Health Evidence Review Commission's Value-based Benefits Subcommittee

August 10, 2017

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 10, 2017
8:00am - 1:00pm
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
A working lunch will be served at approximately 12:00 PM
All times are approximate

I. Call to Order, Roll Call, Approval of Minutes – Kevin Olson **8:00 AM**

II. Staff report – Ariel Smits, Cat Livingston, Darren Coffman **8:05 AM**

A. Errata
   A. Errata summary
   B. Further psoriasis errata

B. Other staff reports

III. Straightforward/Consent agenda – Ariel Smits **8:10 AM**

A. Consent table
B. Lower extremity amputations for severe pressure ulcers
C. Medical treatment of missed spontaneous abortions
D. Non-major neonatal infections
E. Surgical Treatment of Bone/Joint Prostheses with Infection or Inflammatory Reaction

IV. New discussion items **8:15 AM**

A. Lattice degeneration, retinal breaks, and retinal holes—with Dr. Andreas Lauer

V. Advisory panel reports **8:45 AM**

A. OHAP report
   A. Treatment of craniofacial anomalies with orthodontics—with Dr. Judah Garfinkle
   B. Frenulectomy
   C. Early childhood caries—multisector intervention

B. BHAP report
   A. BHAP minutes review
   B. BHAP code and guideline change recommendations for VBBS action
   C. Supported employment

VI. 2018 ICD-10 code placement **9:15 AM**

A. Straightforward
B. ICD-10 code placement issues

VII. New discussion items continued **9:45 AM**

- **A.** Recurrent acute sinusitis treatments
- **B.** Physical therapy for interstitial cystitis
- **C.** Intrathecal/epidural pumps
- **D.** Acute peripheral nerve injuries
- **E.** Testicular prostheses
- **F.** Capsulorrhaphy for recurrent shoulder dislocation
- **G.** Transcutaneous neurostimulators
- **H.** Statement of Intent 1 Palliative Care revisions

VIII. Previous discussion items **11:15 AM**

- **A.** Vision training
- **B.** Back guidelines
    A. Back surgery guideline
- **C.** Guidelines on treatments with marginal or no clinical benefit/low cost-effectiveness (Services of Low Importance)
    A. Treatments previously on the Services Recommended for Non-Coverage
    B. Medications

IX. Coverage guidances – Wally Shaffer **12:15 PM**

- **A.** Continuous blood glucose monitoring

X. Public comment **12:55 PM**

XI. Adjournment – Kevin Olson **1:00 PM**

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on May 18, 2017

For specific coding recommendations and guideline wording, please see the text of the 5/18/2017 VbBS minutes.

RECOMMENDED CODE MOVEMENT (effective 10/1/2017 unless otherwise noted)

- Various straightforward coding changes were made
- Add a procedure code for endometrial ablation to the gender dysphoria line
- Add codes for corneal ring segment insertion to a covered line with a new guideline for treatment of keratoconus
- Add procedure codes for treatment of synovitis to a covered line for treatment of benign joint conditions that affect function
- Place procedure codes for the treatment of low back pain with corticosteroid injections on a noncovered line (previously on the Services Not Recommended for Coverage Table) based on the coverage guidance recommendations of the Evidence-based Guidelines Subcommittee

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- The opioid for back conditions guideline was reviewed but no changes were recommended
- Cranial electrical stimulation (Alpha-Stim) was reviewed but no change was recommended

RECOMMENDED GUIDELINE CHANGES (effective 10/1/2017 unless otherwise noted)

- Add a new guideline specifying when cholecystectomy for gallstones was included on the upper gallstone line (1/1/2018 implementation)
- Modify the ancillary guideline for tobacco cessation for elective procedures to clarify that only reproductive procedures with the intent of contraception are exempted
- Modify the guidelines that required prolonged smoking cessation prior to a procedure to specify that the cessation from all tobacco products is required
- Replace the guideline note on MRI for breast cancer with new language specifying coverage criteria for supplemental screening for women at above-average risk of breast cancer (1/1/2018 implementation)
- Modify Guideline Note 104 to add a CPT code
- Add an additional line to Guideline note 74

VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
May 18, 2017
8:00 AM – 1:00 PM

Members Present: Susan Williams, MD, Chair Pro Tempore; David Pollack, MD (12:30 PM departure); Mark Gibson; Irene Croswell, RPh; Holly Jo Hodges, MD; Vern Saboe, DC; Gary Allen, DMD.

