moderate rates of false-positive and false-negative test results depending on the substance and cutoff values (see Table 1 in the Evidence Review for further details) ●○○○ Very low certainty			

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Should urine drug testing be recommended in the management of patients receiving opioid prescriptions for chronic pain?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Change in management of chronic pain or substance use disorder *(Important outcome)*	Insufficient evidence			

Balance of benefits and harms: Insufficient evidence exists to support the clinical utility of UDT or to address the relative balance of benefits to harms. Theoretically, UDT would provide a significant benefit for safe and appropriate prescribing by ensuring that the patient is using the prescribed medication appropriately and to verify that there is not concurrent use of other substances, which could increase harms. The theoretical harms of UDT include undermining the patient-physician relationship and creating a suboptimal change in management based on erroneous information. Given that opioid medications have well-known risks including overdose, death, and diversion, and lack of proven benefit, the expected benefits of UDT significantly outweigh the potential harms.

Rationale: Despite the lack of evidence, UDT can theoretically help to identify appropriate adherence to a prescribed regimen, confirm absence of illicit substances, and identify diversion. UDT is universally recommended by guidelines and other payers as a mechanism to objectively identify the appropriate use of opioids and avoidance of other concerning substances. The harms are in the false-positive and false-negative rates, which could lead to inappropriate changes in management and undermine trust in the patient-provider relationship. The data suggest that overuse of UDT occurs, resulting in significant costs, particularly when frequent definitive testing is performed for large numbers of substances. Therefore, we make a recommendation for coverage with restrictions.

Recommendation: UDT is recommended for coverage, with specified restrictions on the type and quantity of testing (see full recommendation on page 1) (*weak recommendation*).

Should urine drug testing be recommended in the management of patients with a known or suspected substance use disorder?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Overdose and death *(Critical outcome)*	Insufficient evidence	Point-of-care presumptive (qualitative) testing is much less expensive than (quantitative) confirmatory testing. Routinely performing definitive testing adds significant cost, especially when testing for a large number of substances. A strategy of using definitive testing as confirmatory after unexpected presumptive test results could	Some patients would prefer not to have UDT to verify their reported substance abstinence or use. Many patients will do whatever is necessary for treatment, including UDT, but they likely would prefer testing to be done less frequently rather than more frequently. Patients would generally prefer tests that have a low false-positive rate for illicit substances because false-positives would decrease trust in the patient-clinician relationship, and potentially erroneously decrease earned privileges (such as in an Opioid Treatment	Random UDT, rather than predictable UDT, is widely recommended by expert organizations. UDT is an essential part of law enforcement and child custody requirements for many patients to ensure ongoing abstinence or adherence to a treatment program.
Identification of diversion *(Critical outcome)*	Insufficient evidence			
Identification of other substance use disorders *(Critical outcome)*	Insufficient evidence			
Test performance characteristics *(Important outcome)*	Limited evidence from single-center diagnostic accuracy studies comparing point-of-care immunoassays to a reference standard (liquid chromatography or mass spectroscopy) suggests low to moderate rates of false-positive and false-negative test results depending on the substance and cutoff values (see Table 1 in the Evidence Review for further details) ●○○○ Very low certainty			

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Should urine drug testing be recommended in the management of patients with a known or suspected substance use disorder?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Change in management of chronic pain or substance use disorder *(Important outcome)*	Insufficient evidence	optimize resource allocation. Frequency of testing also affects overall cost. There are some patients for whom very frequent definitive testing has been completed (e.g., every few days) for multiple substances (> 20) over extended periods of time.	Program). In contrast, some patients might prefer less accurate tests with high false-negative rates if they are actively using other substances that they would prefer not to disclose. From a societal perspective, there would be value that patients receiving substance use disorder treatment are confirming receipt of safe and effective treatment (without high-risk concurrent use of illicit substances) and that there is not active diversion occurring, which threatens public safety.	

Balance of benefits and harms: Insufficient evidence on the clinical utility of UDT is available. There is a compelling theoretical argument that in patients with a substance use disorder, it is critical to understand adherence to a high-risk treatment (i.e., opioid agonist therapy) and concurrent use of other substances that put the patient at high risk of death or overdose. Additionally, identifying patients who are diverting these high-risk medications into the public could be a significant societal benefit if the testing helped to decrease diversion. The harms in this population are relatively small, although tests with high false-positive or false-negative results might result in changes to the treatment plan that could negatively affect patient outcomes.

Should urine drug testing be recommended in the management of patients with a known or suspected substance use disorder?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Rationale: There is insufficient evidence to demonstrate the relative benefits and harms of UDT in individuals with a substance use disorder. Despite the lack of evidence, UDT can theoretically help to identify appropriate adherence to a prescribed regimen, confirm absence of illicit substances, and help to identify diversion. UDT is universally recommended by guidelines as a mechanism to monitor adherence to the treatment plan and determine whether changes in the treatment plan are needed. Harms could involve false-positives (or false-negatives), which might lead to unwarranted changes in the management plan. Frequent drug testing might also feel like a burden or invasion of privacy for patients. There are data suggesting overuse of UDT, which entails significant costs, particularly when frequent definitive testing is performed. Therefore, we make a recommendation for coverage with restrictions. The expected benefits of performing UDT on individuals with a substance use disorder outweigh the expected harms, although patient values of accurate and less frequent testing and moderate expense temper the recommendation, resulting in a weak recommendation in favor of coverage with restrictions.				
Recommendation: UDT is recommended for coverage in patients with a substance use disorder, with specified restrictions on the type and quantity of testing (see full recommendation on page 1) (*weak recommendation*).				

Note: GRADE table elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.

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Background

Urine drug testing (UDT) is a noninvasive procedure used to screen for drug use among patients being treated for a substance use disorder (SUD) and patients prescribed opioids for chronic pain, to test for the use of prescribed medications and other substances. UDT can fulfill multiple purposes during substance use treatment as:

- Part of the initial assessment of a patient being evaluated for a diagnosis of a SUD
- A screen to prevent potential adverse effects of pharmacotherapy (e.g., opioid screen prior to starting naltrexone)
- A component of the treatment plan for a SUD
- A way to monitor the patient's use of illicit substances or adherence to pharmacotherapy treatment for a SUD
- A way to assess the efficacy of the treatment plan (i.e., level of care) (Substance Abuse and Mental Health Services Administration [SAMHSA], 2012)

Although UDT had been used in SUD treatment for decades, UDT has increased in recent years because of increases in prescriptions for opioid medications, the number of patients with opioid use disorders (OUDs), and overdose deaths (American Society of Addiction Medicine [ASAM], 2013). Opioid Treatment Programs (which can administer methadone or buprenorphine) are federally mandated to provide adequate testing or analysis for drugs of abuse for patients in OUD maintenance treatment, including a minimum of eight random drug abuse tests each year. Patients receiving long-term detoxification treatment (opioid agonist medication in decreasing doses for more than 30 days) in an Opioid Treatment Program must receive an initial drug abuse test and then monthly random tests (Code of Federal Regulations, 2015).

In recent years, there have been concerns about the overuse of drug tests. For example, the U.S. Department of Justice announced a settlement with Millennium Health in 2015 to resolve alleged violations of the False Claims Act for billing Medicare, Medicaid, and other federal health care programs for medically unnecessary urine drug tests (U.S. Department of Justice, 2015). Millennium Health allegedly gave physicians free UDT cups in exchange for referring drug testing to their labs, which violated the federal Physician Self-Referral Law (Stark law) and Anti-Kickback Statute (Office of Inspector General, U.S. Department of Health & Human Services, n.d.). Millennium Health encouraged physicians to order "custom profiles," which caused physicians to order a large number of tests for each patient without an individualized assessment of that patient's needs. Millennium Health agreed to pay more than $200 million for excessive and unnecessary urine drug tests from 2008 to 2015 (U.S. Department of Justice, 2015).

Indications

There are generally two types of patients that are given periodic UDT. First, patients being treated for a SUD can be given UDT to screen for use of substances that the patient might be abusing. Second, patients with chronic pain who are being treated with opioids can be given UDT to ensure that the patient is taking the prescribed medications (and not diverting the opioids and distributing to others) and that the patient is not using other drugs of abuse.

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Technology Description

Presumptive (sometimes called qualitative) drug tests are generally performed by immunoassay, and definitive (sometimes called quantitative) drug tests are performed by gas chromatography-mass spectrometry (GC-MS) or liquid chromatography-tandem mass spectrometry (LC-MS/MS). Definitive testing is more accurate and more expensive than presumptive testing. Definitive testing is often used as a confirmation test when results of the presumptive test are unexpected. More recently, definitive testing has been used without an initial presumptive test to provide information about an array of medications, including those that cannot be reliably detected by presumptive tests (ASAM, 2013).