Members Absent: Kevin Olson, MD.

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Denise Taray, RN; Jason Gingerich; Daphne Peck.

Also Attending: Kim Wentz, MD MPH, (Oregon Health Authority); Adam Obley, MD, MPH, Craig Mosbaek, MPH (OHSU Center for Evidence-based Policy); Heather Khan, MD, Arthur Sherman, Cassandra Ventrella.(Rogue Medicine); Jay Hala (Alleva Health); Margaret Olmon, (AbbVie); Lorren Sandt (Caring Ambassadors); Mike Willett (Pfizer).

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

  The meeting was called to order at 8:00 am and roll was called. Minutes from the March 9, 2017 VbBS meeting were reviewed and approved with one amendment to change "pharmacy directors" to "medical directors" on page 10.

  Smits reviewed the errata documents. There were no comments or discussion.

  Coffman discussed internal staff discussions about the creation of a statement of intent to specify when items not on the Prioritized List are covered (diagnostic, support/DME type of services, etc.) and regarding the exceptions process for noncovered procedures in certain cases. Allen considered this to be a valuable idea and recommended pursuing it. Hodges agreed.

- **Topic: Straightforward/Consent Agenda**

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

Recommended Actions:

1) Add 44130 (Enteroenterostomy, anastomosis of intestine, with or without cutaneous enterostomy) to line 51 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS
2) Add 44110 (Excision of 1 or more lesions of small or large intestine not requiring anastomosis, exteriorization, or fistulization; single enterotomy) to line 170 ANAL, RECTAL AND COLONIC POLYPS
3) Add 45340 (Sigmoidoscopy, flexible; with transendoscopic balloon dilation) and 46080 (Sphincterotomy, anal, division of sphincter) to line 458 RECTAL PROLAPSE
4) Add 46614 (Anoscopy; with control of bleeding (eg, injection, bipolar cautery, unipolar cautery, laser, heater probe, stapler, plasma coagulator)) to line 60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE
5) Add E72.20 (Disorder of urea cycle metabolism, unspecified) to line 226 DISORDERS OF FLUID, ELECTROLYTE, AND ACID-BASE BALANCE
6) Add K63.81 (Dieulafoy lesion of intestine) to line 60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE and remove from line 32 REGIONAL ENTERITIS, IDIOPATHIC PROCTOCOLITIS, ULCERATION OF INTESTINE
7) Add K63.89 (Other specified diseases of intestine) to lines 161 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS and 664 GASTROINTESTINAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
    a. Remove K63.89 from line 231 RUPTURED VISCUS
8) Add 43273 (Endoscopic cannulation of papilla with direct visualization of pancreatic/common bile duct(s)) to line 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
9) Add 10160 (Puncture aspiration of abscess, hematoma, bulla, or cyst), 43274-43276 (Endoscopic retrograde cholangiopancreatography (ERCP), and 49405 (Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); visceral (eg, kidney, liver, spleen, lung/mediastinum), percutaneous) to line 368 CYST AND PSEUDOCYST OF PANCREAS
10) Add 37244 (Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation) to line 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
11) Add 10160 (Puncture aspiration of abscess, hematoma, bulla, or cyst) and 49405 (Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); visceral (eg, kidney, liver, spleen, lung/mediastinum), percutaneous) to line 298 ANOMALIES OF GALLBLADDER, BILE DUCTS, AND LIVER
12) Add 44345 (Revision of colostomy; complicated (reconstruction in-depth)) to line 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT

13) Add 43255 (Esophagogastroduodenoscopy, flexible, transoral; with control of bleeding, any method), 44120 (Enterectomy, resection of small intestine; single resection and anastomosis) and 45382 (Colonoscopy, flexible; with control of bleeding, any method) to line 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
14) Add 20610 (Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance) and 20611(With ultrasound guidance) to line 361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE
15) Add 28120 (Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (eg, osteomyelitis or bossing); talus or calcaneus), 28122 (Tarsal or metatarsal bone, except talus or calcaneus), 28805 (Amputation, foot; transmetatarsal), 28810 (Amputation, metatarsal, with toe, single), 28820 (Amputation, toe; metatarsophalangeal joint), 28825 (Amputation, toe; interphalangeal join), 13101-13113 (Repair, complex wounds) to line 384 CHRONIC ULCER OF SKIN
16) Add M35.01 (Sicca syndrome with keratoconjunctivitis) to line 476 KERATOCONJUNCTIVITIS
17) Add 21198 (Osteotomy, mandible, segmental) to line 561 BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE INCLUDING OSTEOID OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE
18) Add 26123 (Fasciectomy, partial palmar with release of single digit including proximal interphalangeal joint, with or without Z-plasty, other local tissue rearrangement, or skin grafting (includes obtaining graft);) and 26125 (Each additional digit) to line 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
19) Add 23462 (Capsulorrhaphy, anterior, any type; with coracoid process transfer), 29822 (Arthroscopy, shoulder, surgical; debridement, limited) and 29823 (Extensive) to line 364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS
20) Add 25230 (Radial styloidectomy) to line 361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE
21) Add 96150-96155 (Health and behavior assessment) to lines 111 GIANT CELL ARTERITIS, POLYMYALGIA RHEUMATICA AND KAWASAKI DISEASE and 210 SUPERFICIAL ABSCESSES AND CELLULITIS
22) Add 28304 (Osteotomy, tarsal bones, other than calcaneus or talus) to line 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS
23) Add 27033 (Arthrotomy, hip, including exploration or removal of loose or foreign body) to line 364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS
24) Add 19020 (Mastotomy with exploration or drainage of abscess, deep) to line 210 SUPERFICIAL ABSCESSES AND CELLULITIS
25) Remove E23.7 (Disorder of pituitary gland, unspecified) from line 347 OTHER AND UNSPECIFIED ANTERIOR PITUITARY HYPERFUNCTION, BENIGN NEOPLASM OF THYROID GLAND AND OTHER ENDOCRINE GLANDS and add to line 656 ENDOCRINE AND

METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

26) Add 51700 (Bladder irrigation, simple, lavage and/or instillation) to line 75 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
27) Add 52330 (Cystourethroscopy (including ureteral catheterization); with manipulation, without removal of ureteral calculus) to line 184 URETERAL STRICTURE OR OBSTRUCTION; HYDRONEPHROSIS; HYDROURETER
28) Add 51102 (Aspiration of bladder; with insertion of suprapubic catheter) and 51700 (Bladder irrigation, simple, lavage and/or instillation) to line 357 URINARY SYSTEM CALCULUS
29) Add 50220 (Nephrectomy, including partial ureterectomy, any open approach including rib resection) to line 184 URETERAL STRICTURE OR OBSTRUCTION; HYDRONEPHROSIS; HYDROURETER
30) Modify GN104 as shown in Appendix A
31) Add line 347 OTHER AND UNSPECIFIED ANTERIOR PITUITARY HYPERFUNCTION, BENIGN NEOPLASM OF THYROID GLAND AND OTHER ENDOCRINE GLANDS to Guideline Note 74, GROWTH HORMONE TREATMENT

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

- **Topic: Back Guidelines**

Discussion: Smits reviewed the staff summary and recommendations. There was discussion about the need to clarify when spondylolisthesis is covered. It appears twice in the guideline, once to specify that by itself, spondylolisthesis is only a surgical indication if it results in neurogenic claudication; under these conditions coverage for both decompression and fusion is appropriate. To result in neurogenic claudication, the spondylolisthesis must result in central spinal stenosis, not foraminal stenosis. The staff suggestion to add "central" to the description of spinal stenosis resulting from spondylolisthesis was not accepted as VbBS members felt that the neurogenic claudication phrase was sufficient.

The second mention of spondylolisthesis is to specify that spinal stenosis is only paired with fusion when spondylolisthesis is also present. There was a suggestion to add a phrase to the spinal stenosis sentence, "Surgical correction of spinal stenosis (ICD-10-CM M48.0), with or without spondylolisthesis, is only included on Line 351…"

The staff suggestion to add wording specifying that spondylolisthesis must be "demonstrated on flexion/extension films (x-rays) showing at least a 5 to 7 mm translation" was accepted.

The staff suggestion to specify that radiating pain alone caused by foraminal or central spinal stenosis was only included on line 532 was discussed. Saboe was concerned about

the inclusion of radiating pain. He felt the wording should be "radicular," but several other members did not agree. The staff suggestion to add "Foraminal or central spinal stenosis causing only radiating pain (e.g. radiculopathic pain) is included only on line 532" was accepted, with an e.g. rather than an i.e. as the only change.