Presumptive immunoassay tests can be analyzed at the point of care or sent to a laboratory. In immunoassay tests, competitive binding and antibodies to the drug of interest are used to detect the presence of a drug at a specific level. A fixed amount of labeled drug is added to a urine sample, and the drug present in the urine competes with the labeled drug to bind to the antibodies. The test measures the amount of labeled drug that binds to the antibody, which is inversely proportional to the concentration of drug in the urine. Immunoassay tests for different drugs vary in their accuracy and cross-reactivity (i.e., ability of the antibody to bind with drugs other than the drug of interest). Presumptive drug tests are reported as "positive" or "negative," based on a specified level of drug detected. Immunoassay tests analyzed at the point of care can be interpreted within minutes, and those sent to a laboratory for analysis are typically analyzed within one to four hours (SAMHSA, 2012).

Definitive tests are performed in a laboratory and typically take several days to analyze. Gas or liquid chromatography is used to separate the urine analytes, and then mass spectrometry is used to identify the drugs and metabolites by their molecular structure. Results are reported as drug concentrations detected in the urine. Single-drug definitive tests are available, and definitive drug test panels can assess for multiple drugs (ASAM, 2013). According to SAMHSA (2012), common drug test panels include the following:

- Amphetamine, methamphetamine
- Barbiturates (amobarbital, butabarbital, butalbital, pentobarbital, phenobarbital, secobarbital)
- Benzodiazepines (alprazolam, chlordiazepoxide, clonazepam, clorazepate, diazepam, flurazepam, lorazepam, oxazepam, temazepam)
- Illicit drugs (cocaine, methylenedioxyamphetamine [MDA], methylenedioxymethamphetamine [MDMA], methylenedioxyethylamphetamine [MDEA], marijuana)
- Opiates/opioids (codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, meperedine, methadone, morphine, oxycodone, oxymorphone, propoxyphene)

Evidence Review

The search for evidence found four systematic reviews and two diagnostic accuracy studies pertaining to the use of UDT for patients with chronic pain or SUD. An updated search of the literature did not find any randomized controlled trials published since 2014, the date of the most recent systematic reviews.

The first systematic review (Chou et al., 2009) was a good-quality systematic review of studies examining the use of UDT for patients receiving treatment for chronic pain. No studies reported on the effects of UDT on patient outcomes. The authors did identify two studies of the effects of UDT on concomitant use of illicit or other controlled substances in patients with chronic pain. In one of the studies (Manchikanti, Manchukonda, Pampati, et al., 2006), a historically controlled cohort study, UDT

was associated with decreased use of marijuana, but no difference in the use of other illicit drugs. The second study (Manchikanti, Manchukonda, Damron, et al., 2006), also a historically controlled cohort study, found that UDT, when used as part of a multicomponent approach that also included treatment contracts, pill counts, and frequent monitoring and education, was associated with a reduction in controlled substance abuse from 18% to 9%. These studies were limited by the use of historical controls and the use of multiple interventions.

The second systematic review (Starrels et al., 2010) was a good-quality review that summarized the effects of treatment contracts and routine UDT in patients with chronic non-cancer pain. The authors identified seven cohort studies that examined the use of treatment contracts and UDT; six of the studies were rated as fair quality and one was rated as poor quality. The studies were performed in outpatient settings including pain clinics and primary care clinics. Notably, four of the studies relied on confirmatory tests (mass spectroscopy or chromatography) rather than immunoassays. Approximately 15% of the patients included in these studies had a history of substance abuse. In one retrospective study (Wiedemer et al., 2007) conducted in a Veterans Affairs primary care setting, the use of treatment contracts and UDT was associated with a reduction in opioid misuse (51% to 28%). Two historically controlled cohort studies (Manchikanti, Manchukonda, Damron, et al., 2006; Manchikanti, Manchukonda, Pampati, et al., 2006) conducted in pain clinics found reductions in the use of opioids prescribed by another source (18% to 9%) and the use of illicit substances (23% to 16%) with the introduction of treatment agreements and UDT. Both of these studies were also included in the review by Chou et al. (2009) mentioned above. None of the studies included in this systematic review examined outcomes of opioid use or dependence, overdose, death, or diversion.

The third systematic review (Chou, Deyo et al., 2014) was a good-quality systematic review for the Agency for Healthcare Research and Quality (AHRQ) that examined evidence for long-term use of opiates for chronic pain and included a key question on risk mitigation approaches including UDT. The AHRQ review identified no studies that addressed clinical outcomes related to UDT.

Two diagnostic accuracy studies compared the performance of point-of-care immunoassay tests to confirmatory tests. Those results are summarized in Table 1. However, these results should be interpreted with caution because they represent the experience of a single center using one type of point-of-care immunoassay and with different cutoffs defining positivity for the index and the reference tests. Additionally, Millennium Health sponsored both studies, provided the urine drug tests, and conducted the reference testing.

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Table 1. Diagnostic Accuracy of Immunoassay Testing Compared to LC-MS/MS

<table>
<tr><th>Citation and Study Details</th><th>Findings</th><th>Cutoff values (Immunoassay vs. LC-MS/MS, ng/mL)</th><th>Comments</th></tr>
<tr>
<td>Manchikanti et al. (2011b)

Setting:
U.S. tertiary referral center and intervention pain management practice

Comparators: immunoassay and LC-MS/MS
N = 1,000</td>
<td>Compared to LC-MS/MS, immunoassay had the following:

<table>
<tr><th>False- Negative Reports</th><th>n</th><th>%</th></tr>
<tr><td>Morphine</td><td>52</td><td>8%</td></tr>
<tr><td>Oxycodone</td><td>34</td><td>25%</td></tr>
<tr><td>Methadone</td><td>2</td><td>4%</td></tr>
<tr><td>Marijuana</td><td>3</td><td>9%</td></tr>
<tr><td>Cocaine</td><td>6</td><td>75%</td></tr>
<tr><td>Methamphetamines</td><td>3</td><td>60%</td></tr>
<tr><td>Amphetamines</td><td>9</td><td>53%</td></tr>
</table>

<table>
<tr><th>False-Positive Reports</th><th>n</th><th>%</th></tr>
<tr><td>Morphine</td><td>23</td><td>7%</td></tr>
<tr><td>Oxycodone</td><td>66</td><td>8%</td></tr>
<tr><td>Methadone</td><td>11</td><td>1%</td></tr>
<tr><td>Marijuana</td><td>19</td><td>2%</td></tr>
<tr><td>Cocaine</td><td>0</td><td>0%</td></tr>
<tr><td>Methamphetamines</td><td>12</td><td>1%</td></tr>
<tr><td>Amphetamines</td><td>9</td><td>1%</td></tr>
</table>
</td>
<td>Morphine: 300 vs. 50
Oxycodone: 100 vs. 50
Methadone: 300 vs. 100
Marijuana: 50 vs. 15
Cocaine: 300 vs. 50
Methamphetamines: NA vs. 50
Amphetamines: 1000 vs. 100</td>
<td>The authors concluded that confirmatory testing will be needed 20% to 32% of the time, but that overall point-of-care testing is efficient in this population.

(The authors assumed that if someone is prescribed an opioid they are actually taking it. Thus, they regard the 11% of people who had negative immunoassay and negative LC-MS for opioids in spite of a prescription as having two false-negative results rather than evidence that the person wasn't taking the medication.)</td>
</tr>
<tr>
<td>Manchikanti et al. (2011b)

Setting:
U.S. tertiary referral center and intervention pain management practice</td>
<td>Compared to LC-MS/MS, immunoassay had the following for benzodiazepines [n (%)]

Patients prescribed benzodiazepines
False-negative reports:
99 (24.5%)
False-positive reports:
10 (10.5%)

Patients NOT prescribed benzodiazepines</td>
<td>300 ng/mL vs. not reported</td>
<td></td>
</tr>
</table>

Citation and Study Details	Findings	Cutoff values (Immunoassay vs. LC-MS/MS, ng/mL)	Comments
Comparators: immunoassay and LC-MS/MS N = 1,000	False-negative reports: 16 (36.4%) False-positive reports: 1 (0.2%)		

The fourth systematic review (Dupuoy et al., 2014) was a good-quality systematic review of the effects of UDT in patients with a known or suspected SUD in inpatient or outpatient settings. These studies mainly relied on point-of-care or laboratory immunoassay testing with or without confirmatory testing. Of the eight included studies, six were conducted in inpatient settings. With the exception of one fair-quality randomized controlled trial, all the studies were judged to be poor quality. In the single included RCT, patients in a psychiatric emergency setting were randomly assigned to receive a mandatory UDT or routine care directed by the psychiatrist's clinical judgement (which could include UDT). There was no difference between the two groups with respect to disposition or duration of hospitalization in the intention-to-treat analysis. In an as-treated analysis, patients who were in the routine care arm and who did not receive a UDT were more likely to be admitted to an inpatient unit at a county hospital compared to those who received a UDT. In a cross-sectional study of primary care providers who manage patients with OUD in France, many reported that UDT influenced their decisions about referral to counseling, consultation, and whether to prescribe medication-assisted treatment. The authors concluded that there was insufficient evidence to assess the usefulness of UDT for managing patients with a known or suspected SUD.