The staff suggestion to add the ICD-10 codes for radiculopathy to the upper back surgery line was considered a good idea.

There was further discussion about the confusing wording of the guideline. It was decided that HERC staff would work with Williams and the CCO medical directors to further clarify the wording and bring back to the August meeting.

Note: additional edits were suggested to the back surgery guideline during the discussion later in the meeting regarding epidural steroid injections.

Smits then turned to the Opioid and Non-Interventional Back Treatment Guidelines. Gingerich presented data on utilization of conservative therapies, which showed acupuncture and chiropractic services had significant increases for back diagnoses from late 2015 to late 2016, while small increases were seen in CBT, PT/OT and osteopathic treatments. Opioid prescribing has been falling for back conditions, likely for a variety of reasons and due to multiple statewide initiatives. Saboe shared the positive experiences in his practice with new back pain referrals and treatment outcomes. He said chiropractors provide more services than manipulation and may use other modalities.

Gibson suggested changing the non-interventional guideline title to "non-invasive" as PT, acupuncture, etc. are interventions. Wentz pointed out that CBT is considered interventional. The overall feeling was that the title was not causing problems and should not be changed. Staff will consider the issue and bring back the guideline title for possible reconsideration in August.

The staff suggestion for no edits to the current guideline regarding opioids for back pain was accepted, with the current deadline for tapering patients off chronic opioids by the end of 2017. VbBS requested to see additional data on opioid prescribing and alternate therapy utilization in the fall of 2017.

Recommended Actions:

1) HERC staff to work with Williams and the CCO medical directors to further refine wording for the back surgery guideline.
2) Staff to consider a title change for the Non-Interventional Back Treatment Guideline

- **Topic: Cholecystectomy for Biliary Colic**

Discussion: Smits reviewed the summary document. The major concern from the HERC Commissioners who brought this topic back to VbBS was the results of the Gurusamy 2013 study, which found significant harms in watchful waiting for biliary colic. Gibson criticized this study, noting that it was done in the Turkish health system and may not be translatable to the US health system. The patients were randomized to waiting lists, not actually "watchful waiting." He said the mean wait was over 4 months. Overall, Gibson felt that the Gurusamy study constituted very poor evidence as the trial had numerous deficiencies. He also pointed out that high risk patients are getting exceptions from CCOs currently to have surgery, based on CCO medical director testimony at the March meeting. He felt that biliary colic should be left on the lower line.

Coffman said other payers are covering the procedure. He noted that since surgeons feel this is standard of care, future studies are not likely to happen. Coffman said exceptions criteria are not standard across CCOs. Hodges said standardization of criteria across CCOs for when cholecystectomy should be approved for biliary colic would be helpful.

The group agreed that coverage for biliary colic with a guideline was justified. They discussed how to clarify the proposed guideline language. The third clause in the guideline, for ICD-10 K82.8, was actually a coding specification. This portion of the language was removed and placed into a new coding specification. The remaining two clauses were clarified as the two indications for cholecystectomy on the upper gallstone line (cholecystitis and recurrent biliary colic).

Recommended Actions:

1) Reverse the previously VbBS recommended line name change for line 645 (not accepted by HERC and therefore not implemented)
    a. 645 GALLSTONES WITHOUT CHOLECYSTITIS~~; BILIARY COLIC~~
2) Adopt a new guideline for lines 59 and 645 as shown in Appendix B
3) Add a new coding specification to lines 59 and 645
    a. "ICD-10 K82.8 (Other specified diseases of gallbladder) is included on line 59 when the patient has porcelain gallbladder or gallbladder dyskinesia with a gallbladder ejection fraction <35%. Otherwise, K82.8 is included on line 645."

MOTION: To approve the reversal of the line title change, the amended new guideline and the new coding specification. CARRIES 7-0.

- **Topic: Gender Dysphoria Updates**

Discussion: Smits reviewed the staff recommendations. There was minimal discussion.