Evidence Summary

Limited observational evidence suggests that UDT, particularly when combined with other interventions, could be associated with reductions in opioid misuse and concomitant use of marijuana, but not with other illicit substances in patients with chronic non-cancer pain. There is insufficient evidence to assess the effects of UDT on clinical outcomes including opioid dependence or abuse, overdose, death, or diversion. There was insufficient evidence to draw conclusions about the effects of UDT in patients with a known or suspected SUD.

Policy Landscape

Payer Coverage Policies

Medicaid

Washington

As outlined in the *Physician-Related Services/Health Care Professional Services Billing Guide*, the Washington Medicaid program covers drug testing for SUD when both of the following apply:

- The screen is medically necessary and ordered by a physician as part of a medical evaluation
- The drug or alcohol screen is required to assess suitability for medical tests or treatment being provided by the physician

The Washington Medicaid billing guide states that, "Periodic reviews of ordering patterns will be performed to look for and contact practices that appear to be outliers compared to their peers" (Washington State Health Care Authority, 2017, p. 146).

For patients receiving medication-assisted treatment (MAT) for a SUD, the Washington Medicaid program considers presumptive (in office) testing with a point-of-care immunoassay test medically necessary to:

- Confirm the use of prescribed substances
- Identify the presence of illicit or non-prescribed substances
- Start a patient on MAT for a SUD

Confirmatory testing with GC-MS or LC-MS/MS is considered medically necessary when there is a discrepancy between a presumptive drug test and the patient report. In addition, confirmatory testing should only be ordered and performed on a patient- and drug-specific basis with clinical documentation of a follow-up plan based on the test results. The Washington Medicaid program covers a maximum of 24 presumptive drug tests each year. The allowed Current Procedural Terminology (CPT) codes for presumptive UDT are 80305, 80306, and 80307, and only one of the three codes can be billed per client per day. A maximum of 12 definitive tests, used as follow-up to presumptive tests, are allowed each year. The allowed Healthcare Common Procedure Coding System (HCPCS) codes for definitive UDT are G0480 and G0481, and only one of the two codes can be billed per client per day. If additional tests are needed, providers can submit a limitation extension request to the agency.

Washington Medicaid does not pay for routine drug screening panels or monitoring for program compliance in residential or outpatient drug or alcohol treatment programs. When monitoring a patient for drug or alcohol use, providers are instructed to refer the client to a program approved by the Division of Behavioral Health and Rehabilitation for evaluation and treatment, where the patient may receive drug or alcohol screening as determined by their treating provider.

Drug testing for patients who are on chronic opioid therapy for the treatment of chronic non-cancer pain must follow the Agency Medical Directors' Group *Interagency Guideline on Prescribing Opioids for Pain* (Washington State Agency Medical Directors' Group, 2015). These guidelines recommend UDT annually for those at low risk of abuse or diversion, twice yearly for those at moderate risk, and three to four times yearly for those at high risk. Testing is also recommended as needed for aberrant behavior identified during an office visit. Because of cross-reactivity and the differences in sensitivity and specificity among immunoassay tests, a confirmatory (definitive) test is required unless the result was expected or the patient has disclosed drug use.

North Carolina

North Carolina Medicaid's drug testing policy covers presumptive testing up to 24 times and definitive testing up to 24 times per fiscal year. Only one presumptive and one definitive test will be reimbursed per beneficiary, per day, regardless of the number of providers performing this service.

Testing frequency for a SUD is based upon consecutive days of beneficiary abstinence from illicit substances:

- Zero to 30 days: Once per calendar week
- 31-90 days: Twice per calendar month
- Greater than 90 days: Once per 30 calendar days

Testing frequency for patients treated for chronic pain is based on risk assessment:

- Low-Risk Beneficiaries: Up to two times every 365 consecutive days
- Moderate-Risk Beneficiaries: Up to four times every 365 consecutive days
- High Risk: Up to three times every 90 consecutive days

New York

In New York Medicaid's drug testing policy, CPT codes 80305, 80306, or 80307 must be used for presumptive drug screening. Only substances that return a positive result on a presumptive test or are inconclusive or inconsistent with clinical presentation are reimbursable for definitive testing, using CPT codes 80320–80377. Definitive testing without a prior presumptive test is only reimbursable when no presumptive screening method is available, using HCPCS code G0480. This direct to definitive testing is reimbursable once per date of service, up to a maximum of six times within 365 days.

Provision of drug tests must be based on the patient's medical history or current clinical presentation, and medical records must support the need for each test and be kept on file for a minimum of six years for audit purposes.

Alabama

Alabama Medicaid's policy on presumptive drug limits presumptive drug testing to one specimen every seven days per recipient, using CPT codes 80100, 80101, 80102, and 80104. The ordering/referring provider must retain documentation supporting medical necessity in the medical record.

A 2015 update to the Alabama Medicaid drug testing policy delineates coverage for HCPCS codes G0434 and G6058:

- HCPCS code G0434 will cover one drug screen, regardless of the number of drugs or classes, procedure(s)/methodology(ies), any source(s), per appropriately billed date of service.
- HCPCS code G6058 will cover one drug test (confirmatory and/or definitive, qualitative and quantitative), regardless of the number of drugs or drug classes, procedure(s)/methodology(ies), source(s), including sample validation.

Medicare

No National Coverage Determination was identified for drug testing, and 10 Medicare Local Coverage Determinations (LCDs) were identified. Three (L34501, L34645, L35920) of these 10 LCDs are less comprehensive than the others, although generally consistent with the more comprehensive LCDs.

The seven more comprehensive LCDs (L35006, L36037, L36029, L36393, L36668, L36707, L35724) categorize patients needing UDT into three groups:

- Group A – Symptomatic patients, multiple drug ingestion, or patients with unreliable history
- Group B – Diagnosis and treatment for substance abuse or dependence
- Group C – Treatment for patients on chronic opioid therapy

Group A patients can present in a variety of medical settings, and patients with symptoms such as coma, altered mental status or seizures can be given presumptive UDT as part of evaluation and management. The presumptive drug test findings, any definitive drug tests ordered, and reasons for the testing must be documented in the patient's medical record.

For diagnosis of a SUD in Group B, the clinician may screen for a broad range of commonly abused drugs using presumptive UDT for patients with no known indicators of risk for a SUD. For patients with known indicators of risk for a SUD, the clinician may screen for a broad range of commonly abused drugs using definitive UDT.

For patients with a diagnosed SUD, the clinician should perform random UDT in order to properly monitor the patient. The expected frequency of UDT is one to three tests per week for patients with less than 90 consecutive days of abstinence and one to three tests per month for patients with more than 90 consecutive days of abstinence.

Six of the seven comprehensive LCDs also have limits on the frequency of definitive UDT:

- For patients with zero to 30 consecutive days of abstinence, definitive UDT is expected at a frequency not to exceed one testing profile in one week
- For patients with 31 to 90 consecutive days of abstinence, definitive UDT is expected at a frequency of 1-3 testing profiles in one month
- For patients with >90 days of consecutive abstinence, definitive UDT is expected at a frequency of 1-3 testing profiles in three months

For Group C patients on chronic opioid therapy, medical necessity for drug testing must be based on patient-specific elements and documented in the patient's medical record, including:

- Patient history, physical examination, and previous laboratory findings
- Current treatment plan
- Prescribed medications
- Risk assessment plan

Six of the seven comprehensive LCDs have frequency limitations on UDT for patients on chronic opioid therapy:

- Low Risk: Random testing 1-2 times every 12 months
- Moderate Risk: Random testing 1-2 times every six months
- High Risk: Random testing 1-3 times every three months

Across all three groups of patients (A, B, C), definitive testing to confirm a positive presumptive UDT result is reasonable and necessary when the result is inconsistent with the expected result, a patient's self-report, presentation, medical history, or current prescribed medication plan. Definitive testing to confirm a negative presumptive UDT result is reasonable and necessary when:

- The result is inconsistent with a patient's self-report, presentation, medical history, or current prescribed medication plan
- The clinician suspects use of a substance that is inadequately detected or not detected by a presumptive UDT
- To rule out an error as the cause of a negative presumptive UDT result

Definitive UDT without a prior presumptive UDT is reasonable and necessary, when individualized for a particular patient.

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Private Payers

Center researchers searched private payer policies for UDT for Aetna, Cigna, Moda, and Regence. No national policy was found for Aetna, but an update for Aetna's Western Region in 2016 stated that the frequency limit for drug testing per year is eight times each for definitive and presumptive testing.

Cigna's drug testing policy covers UDT when these criteria are met:

- The diagnosis, history and physical examination and/or behavior of the individual being tested support the need for the specific drug testing being requested
- The results of testing will affect treatment planning
- Testing is performed in a physician-supervised treatment setting

Cigna covers presumptive drug testing not to exceed one unit per date of service up to 32 units per year, and definitive drug testing not to exceed 16 dates of service per year for a maximum of eight units per date of service up to 128 units per year. A unit may include testing for a specific individual drug and/or its metabolites, or its structural isomers. Definitive drug testing is allowed only if the presumptive test results are inconsistent with the individual's condition, history, and examination, or if a presumptive drug test is not available for the drug for which there is a suspicion of abuse or misuse.

Moda's policy on *Therapeutic Drug Monitoring (Urine drug testing)* covers presumptive urine drug screening up to 12 units per plan year for patients:

- Where there is a suspicion of drug misuse or abuse
- With a diagnosis where drug toxicity may be a contributing factor
- Who are pregnant and there is possible exposure of the fetus to drug abuse
- Who are being treated for chronic non-cancer pain with opioid therapy, to establish a baseline and random monitoring for adherence or diversion of prescribed medications
- Who are in treatment for chemical dependency—more frequent UDT might be required to monitor compliance with the treatment program

Definitive drug testing to confirm a positive presumptive screening is covered up to 12 units per plan year.

Regence's policy on UDT for substance abuse and chronic pain limits presumptive tests to one per day and 15 times each year unless there is suspected abuse, misuse, or diversion, and documentation indicates how test results will affect management. These same restrictions apply to definitive UDT. Drug testing is not covered in conjunction with participation in a substance abuse facility because UDT is included in the facility reimbursement.

Recommendations from Others

Guidelines: Substance Use Disorder

Four guidelines were identified related to the use of UDT for patients with a SUD:

- *VA/DoD Clinical Practice Guideline for the Management Of Substance Use Disorders* (U.S. Department of Veterans Affairs & Department of Defense, 2015)
- SAMHSA's *Clinical Drug Testing in Primary Care* (SAMHSA, 2012)
- ASAM's *Appropriate Use of Drug Testing in Clinical Addiction Medicine* (ASAM, 2017)

- *Methadone Safety: A Clinical Practice Guideline from the American Pain Society and College on Problems of Drug Dependence, in Collaboration with the Heart Rhythm Society* (Chou, Cruciani et al. 2014)

These guidelines recommend drug testing at baseline and then periodic monitoring during drug treatment. The guidelines often do not mention a specific interval for ongoing drug testing, explaining that evidence is not available on the most appropriate frequency of testing and that testing frequency should be based on individual patient characteristics. The most detailed recommendations are in ASAM's guidelines, which recommend that drug testing be done at least weekly during the initial phase of treatment and at least monthly when a patient is stable in treatment.

Guidelines: Chronic Pain

Four guidelines were identified that are related to the use of UDT for patients undergoing treatment for chronic pain:

- *CDC Guideline for Prescribing Opioids for Chronic Pain* (Dowel et al., 2016)
- *VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain* (U.S. Department of Veterans Affairs & Department of Defense, 2017)
- SAMHSA's *Clinical Drug Testing in Primary Care* (SAMHSA, 2012)
- *American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain* (Manchikanti et al., 2012)

These guidelines recommend UDT before starting opioid therapy and then ongoing monitoring to assess for prescribed medications and other controlled prescription drugs and illicit drugs. The CDC guidelines recommend UDT at least annually. The ASIPP guidelines recommend that patients at low risk for aberrant behaviors should have UDT every one to two years, patients at medium risk should have UDT every six to 12 months, and patients at high risk should have UDT every three to six months. The guidelines from SAMHSA and VA/DoD are less specific, stating the UDT frequency should be based on individual patient characteristics.

Quality Measures

One quality measure was identified when searching the National Quality Measures Clearinghouse for measures related to drug testing. The Institute for Clinical Systems Improvement developed the measure: *percentage of patients diagnosed with chronic pain who are prescribed an opioid who have an opioid agreement form and urine toxicology screen documented in the medical record*.

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Appendix A. GRADE Table Element Descriptions

Element	Description
Balance of benefits and harms	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. An estimate that is not statistically significant or has a confidence interval crossing a predetermined clinical decision threshold will be downgraded.
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed in the absence of likely cost offsets—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted
Other considerations	Other considerations include issues about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.

Strong recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors., but further research or additional information could lead to a different conclusion.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the balance of benefits and harms, cost and resource allocation, and values and preferences, but further research or additional information could lead to a different conclusion.

Confidence in estimate rating across studies for the intervention/outcome

Assessment of confidence in estimate includes factors such as risk of bias, precision, directness, consistency and publication bias.

High: The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

Moderate: The subcommittee is moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical

sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

Low: The subcommittee's confidence in the estimate of effect is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

Very low: The subcommittee has very little confidence in the estimate of effect: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

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Appendix B. GRADE Evidence Profile

Quality Assessment (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Overdose and death							
0							Insufficient
Identification of diversion							
0							Insufficient
Identification of other substance use disorders							
0							Insufficient
Test performance characteristics							
2	Diagnostic accuracy studies	Moderate	N/A	Not serious	N/A	Sparse single-center data	Very low ●○○○
Change in management of chronic pain or substance use disorder							
0							Insufficient

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Appendix C. Methods

Scope Statement

Populations

Patients receiving opioids for chronic pain and patients with a substance use disorder

Population scoping notes: None

Interventions

Urine drug testing (screening and confirmatory testing, presumptive and definitive, individual drug assays and panels of tests)

Intervention exclusions: None

Comparators

Standardized risk assessment tools, no testing, other interventions

Outcomes

Critical: Overdose and death, identification of diversion, identification of other substance use disorders

Important: Test performance characteristics, change in management of chronic pain or substance use disorder

Considered but not selected for the GRADE table: None

Key Questions

KQ1: What is the comparative effectiveness of presumptive versus definitive and screening versus diagnostic urine drug testing?

KQ2: What is the comparative effectiveness of different testing strategies?

KQ3: How does the comparative effectiveness vary by:

a. Underlying patient risk
b. Presence of comorbid conditions
c. Presence of multiple controlled substances
d. Types of drugs tested (e.g., illicit such as cocaine, methamphetamines, cannabinoids; licit such as alcohol, or prescription such as benzodiazepines)
e. Frequency of testing
f. Observed versus unobserved testing
g. Dose of prescribed opioid medication

Contextual Questions

CQ1: What is the cost-effectiveness of the different screening/diagnostic test strategies?

CQ2: What is the effectiveness of urine drug testing in patients receiving acute treatment (e.g., in an urgent care or emergency department setting) in patients who also meet the population criteria?

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Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, and technology assessments that meet the criteria for the scope described above. Searches of core sources were limited to citations published after 2012.

The following core sources were searched:

Agency for Healthcare Research and Quality (AHRQ)
Blue Cross/Blue Shield Center for Clinical Effectiveness
Canadian Agency for Drugs and Technologies in Health (CADTH)
Cochrane Library (Wiley Online Library)
Institute for Clinical and Economic Review (ICER)
Medicaid Evidence-based Decisions Project (MED)
National Institute for Health and Care Excellence (NICE)
Tufts Cost-Effectiveness Analysis Registry
Veterans Administration Evidence-based Synthesis Program (ESP)
Washington State Health Technology Assessment Program

A MEDLINE® search was also conducted to identify systematic reviews, meta-analyses, and technology assessments, using search terms for urine drug tests and substance abuse disorders. The search was limited to publications in English published since 2012. In addition, a MEDLINE® search was conducted for randomized controlled trials published after the search dates of the most recent systematic reviews (2014). In addition, a MEDLINE® search was conducted for randomized controlled trials published after the search dates of the selected systematic reviews.

Searches for clinical practice guidelines were limited to those published since 2009. A search for relevant clinical practice guidelines was also conducted using MEDLINE® and the following sources:

Australian Government National Health and Medical Research Council (NHMRC)
Canadian Agency for Drugs and Technologies in Health (CADTH)
Centers for Disease Control and Prevention (CDC), Community Preventive Services
National Guidelines Clearinghouse
National Institute for Health and Care Excellence (NICE)
Scottish Intercollegiate Guidelines Network (SIGN)
United States Preventive Services Task Force (USPSTF)
Veterans Administration/Department of Defense (VA/DoD) Clinical Practice Guidelines

Inclusion/Exclusion Criteria

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, randomized controlled trials, or clinical practice guidelines.