Recommended Actions:

1) Add CPT 58353 (Endometrial ablation, thermal, without hysteroscopic guidance), 58356 (Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed), and 58563 (Hysteroscopy, surgical; with endometrial ablation (eg, endometrial resection, electrosurgical ablation, thermoablation)) to line 317 GENDER DYSPHORIA

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

- **Topic: Tobacco Cessation and Elective Surgery**

Discussion: Livingston reviewed the summary document. Gibson asked to clarify how gender dysphoria surgeries were affected by the guideline with regard to the reproductive procedures conversation. Livingston stated that gender dysphoria surgeries would be similar to any other elective surgery included with this guideline and require 1 month of smoking cessation. There was minimal further discussion.

Recommended Actions:

1) Modify Ancillary Guideline A4 as shown in Appendix A
2) Modify GN 100, GN112 and GN159 as shown in Appendix A

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

- **Topic: Treatments With Marginal Effectiveness/Low Cost-Effectiveness**

Discussion: Smits introduced the summary document, which was a starting point for group discussion with no action items. The group discussed where to place experimental therapies and decided to locate them on the lowest line (line 660). Federally excluded services, such as medications for weight loss, cosmetic procedures, and travel vaccines, will not be placed anywhere on the Prioritized List.

VbBS members decided that the guideline 168 and 169 tables should include an English description for the condition (not ICD-10 codes), the CPT code(s) an English description of the procedure, a rationale statement about why that condition/treatment pair was included, a notation of the last date of review and a link to the relevant minutes. For the rationale column, a statement indicating that the reason was complicated and referring readers to minutes may be reasonable in certain circumstances. In general, the group felt that a rationale statement was useful to readers and medical directors and was similar to the GRADE process used in other HERC work.

Public testimony was heard from Lorren Sandt, from Caring Ambassadors. She said her organization does receive funding from pharmaceutical companies. She requested that the HERC consider the definitions used to place various treatments into these guidelines be carefully thought out and specific. She requested that if cost-effectiveness is used as a criteria, that the HERC re-review those therapies on a regular basis as the cost of therapies could possibly come down. She also noted that many cancer therapies may qualify, which might be in conflict with federal law regarding inability to discriminate on stage of disease or length of life in coverage.

Staff will have further conversations about the definitions, including the level of detail and where such definitions would be placed (website, on the List, etc.).

Cost effectiveness

Livingston reviewed a separate summary document regarding the definition of cost-effectiveness. Gibson discussed the various approaches and identified that the Prioritized List is a kind of league table. ICER's incremental cost-effectiveness ratio tool can assist in implementation of supporting our approach.

Saboe raised the issue of the value of low-cost, non-invasive interventions without much evidence. He gave 2 specific examples, and said that there is no evidence and unlikely to be any. If they are low cost and not harmful there could be an argument for covering them based on case reports. Livingston discussed that low cost interventions are appealing; however, some evidence of efficacy is necessary in order to achieve any reasonable cost-effectiveness ratio.

Williams discussed the value of league tables that take the budget into consideration. If one just picks a cost per QALY threshold but it exceeds the budget, then the appropriate decision has not been made. We need to maximize benefit for the budget that we have.

Allen said dental procedures may be underrepresented in this, and that there are unfunded dental interventions which are likely to be cost-effective.

The subcommittee agreed to use these cost-effectiveness approaches as helpful tools, specifically league tables and cost per QALY thresholds, but no specific cutoffs were recommended.

Recommended Actions:

1) HERC staff will continue to work on guideline notes 168 and 169 and bring back to the August 2017 meeting for further discussion.

- **Topic: Vision Training**

  Discussion: Smits reviewed the summary document. Hodges noted that there were specific OARs regarding vision training. These OARs include age limitations and a limit of 6 visits with no PA, then unlimited visits with a PA for persons under age 19. Wentz noted that OAR would override any changes to the Prioritized List, although HSD tries to have OARs to follow the List. Taray said the List identifies the conditions that would be covered for vision therapy, and then the OAR would set forth the limits on the vision therapy for those conditions. Wentz also noted that the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit may be a factor in determining the amount of vision training given to a child. Hodges said there was another CPT code (97530) which was not included in the staff recommendations which she sees used for billing for vision therapy.

  HERC staff will work with Hodges and HSD staff on this topic and bring it back for further discussion at the August meeting.

  Recommended Actions:
  1) Tabled until the August, 2017 VbBS meeting

- **Topic: Corneal Ring Segments**

  Discussion: Smits reviewed the staff recommendations. There was minimal discussion.

  Recommended Actions:
  1) Add CPT 65785 (Implantation of intrastromal corneal ring segments) to line 315 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA
     a. Contains keratoconus (ICD-10 H18.6)
  2) Adopt a new guideline for line 315 as shown in Appendix B

  MOTION: To recommend the code changes and new guideline note as presented. CARRIES 6-0. *(Absent: 1 (Williams); Abstained: 0)*

- **Topic: Treatment of Acute Recurrent Sinusitis**

  Recommended Actions:
  1) Tabled to August 2017

- **Topic: Cranial Electrical Stimulation (CES)**

  Discussion: Smits reviewed the summary documents.

Testimony was heard from Dr. Heather Khan, a physician who uses CES in her practice. Dr. Khan had no expressed conflicts of interest. She provided a large packed of literature and other written information/testimony. She urged the VbBS to consider CES as an effective non-opioid modality for treatment of pain. She testified that CES was a safe, clinically proven, non-pharmacologic treatment for several conditions. It is FDA approved for pain, insomnia, depression and anxiety. Dr. Khan presented cost-effectiveness data compared to various medications. CES that is used in her office uses CPT 97032 as the billing code, although home devices use other billing codes. She noted that some private payers are covering CES, notably the Veteran's Administration (VA) through the Wounded Warrior project; no state Medicaid programs are coving it currently. She testified that CES has no significant side effects; all adverse effects were mild and self-limiting. Pharmacologic treatment has serious complications including death. Alpha-Stim is superior to other CES devices due to its unique waveform. This waveform makes CES more effective than TENS. She testified that the studies reviewed in her packet support its use. She said the United Kingdom (UK) is currently doing a large clinical trial for the National Health Service (NHS). She critiqued studies that found mixed or negative results. She respectfully asked that submitted articles be reviewed.

When asked by committee members how CES was used in her office, she noted that ideally, a patient would come in daily. Sessions last from 20 min to 2 hours. The patient is seated in a comfortable chair and has soothing music playing with coloring or other activities offered. For the pilot project for AllCare, the patients could only come in 3 days a week, and compliance was not good since patients were not able to make 3 sessions a week consistently. The patients who were able to come in for the recommended visits seemed to have better results. Dr. Khan noted an increase in patient empowerment.

Pollack was concerned about the lack of methodically rigorous studies. He did see some promise in CES for treatment of anxiety and possibly other indications, but not for pain. The general consensus was that CES did not have evidence of effectiveness and should not be added to the Prioritized List. Gibson suggested reconsidering coverage of CES if the NHS publishes a larger, good quality study, or if other large, good quality studies become available.

Recommended Actions:

1) Add an entry for CES for all indications to GUIDELINE NOTE 169, TREATMENTS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

- **Topic: Pigmented Villonodular Synovitis**

Discussion: Smits presented the staff recommendations. There was minimal discussion.

Recommended Actions:

1) Add the CPT codes listed below to line 406 BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS and line 561 BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE INCLUDING OSTEOID OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE (if absent)

23105	Arthrotomy; glenohumeral joint, with synovectomy, with or without biopsy
23106	Arthrotomy; sternoclavicular joint, with synovectomy, with or without biopsy
24102	Arthrotomy, elbow; with synovectomy
25105	Arthrotomy, wrist joint; with synovectomy
25320	Capsulorrhaphy or reconstruction, wrist, open (eg, capsulodesis, ligament repair, tendon transfer or graft) (includes synovectomy, capsulotomy and open reduction) for carpal instability
26130	Synovectomy, carpometacarpal joint
27054	Arthrotomy with synovectomy, hip joint
27334	Arthrotomy, with synovectomy, knee; anterior OR posterior
27335	Arthrotomy, with synovectomy, knee; anterior AND posterior including popliteal area
28070	Synovectomy; intertarsal or tarsometatarsal joint, each
28072	Synovectomy; metatarsophalangeal joint, each
27625	Arthrotomy, with synovectomy, ankle
27626	Arthrotomy, with synovectomy, ankle; including tenosynovectomy
29820	Arthroscopy, shoulder, surgical; synovectomy, partial
29821	Arthroscopy, shoulder, surgical; synovectomy, complete
29835	Arthroscopy, elbow, surgical; synovectomy, partial
29836	Arthroscopy, elbow, surgical; synovectomy, complete
29844	Arthroscopy, wrist, surgical; synovectomy, partial
29845	Arthroscopy, wrist, surgical; synovectomy, complete
29863	Arthroscopy, hip, surgical; with synovectomy
29875	Arthroscopy, knee, surgical; synovectomy, limited
29876	Arthroscopy, knee, surgical; synovectomy, major, 2 or more compartments (eg, medial or lateral)
29895	Arthroscopy, ankle (tibiotalar and fibulotalar joints), surgical; synovectomy, partial
29905	Arthroscopy, subtalar joint, surgical; with synovectomy