Appendix D. Applicable Codes

CODES	DESCRIPTION
CPT Codes	
80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service
80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; read by instrument assisted direct optical observation (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service
80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; by instrument chemistry analyzers (e.g., utilizing immunoassay [e.g., EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (e.g., GC, HPLC), and mass spectrometry either with or without chromatography, (e.g., DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service
80320-80377	Definitive drug tests of individual substances (many payers do not cover these tests, preferring to use the G0480-G0483)
HCPCS Level II Codes	
G0477	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service
G0478	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) read by instrument-assisted direct optical observation (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service
G0479	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analyzers utilizing immunoassay, enzyme assay, tof, maldi, ldtd, desi, dart, ghpc, gc mass spectrometry), includes sample validation when performed, per date of service
G0480	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 1-7 drug class(es), including metabolite(s) if performed
G0481	…8-14 drug class(es)…
G0482	…15-21 drug class(es)…
G0483	…22 or more drug class(es)…

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CODES	DESCRIPTION
G0659	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes

Note: Inclusion on this list does not guarantee coverage.

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CG - Urine Drug Testing Coverage Guidance

Question: How should the draft Coverage Guidance on Urine Drug Testing be applied to the Prioritized List?

Question source: Evidence-based Guidelines Subcommittee (EbGS)

Issue: EbGS approved a coverage guidance on urine drug testing that addresses parameters for testing in the treatment of opioid use disorder and in those receiving chronic opioids for chronic pain. Key issues raised during the EbGS discussions involved 1) the lack of evidence supporting the use or frequency of urine drug testing and 2) evidence of excess use/waste. EbGS settled on coverage recommendations that they thought would more than meet medically necessary testing for the vast majority of patients.

Chronic pain conditions for which patients receive chronic opioid therapy are on many lines on the Prioritized List.

The EbGS box language is as follows:

HERC Coverage Guidance

Urine drug testing (UDT) using presumptive testing is recommended for coverage (*weak recommendation*) when the results will affect treatment planning.

Definitive testing is recommended for coverage as a confirmatory test only when the result of the presumptive testing is inconsistent with the patient's history, presentation, or current prescribed medication plan, and the results would change management.

Definitive testing other than to confirm the results of a presumptive test as specified above is not recommended for coverage (*weak recommendation*), unless the clinician suspects use of a substance that is inadequately detected by presumptive UDT (e.g., fentanyl).
Definitive testing is recommended for coverage for no more than seven substances per day.

In patients receiving treatment for a substance use disorder, random UDT is recommended for coverage (*weak recommendation*). Up to 36 presumptive tests and 12 definitive tests are recommended per year. These limits must be applied in accordance with mental health parity law.

In patients receiving chronic opioid therapy for chronic pain, random UDT is recommended for coverage (*weak recommendation*), with frequency of testing depending on the patient's risk level (using a validated opioid risk assessment tool). Definitive testing should be conducted only for confirmatory purposes as described above and should not exceed 12 tests per year:

- Low Risk: Random presumptive testing up to two times per year

- Moderate Risk: Random presumptive testing up to four times per year
- High Risk: Random presumptive testing up to 12 times per year

In patients with unexplained alteration of mental status and when knowledge of drug use is necessary for medical management (e.g., emergency department evaluation for altered mental status), UDT (presumptive and confirmatory definitive testing, if indicated) is recommended for coverage not subject to the above limitations (*weak recommendation*).

Prioritized List Status:

Line: 4
Condition: SUBSTANCE USE DISORDER (See Guideline Notes 64,65,175)
Treatment: MEDICAL/PSYCHOTHERAPY
ICD-10: F10.10-F10.11,F10.20-F10.21,F11.10-F11.11,F11.20-F11.21,F12.10-F12.11, F12.20-F12.21,F13.10-F13.11,F13.20-F13.21,F14.10-F14.11,F14.20-F14.21, F15.10-F15.11,F15.20-F15.21,F16.10-F16.11,F16.20-F16.21,F18.10-F18.11, F18.20-F18.21,F19.10-F19.11,F19.20-F19.21,Z71.51
CPT: 90785,90832-90840,90846-90853,90882,90887,93792,93793,96150-96155, 97810-97814,98966-98969,99051,99060,99201-99239,99324-99357,99366, 99408,99409,99415,99416,99441-99449,99487-99490,99495-99498,99605-99607
HCPCS: G0248-G0250,G0396,G0397,G0406-G0408,G0410,G0411,G0425-G0427, G0443,G0459,G0463-G0467,G0469,G0470,G0508-G0511,G0513,G0514, H0004-H0006,H0010-H0016,H0018-H0020,H0032-H0035,H0038,H2010, H2013,H2033,H2035,T1006,T1007,T1502

CODES	DESCRIPTION	CURRENT PLACEMENT	PRICE (FFS Fee Schedule)
80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service	Diagnostic Procedures File	$9.42
80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; read by instrument assiste1d direct optical observation (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service	Diagnostic Procedures File	$12.57

80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; by instrument chemistry analyzers (e.g., utilizing immunoassay [e.g., EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (e.g., GC, HPLC), and mass spectrometry either with or without chromatography, (e.g., DART, DESI, GC-MS, GC-MS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service	Diagnostic Procedures File	$50.28
80320-80377	Definitive drug tests of individual substances (many payers do not cover these tests, preferring to use the G0480-G0483)	Diagnostic Procedures File	Not on fee schedule
HCPCS Level II Codes			
G0477	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service	Ancillary Procedures File	Not listed on fee schedule (corresponds to 80305)
G0478	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) read by instrument-assisted direct optical observation (e.g., dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service	Ancillary Procedures File	Not listed on fee schedule (corresponds to 80306)
G0479	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analyzers utilizing immunoassay, enzyme assay, tof, maldi, ldtd, desi, dart, ghpc, gc mass spectrometry), includes sample validation when performed, per date of service	Ancillary Procedures File	Not listed on fee schedule (corresponds to 80307)
G0480	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between	Ancillary Procedures File	$80.10

	structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 1-7 drug class(es), including metabolite(s) if performed		
G0481	…8-14 drug class(es)…	Ancillary Procedures File	$109.61
G0482	…15-21 drug class(es)…	Ancillary Procedures File	$139.12
G0483	…22 or more drug class(es)…	Ancillary Procedures File	$172.84
G0659	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per	No current placement (code was implemented in 2018)	$50.28

	day, any number of drug classes		
H0048	Alcohol and/or other drug testing: collection and handling only, specimens other than blood	Diagnostic Procedures File	$11.48
H0049	Alcohol and/or drug screening	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	Not listed on fee schedule

HERC Staff Summary

There are no current specific limitations or guidance on the use of urine drug testing on the Prioritized List. A diagnostic guideline is proposed to apply the Coverage Guidance recommendations to the Prioritized List. Quantity limits are straightforward to implement, but must be applied in compliance with mental health parity laws when being used for opioid use disorder.

While state Medicaid programs can, by law, only cover medically-necessary services, advocates have requested exclusions from the above limits when the patient is participating in court-ordered drug testing, or testing for child welfare purposes. EbGS considered this and thought these draft Coverage Guidance limitations were appropriate, regardless of setting, when done for medical purposes.

There were concerns raised in public comment about implementation considerations regarding dates of service versus actual testing, for example, if a presumptive and definitive tests were done on different days for the same patient and same urine collection. EbGS reviewed some proposed language but felt it was unclear. The proposed diagnostic guideline below modifies the box language somewhat to clarify that a maximum number of dates of service (36 for presumptive and 12 for definitive) rather than tests, are allowed.

HERC Staff Recommendations:

1) **Advise HSD to move the urine drug testing CPT and HCPCS codes from Ancillary to Diagnostic.** Signs and symptoms codes may be used as well as unfunded diagnoses.
2) **Add HCPCS codes G0481 (definitive testing of 8-14 drug classes) G0482 (definitive testing of 15-21 drug classes) and G0483 (definitive testing of 22 or more drug classes) to Line 660** CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS. Advise HSD to remove from the Ancillary File.
3) **Advise HSD to consider adding G0659 (definitive drug testing) to the Diagnostic File**

4) Add a diagnostic guideline

DIAGNOSTIC GUIDELINE XX URINE DRUG TESTING

Urine drug testing (UDT) using presumptive testing is a covered diagnostic benefit when the results will affect treatment planning. Definitive testing is covered as a confirmatory test only when the result of the presumptive testing is inconsistent with the patient's history, presentation, or current prescribed medication plan, and the results would change management.

Definitive testing other than to confirm the results of a presumptive test as specified above is not covered, unless the clinician suspects use of a substance that is inadequately detected by presumptive UDT (e.g., fentanyl). Definitive testing is limited to no more than seven substances per date of service.

For patients receiving treatment for a substance use disorder, presumptive testing on up to 36 dates of service and definitive testing on up to 12 dates of service per year are covered. These limits must be applied in accordance with mental health parity law.

For patients receiving chronic opioid therapy for chronic pain, frequency of testing depending on the patient's risk level (using a validated opioid risk assessment tool). Definitive testing should be conducted only for confirmatory purposes as described above and should not exceed 12 dates of service per year:

- Low Risk: Random presumptive testing on up to two dates of service per year
- Moderate Risk: Random presumptive testing on up to four dates of service per year
- High Risk: Random presumptive testing on up to 12 dates of service per year

In patients with unexplained alteration of mental status and when knowledge of drug use is necessary for medical management (e.g., emergency department evaluation for altered mental status), UDT (presumptive and confirmatory definitive testing, if indicated) is covered in excess of the above limitations.

HERC Coverage Guidance: Urine Drug Testing
Disposition of Public Comments

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Discussion Table

IDs/#s	Summary of Issue	Subcommittee Response
All	General concerns that urine drug testing (UDT) limits are too prohibitive in testing in those with substance use disorder and not in alignment with provider perspective or national guidelines	EbGS debated a range of options for coverage limitations and, based on verbal comments offered at meetings, settled on 36 for presumptive testing and 12 for definitive testing in substance use disorder.
B1, C1	Concern that drug courts require frequent testing that would surpass the proposed limits	The use of urine drug testing for forensic purposes (i.e., drug courts) must be medically necessary in order to warrant coverage by Medicaid. EbGS believes that the proposed limits are consistent with what is medically necessary.
D1, F2	Concerns about mental health parity and limits on definitive tests	Language acknowledging mental health parity is included in the draft coverage guidance. Although "hard" limits cannot be placed on these services, "soft" limits are appropriate, and individualized clinical review might be indicated to determine whether exceeding these limits is justified.
E4, G1	Concerns about the use of *qualitative* and *quantitative* rather than *presumptive* and *definitive* testing. Commenters postulate that only definitive testing or high amounts of definitive testing are required for clinical decision making (e.g., > 6 definitive tests per year for chronic opioid patients).	The coverage guidance was revised so that the terminology is clarified in the background section, and *presumptive* and *definitive* are primarily used throughout the coverage guidance. EbGS disagrees with commenters that only definitive testing is appropriate for clinical decision making or that large numbers of definitive tests are medically necessary.

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HERC Coverage Guidance: Urine Drug Testing
Disposition of Public Comments

IDs/#s	Summary of Issue	Subcommittee Response
F3	Other payment arrangements could be effective at reducing unnecessary costs (e.g., contracts with labs to lower the unit cost of the test), and the argument is that more tests can be performed for lower costs	Plans should make the best cost arrangements they can, regardless of the quantitative limits to testing. EbGS does not believe more frequent testing is necessary for most patients.
G2	Concern about limitations regarding number of substances definitively tested for per day	Definitive testing for more than 7 substances per day is very rarely likely to be indicated based on expert input and subcommittee discussion.

Commenters

Identification	Stakeholder
A	Sheila Pakkala, CADC-I *[Submitted May 3, 2018]*
B	Jen Kuhn *[Submitted May 9, 2018]*
C	Brandy J. Juarez *[Submitted May 9, 2018]*
D	Heather Jefferis, MA, Executive Director Oregon Prevention Education and Recovery Association (OPERA) *[Submitted May 11, 2018]*
E	Leland McClure, MSci, PhD, F-ABFT, Director, Medical Science Liaison, Medical Affairs, Fellow, American Board of Forensic Toxicology, Quest Diagnostics *[Submitted May 11, 2018]*
F	Tony Howell, LCSW, Program Manager, Linn County Alcohol & Drug Program *[Submitted May 11, 2018]*
G	Maria Chianta, PharmD, Director, Clinical Affairs, Managed Markets Lead, Millennium Health *[Submitted May 14, 2018]*

Public Comments

ID/#	Comment	Disposition
A1	I respectfully disagree with the decision to drug test our clients via urine screening to only one time monthly. As part of an agency the state demands to prove medical necessity for alcohol and drug counseling, it would not be in the best interest of our	*Thank you for your comments.*

ID/#	Comment	Disposition
	client or the agency to follow this guideline. Our clients provide urine samples at least weekly to direct the appropriateness of treatment.	*It should be noted that the coverage recommendation does not limit UDT to once monthly.*
B1	My name is Jen Kuhn, I am a pending CADC 1, and I work for Emergence (see contact information in signature). I see you are proposing a guideline stipulating a maximum of 36 urine drug test screenings per year and I believe that would be a disservice to the individuals receiving substance abuse treatment. Studies show that giving intensive substance abuse treatment for individuals with high risk and high needs in society is the most cost-effective way of helping society. Reducing their dependence and use of substances reduces recidivism, ER costs, medical complications, and death. One of the most effective best-practices for intensive treatment and dealing with high risk/need individuals is consistent, random and frequent urine testing - in Drug court this was twice per week, seven days per week. It was the key support for lasting change for many of our difficult cases. The majority of treatment facilities have negotiated special contracts with laboratories for bulk and discounted rates on urinalysis tests. They already know that the American Society of Addiction Medicine (ASAM) defines urine drug testing as a "key diagnostic and therapeutic tool" in substance abuse treatment. ASAM advocates that continuous monitoring of drug use through urine testing is a critical mechanism for holding patients accountable and for ensuring that their treatment plans address their individual medical needs. The American Society of Addiction Medicine (ASAM) has repeatedly advocated that the drug testing should be determined by the provider based on patient-specific needs, not by arbitrary insurance limits. I would urge you to reconsider these proposed guidelines. In my experience urine testing is an individualized part of treatment planning. It would be a disservice to restrict one of the most effective tools we have for helping individuals seek abstinence and improve their lives.	*Thank you for your comments.* *EbGS agrees that intensive, evidence-based substance use disorder treatment is valuable. The subcommittee also acknowledges that UDT is an important tool in caring for people with substance use disorder, but only when the results are used to change management.* *The use of UDT for forensic purposes (i.e., drug courts) must be medically necessary in order to warrant coverage by Medicaid.* *The ASAM principles were included in the coverage guidance and reviewed by the subcommittee. ASAM acknowledges the paucity of high-quality evidence for the utility of UDT, noting that "[o]verall, the literature review revealed that drug testing has rarely been examined for its value as a clinical intervention or as a differential source of information. Many research studies include drug testing as an outcome measure of treatment adherence or progress, but few examined whether and how drug testing itself works to improve outcomes for patients with, or at risk for, addiction." (p.43)*

HERC Coverage Guidance: Urine Drug Testing
Disposition of Public Comments

ID/#	Comment	Disposition
C1	I am a Certified Alcohol and Drug Counseling I Candidate currently employed with Emergence Addiction and Behavioral Therapies in Eugene, Oregon. I facilitate the Discovery Plus program at this agency, which provides treatment services for a variety of clients, the majority of whom have been arrested for Driving Under the Influence of Intoxicants. I am writing in to express concern about the proposed change in guidelines for Urine Drug Screening for patients with Substance Use Disorders. These proposed changes, capping the number of urine drug screens that can be performed for our population would be counterintuitive and potentially harmful for motivating them toward recovery and program completion. Without the ability to test these patients regularly, we will be unable to identify substance use, taking away our ability to add supports to their program to help them be successful. If we are unable to identify continued use and offer supports, they will be more likely to experience progression of their disease, which will be a burden on funding in other areas such as medical complications resulting from the addictive process, recidivism rates as they commit further DUIIs, potential accidents and injuries resulting from this recidivism, and burden to the criminal justice system resulting from the progression of their addictive behaviors. Additionally, this takes away our ability to customize and tailor a treatment plan to fit each patient, as is recommended by ASAM. In summary, please reconsider this proposed limit on urine drug testing and allow us, as treatment professionals to tailor our patient's treatment to his or her individual needs, rather than a short sighted attempt to save money in a way that will absolutely harm our ability to support, monitor and hold our patients accountable.	*Thank you for your comments.* *The subcommittee agrees that UDT plays an important role in managing patients with substance use disorder. However, there is no direct evidence that a particular UDT frequency results in the clinical or social benefits asserted here. The proposed coverage provides for a number of tests that is comparable to or greater than that of most of the other payers reviewed for the coverage guidance.*
D1	OPERA is a statewide member association comprised of private and non-profit organizations treating and supporting patients and their families struggling with Substance Use Disorder (SUD) and Mental Health concerns. Our members have an	*Thank you for your comments.* *Mental health parity law would require no "hard" limits on definitive tests, but rather "soft" limits and that any*