MOTION: To recommend the code changes as presented. CARRIES 6-0. *(Absent: 1 (Williams); Abstained: 0)*

- **Topic: Coverage Guidance—Low Back Pain: Corticosteroid Injections**

Discussion: Obley reviewed the draft coverage guidance as recommended by the Evidence-based Guidelines Subcommittee (EbGS) along with the public comments. Livingston presented the rest of the GRADE tables and the draft coverage recommendation. There was a discussion about the role Values and Preferences plays in determining the strength of the recommendation. Subcommittee members asked if values and preference could weaken a recommendation *against* a procedure when many of those testifying have a vested financial interested in the subject. This was countered with a statement that providers do appear to passionately believe this is the right thing to do. Ultimately, a strong preference for an unproven procedure is not enough to change a strength of recommendation using GRADE methodology. However, there are some other reasons why the recommendation may be a weak rather than a strong one.

Subcommittee members recommended that staff modify the values and preferences column in the GRADE table to reflect the deliberations pending the HERC decision.

Pollack shared a personal story that makes him question the studies' ability to capture the benefit of epidural steroid injections. He noted the inconsistency between personal experience and the study results.

Saboe discussed the unpredictability of who will benefit from an ESI. Gibson raised the issue of anesthetic alone showing similar benefit and Obley raised that even a saline injection has a similar benefit to epidural steroid injections. Williams discussed that the sham effect needs to be considered.

Livingston reviewed the issue summary for application to the Prioritized List. A question was raised about needing coverage of diagnostic procedures EbGS ends up recommending radiofrequency denervation in a future coverage guidance. Livingston clarified that issue could be addressed once the EbGS recommendations on the new minimally invasive coverage guidance are made available to VbBS.

Recommended Actions:

1. Add corticosteroid epidural injections (62322-62323, 64483-64484), facet joint injections, and medial branch blocks (64493-64495), and SI joint injection (G0260) to Line 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
    a. Remove 64483-64484, and 64493-64495 from the SRNC
    b. Recommended that HSD remove G0260 from Diagnostic Procedures File
    c. Keep 62322- 62323 on Dysfunction lines with a new coding specification as shown in Appendix C
2. Modify Guideline Note 37 as shown in Appendix A
3. Modify Guideline Note 161 as shown in Appendix A

MOTION: To approve the recommended changes to the Prioritized List based on the draft Corticosteroid Injections for Low Back Pain coverage guidance scheduled for review by HERC at the 5/18/17 meeting as presented. CARRIES 6-0. *(Absent: 0; Abstained: 1 (Pollack))*

- **Topic: Coverage Guidance—Breast Cancer Screening in Women at Above Average Risk**

Discussion: Obley reviewed the evidence behind the coverage guidance recommendations by the Health Technology Assessment Subcommittee. Shaffer presented the staff recommended changes to the Prioritized List based on the coverage guidance. There was discussion about making a guideline for average risk women; it was decided to clarify that the testing in the guideline (MRI, etc.) is "only" for women at above average risk. There was no other significant discussion.

Recommended Actions:

1) Diagnostic Guideline D6 was modified as shown in Appendix A

MOTION: To approve the recommended changes to the Prioritized List based on the draft Breast Cancer Screening in Women at Above-Average Risk coverage guidance scheduled for review by HERC at their 5/18/17 meeting. CARRIES 7-0.

- **Public Comment:**

No additional public comment was received.

- **Issues carried over for next meeting:**
  - Spinal surgery guideline
  - Non-Interventional back treatment guideline
  - Guidelines for treatments with marginal effectiveness/low cost-effectiveness
  - Vision training
  - Treatments for acute recurrent sinusitis

- **Next meeting:**

August 10, 2017 at Clackamas Community College, Wilsonville Training Center, Wilsonville, Oregon, Rooms 111-112.