ID/#	Comment	Disposition
	expansive practice and expertise in the field of SUD including some of the longest and largest serving organizations in Oregon. Together, we provide the full continuum of care from prevention through detox helping provide an opportunity for health, life and recovery for thousands of Oregonians annually. As an association that advocates for the recovery and treatment of the chronic disease of addiction we are highly supportive of best-practice and the implementation of research that furthers the efficacy of SUD patient care and recovery. We respectfully submit this letter of public comment and extend our thanks to the Evidence Based Guideline Subcommittee for their many weeks of work and study in retooling the proposed UDT guideline prior to the public comment period. In addition, we appreciate the committee's serious consideration of testimony from OPERA and many other partner organizations and agencies. In the current draft released for public comment, OPERA is appreciative and in support of the following: • The explicit support for flexibility of UDT application to meet medical necessity and clinically informed treatment planning. • The stated acknowledgement of the limitations of presumptive testing for opioid classes and clinical assessment of need for definitive testing to protect patient safety (e.g., Fentanyl). OPERA supports the inclusion of the written clarifier that guidance limits must be applied in accordance with mental health parity law. We do, however, continue to have concerns regarding the implementation of any quantitative behavioral health coverage limits and the potential conflict with current mental health parity laws. Furthermore, we are concerned that quantitative "soft caps" may unintentionally increase the risk of the implementation of non-numerical limits such as complex authorization and review processes once "soft caps" have been reached.	*limits be applied in a way that is comparable to and no more stringently applied than limits to medical/surgical services in the same benefit category.* *EbGS believes it is appropriate that the proposed limits will meet the clinical needs for most patients. If a provider believes these limits need to be exceeded, clinical review is indicated to ascertain that exceeding the limits is appropriate. Each health plan must independently comply with parity law.*

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	Lastly, we wish to comment on the "Note" section of the current guidance. We appreciate the Subcommittee's discussion of transparency and clarity of HERC decision-making processes and matrix criteria. OPERA supports the ongoing evaluation and improvement of practices in all bodies of our complex health care delivery system, particularly those striving to improve clarity, education, and understanding for consumers, providers, and payers. In this vein, OPERA continues to be in support of continued efforts to issue guidance which displays decision matrixes, whether narrative or coded, in an easy to understand format as they encourage transparency and participation in the decision-making process.	
E1	On behalf of Quest Diagnostics, thank you for the opportunity to provide comments on the Health Evidence Review Commission's (HERC) Coverage Guidance: Urine Drug Testing. Quest Diagnostics is the world's leading provider of diagnostic information services, and serves one in three adult Americans and half the physicians and hospitals in the United States annually. We are particularly proud of our presence in Oregon, which includes 22 patient service centers, over 300 employees, and approximately 4,900 physicians and 18 hospitals served. Quest applauds Oregon for its leadership on incorporating drug testing as a tool to combat the opioid epidemic, one of the most significant healthcare crises that our nation faces. Published data show that drug testing along with prescription drug monitoring programs (PDMPs) and other risk mitigation strategies, is critical to the safe prescribing of controlled substances. Clinician-ordered drug testing generates objective information to help healthcare providers better monitor and treat patients with chronic pain.	*Thank you for your comments.*
E2	As HERC undertakes the important work of adopting coverage guidance for urine drug testing, Quest respectfully submits the following comments to the proposed guidance language. First, below find Quest's high-level comments regarding the guidance language:	*The coverage guidance has been revised to ensure consistent use of the presumptive/definitive terminology.* *The coverage guidance did not describe presumptive testing as "providing true results." It did acknowledge*

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	• The guidance introductory section defines drug testing using contemporary terms "presumptive and definitive" but later shifts to outdated "qualitative/quantitative" terminology in the subsequent sections. • The document incorrectly describes presumptive (qualitative) testing as providing true results and identifying the drugs present. Presumptive tests provide only possible detection of drug use or non-use and are not available for many prescription and illicit agents; definitive tests are what provide the actual drugs identity. • The guidance use of 'tests' rather than 'dates of service' and the lesser number of definitive tests relative to presumptive tests compromises healthcare providers access to useful drug testing information. For example, with chronic opioid therapy, six (6) definitive 'tests' per year covers a fraction of the confirmations required to identify compliance with using only prescribed drugs and abstaining from nonprescribed or illicit drugs. The statements for presumptive and definitive testing incorrectly reflect actual utility. Presumptive results are indeed presumptive, and therefore assuming the results are accurate can lead to inappropriate clinical decisions. Presumptive testing detects possible use or non-use of drugs and cannot distinguish true positive from false positive results, and false-negative results may occur due to sensitivity limitations. Definitive testing identifies drugs/metabolites present: • to confirm and identify presumptive-positive results and unexpected presumptive-negative results, • to rule out false-positive presumptive results, • and may be the only test method available for many drugs.	*that in many cases, presumptive testing alone would be sufficient for clinical decision making.* *In 2018, presumptive UDT is billed with a single code and unit of service per date of service, regardless of the number of substances detected by the panel. Definitive testing is also billed with a single code per day, but different codes represent tests for different numbers of substances. The limits in the recommendation reflect the number of units billed using correct coding, not the number of tests done in the laboratory.* *EbGS does not agree that only definitive testing is appropriate for clinical decision making. Definitive testing is only indicated when used as a confirmatory test only when the result of the presumptive testing is inconsistent with the patient's history, presentation, or current prescribed medication plan, and the results would change management.* .
E3	1. Frequency definitions should align with recent CMS publications: Dates of service	*The CMS publication was included in the coverage guidance and reviewed by the subcommittee.*

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	Descriptions should be defined as 'dates of service' to correspond with how providers order testing and how test billing occurs Presumptive and definitive coverage Presumptive and definitive testing 'dates of service' must be equivalent to provide identification of drugs used (e.g., opiates presumptive tests are inconclusive; opiates definitive testing is required) Frequency definitions, substance use disorder and chronic opioid therapy[1] Substance use disorder CMS recommends compliance-based frequency ranges. For challenging patients, the annualized drug testing count is a maximum of 63: • First 90 days, 1-3 times per week (36 maximum) • After 90 days, 1-3 times per month (27 maximum for remainder of year) Chronic opioid therapy CMS recommends risk-based frequency ranges. For highest risk, the annualized drug testing count is a maximum of 12: • Low risk, 1-2 times per year (2 maximum) • Medium risk,1-2 times every 6 months (4 maximum) • High risk, 1-3 times every 3 months (12 maximum)	
E4	2. Presumptive testing is limited to identification of possible drug use. The Resource allocation description (page 4, 5,7, 8), Balance of benefits and harms (pages 6 and 9), and Rationale (7 and 10) are incorrect that presumptive drug testing provides true positive and interpretable results. 3. "Technology Description" uses outdated terminology (qualitative/quantitative). 'Quantitative" testing is incorrectly described as reporting only quantitative results. Definitive testing can be reported as identity of drug/drug metabolite (qualitative) or as identity and concentration (quantitative).	*The subcommittee believes that presumptive testing is sufficient for clinical decision making when it aligns with expected results and further testing would not change management.*

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E5	4. It should be emphasized that Manchikanti et al. study results are heavily weighted by significantly different cutoffs of the two testing methods. 5. The 2017 publication by McClure, et. al., demonstrated that drug testing for actual concurrent benzodiazepines and opioids use far exceeded drug use predicted based upon drugs indicated as prescribed.[2] Drug testing is the only objective tool by which providers can detect actual drug use.	*This limitation of the Manchikanti et al. study was noted in the coverage guidance.* *The study by McClure et al. only established the prevalence of non-prescribed opioid and/or benzodiazepine use based on the experience of a national reference lab. It did not directly address the clinical utility of UDT or provide additional information on the operating characteristics of the assay.*
E6	6. The Medicare description for approved reflex definitive testing is missing the following statements from the CMS Palmetto LCD (L35724) (effective 03/08/2018): *Reflex Testing by Reference Laboratories–since reference laboratories do not have access to patient-specific data, reflex testing under the following circumstances is reasonable and necessary:* *a) To verify a presumptive positive UDT using definitive methods that include, but are not limited to GC-MS or LC-MS/MS before reporting the presumptive finding to the ordering clinician and without an additional order from the clinician; or* b) *To confirm the absence of prescribed medications when a negative result is obtained by presumptive UDT in the laboratory for a prescribed medication listed by the ordering clinician*	*This information on reflex testing will be added to the coverage guidance.*
F1	I appreciate the work of the Evidence-based Guideline Subcommittee in reviewing available information and considering options. However, the draft HERC Coverage Guidance for Urine Drug Testing (UDT) that you are considering is in significant conflict with best practices in the Substance Use Disorder (SUD) treatment field. The proposed limits on frequency, number of analytes, and use of definitive	*Thank you for your comments.*

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	(confirmation) testing are all inconsistent with good treatment of an individual with a SUD.	
F2	The *American Society of Addiction Medicine (ASAM) Public Policy Statement on Drug Testing as a Component of Addiction Treatment and Monitoring Programs and in Other Clinical Settings* (2010), states in part (p. 3): "It is the policy of ASAM that: 1. Urine drug testing is a key diagnostic and therapeutic tool that is useful for patient care and in monitoring of the ongoing status of a person who has been treated for addiction. As such, it is a part of medical care, and should not face undue restrictions. 2. Urine drug testing, compounds tested for, and the composition of testing panels ordered by the physician, should be determined by the ordering physician to deliver quality patient care based on the unique clinical presentation of the patient. 3. Arbitrary limits on reimbursements and restrictions on the number of tests; number of analytes; panel composition and type; frequency of testing; or methodology of testing interfere with the physician's judgment and represent a discriminatory action prohibited by federal mental health and addiction parity legislation, which states that any limitations on addiction care may not be substantially different from limitations in any other area of health care." The *ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use* (2015) states:	*The ASAM principles were included in the coverage guidance and reviewed by the subcommittee. ASAM acknowledges the paucity of high-quality evidence for the utility of UDT, noting that "[o]verall, the literature review revealed that drug testing has rarely been examined for its value as a clinical intervention or as a differential source of information. Many research studies include drug testing as an outcome measure of treatment adherence or progress, but few examined whether and how drug testing itself works to improve outcomes for patients with, or at risk for, addiction." (p.43)* *Mental health parity has been considered and language is included in the coverage guidance box language to indicate that limits must be applied in accordance with mental health parity law.*

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	"Urine drug testing, or other reliable biological tests for the presence of drugs, during the initial evaluation and frequently throughout treatment, is highly recommended." (p. 22) The *ASAM Appropriate Use of Drug Testing in Clinical Addiction Medicine consensus statement* (2017) states: • "It is the ASAM policy that the elements of drug testing (e.g., matrix, drug panel, testing technology) be determined by the provider based on patient-specific needs, not by arbitrary limits form insurance providers." (p.1) • "For people in addiction treatment, frequency of testing should be dictated by patient acuity and level of care." (p. 13) The *ASAM Principles of Addiction Medicine, 5th Edition* (Ries, R.K., et al, 2014), also states: "There are few areas of addiction medicine where drug testing is not central, precisely because drug users are likely to lie about their drug use and because drug users commonly use substances without knowing exactly what they contain. A positive drug test confirms recent use of specific drugs, whereas a negative drug test helps to establish that abstinence exists as a necessary condition of a patient's recovery program." (p. 1724)	
F3	There are multiple citations in each of these documents, and in readily accessible Drug Treatment Court outcome research, to support the effectiveness of frequent UDTs in SUD treatment, especially early in treatment. I am concerned that arbitrary limits on urine drug testing, especially when focused on cost containment rather than patient needs, will undermine the effectiveness of SUD treatment for many individuals suffering from a serious, chronic addiction. Regular, random UDTs, decreasing over the length of treatment, have been a key component	*The subcommittee agrees that UDT plays an important role in managing patients with substance use disorder. However, there is no direct evidence that a particular UDT frequency results in improvement in health outcomes. The proposed coverage provides for a number of tests that is comparable to or greater than that of most other payers reviewed for the coverage guidance.*

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	of outpatient SUD treatment for decades, and are both a valuable tool for clinicians in objectifying progress or set-backs, but also frequently cited by patients as a key to their success. UDTs help confirm progress in maintaining abstinence, help patients avoid the temptation of switching to other drugs as substitutes, help patients get up the courage to report a use and get help in learning from it, and help patients learn from a use they attempted to keep secret. Cost containment should be based on setting dollar limits, reflecting usual and customary fees, rather than on frequency limits. Most outpatient SUD programs serving OHP clients have contracts with labs for reasonable rates. For example, our routine 10-drug panel (with GC-MS confirmation of all positives, and testing for dilution and adulteration) costs $10.50. Our clients should not be deprived of these cost-effective tests due to the gratuitous over-charging by some labs, which are typically serving medical practices. The opioid crisis has highlighted the serious consequences of addiction in our state, as well as the mortality, family trauma, and social impacts that are a result. Parallel impacts exist for those suffering from addictions to other drugs, such as methamphetamine. I cannot stress enough the potential impact of the Guidance you are considering on this critical health crisis. As written, the Guidance document, even with "soft" limits, will seriously restrict the use of a tool that has been a key component of successful SUD treatment for decades. That tool is summarized by the National Institute on Drug Abuse (in *Principles of Drug Addiction Treatment: A Research-based Guide*, 2018), as one of 13 basic treatment principals: "**Drug use during treatment must be monitored continuously, as lapses during treatment do occur**. Knowing their drug use is being monitored can be a powerful incentive for patients and can help them withstand urges to use drugs. Monitoring also provides an early indication of a return to drug	*The quantity limits reflect the subcommittee's recommendation on an appropriate limit for the number of tests for most patients' needs. Mental health parity law would, at a minimum, require exceptions be made in certain circumstances. As with any coverage recommendation, health plans may choose to employ different utilization and cost management strategies appropriate to their context.*

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	use, signaling a possible need to adjust an individual's treatment plan to better meet his or her needs." For a client in relapse, or who has not yet attained a stable abstinence, too infrequent UDTs can result in a return to higher levels of use, dropping out of treatment, overdose, or other medical complications. The Subcommittee has not yet been presented with adequate evidence that the restrictions you are considering will not cause harm, especially for patients in SUD treatment.	
F4	The Subcommittee has been presented with evidence that can be clustered from four sources: 1) Research on effectiveness of urine drug tests (UDTs): The studies cited in the draft Coverage Guidance, with one exception, were all conducted on patients being treated for chronic pain. The one cited non-chronic pain study targeted patients in medical practices. *(Comment truncated because it exceeded the 1,000 word limit)*	*The limitations of the available evidence are discussed in the coverage guidance and reflected in the statements in the GRADE table regarding the confidence in the estimate of effect.*
G1	Subsequent to review of your draft on Urine Drug Testing coverage, we are providing commentary as requested. We agree Urine Drug Testing provides objective information to support improved clinical decision making by identifying recent use of prescription medications, non-prescribed medications, and illicit substances. Due to the known risks of misuse, abuse and diversion with controlled substances that play a role in treating certain health conditions, as well as the prevalence of substance abuse in our country, UDT has become an integral part of an overall risk mitigation program when prescribing certain medications and as a tool for monitoring abstinence in substance use disorder treatment. As you state, Urine Drug Testing is advocated by many states, payer policies, and universally by societal guidelines. Given the limitations of presumptive immunoassay screens and the results they provide as you point out, we support access for health care providers and the patients they treat to individualized definitive Urine Drug Testing with Liquid	*Thank you for your comments.* *Although there are certainly limitations to presumptive tests, the subcommittee believes that presumptive testing is sufficient for clinical decision making when it aligns with expected results and further testing would not change management. A limited number of definitive tests are recommended for coverage, when indicated.*

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	Chromatography Tandem Mass Spectrometry (LC-MS/MS) technology which provides accurate and objective information to support improved clinical decision making thereby helping health care providers: • Monitor and support decisions about medication therapy, particularly controlled substances • Identify recent use of prescription medications, non-prescribed medications, and illicit substances • Detect medications that may result in drug-drug interactions which could otherwise be undetected • Advocate for, and communicate with, patients about individual treatment plans • Identify possible illicit drug or medication abuse, misuse, or diversion	
G2	Considering the clinical value of definitive Urine Drug Testing in treating patients with chronic opioid therapy and other medications with the potential for abuse and for substance use disorders we want to respectfully point out that in certain clinical situations, individualized Urine Drug Testing based on clinical assessment of the patient for risk of misuse, abuse and addiction or their stage in substance use disorder, community trends of abuse and patient history of abuse may create a clinical need for testing a number of substances beyond your recommendations of seven substances per day. This limitation will create a barrier to access of Urine Drug Testing and the benefits discussed in this document and your draft coverage guidance. This barrier will lead to missed opportunities for intervention, missed relapsed with substance abuse disorders, less effective treatment and decision making, higher risk for undetected, clinically significant drug interactions and greater potential for increased side effects for patients.	*Definitive testing of more than seven substances per day is unlikely to be clinically indicated on a routine basis. There could be an option for reference-based pricing in this situation.*

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G3	We know through open channels of communication and collaboration with payers that we can achieve our common goal of supporting medically necessary, guideline driven and policy compliant testing by healthcare providers that benefits patient care. Millennium Health's commitment is demonstrated by the evidence-based education tools we provide to our customers to support clinical decision making and other corporate initiatives. I look forward to your thoughts and discussing a collaborative working relationship to discuss further steps we have proactively taken to support responsible utilization of definitive Urine Drug Testing by our customers as well as a partnership with you in developing utilization and frequency criteria for Urine Drug Testing.	*Thank you for your comments.*

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References Provided by Commenters

ID	References
E	1. Controlled Substance Monitoring and Drugs of Abuse Testing. Centers for Medicare and Medicaid Services (CMS), Palmetto Local Coverage Determination (LCD) LCD ID L35724. 2018. 2. McClure FL, Niles JK, Kaufman HW, Gudin J. Concurrent Use of Opioids and Benzodiazepines: Evaluation of Prescription Drug Monitoring by a United States Laboratory. *Journal of Addiction Medicine*: November/December 2017- Volume 11- Issue 6- p 420-426

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