- **Adjournment:**

The meeting adjourned at 1:10 PM.

Appendix A
Revised Guideline Notes

ANCILLARY GUIDELINE A4, SMOKING CESSATION AND ELECTIVE SURGICAL PROCEDURES

Smoking cessation is required prior to elective surgical procedures for active tobacco users. Cessation is required for at least 4 weeks prior to the procedure and requires objective evidence of abstinence from smoking prior to the procedure.

Elective surgical procedures in this guideline are defined as surgical procedures which are flexible in their scheduling because they do not pose an imminent threat nor require immediate attention within 1 month. Reproductive (i.e. for contraceptive purposes), cancer-related and diagnostic procedures are excluded from this guideline.

The well-studied tests for confirmation of smoking cessation include cotinine levels and exhaled carbon monoxide testing. However, cotinine levels may be positive in nicotine replacement therapy (NRT) users, smokeless tobacco and e-cigarette users (which are not contraindications to elective surgery coverage). In patients using nicotine products aside from combustible cigarettes the following alternatives to urine cotinine to demonstrate smoking cessation may be considered:

- Exhaled carbon monoxide testing
- Anabasine or anatabine testing (NRT or vaping)

Certain procedures, such as lung volume reduction surgery, bariatric surgery, erectile dysfunction surgery, and spinal fusion have 6 month tobacco abstinence requirements. See Guideline Notes 8, 100, 112 and 159.

DIAGNOSTIC GUIDELINE D6, ~~MRI FOR~~ BREAST CANCER SCREENING IN ABOVE-AVERAGE RISK WOMEN

~~Breast MRI is not covered for screening for breast cancer~~

Annual screening mammography and annual screening MRI are covered only for women at above-average risk of breast cancer. This coverage, beginning at 30 years of age, includes women who have one or more of the following:

- Greater than 20% lifetime risk of breast cancer
- BRCA1 or BRCA2 gene mutation, or who have not been tested for BRCA but have a first-degree relative who is a BRCA carrier
- A personal history or a first-degree relative diagnosed with Bannayan-Riley-Ruvalcaba syndrome, Cowden syndrome, or Li-Fraumeni syndrome
- Other germline gene mutations known to confer a greater than 20% lifetime risk of breast cancer

Appendix A
Revised Guideline Notes

For women with a history of high dose chest radiation (≥ 20 Gray) before the age of 30, annual screening MRI and annual screening mammography are covered beginning 8 years after radiation exposure or at age 25, whichever is later.

For women with both a personal history and a family history of breast cancer, annual mammography, annual breast MRI and annual breast ultrasound are covered.

For women with increased breast density, supplemental screening with breast ultrasound, MRI, or digital breast tomosynthesis is not covered.

Breast PET-CT scanning and breast-specific gamma imaging are not covered for breast cancer screening.

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/herc/Pages/Breast Cancer Screening in Women at Above-Average Risk. ~~See http://www.oregon.gov/oha/herc/Pages/blog-mri-breast-cancer-screening.aspx~~

GUIDELINE NOTE 37, SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS

Lines 351,532

Spondylolisthesis (ICD-10-CM M43.1, Q76.2) is included on Line 351 only when it results in spinal stenosis with signs and symptoms of neurogenic claudication. Otherwise, these diagnoses are included on Line 532. Decompression and fusion surgeries are both included on these lines for spondylolisthesis.

Surgical correction of spinal stenosis (ICD-10-CM M48.0) is only included on Line 351 for patients with:

1) MRI evidence of moderate to severe central or foraminal spinal stenosis AND
2) A history of neurogenic claudication, or objective evidence of neurologic impairment consistent with MRI findings. Neurologic impairment is defined as objective evidence of one or more of the following:
    a. Markedly abnormal reflexes
    b. Segmental muscle weakness
    c. Segmental sensory loss
    d. EMG or NCV evidence of nerve root impingement
    e. Cauda equina syndrome
    f. Neurogenic bowel or bladder
    g. Long tract abnormalities

Otherwise, these diagnoses are included on Line 532. Only decompression surgery is included on these lines for spinal stenosis; spinal fusion procedures are not included on either line for spinal stenosis unless:

1) the spinal stenosis is in the cervical spine OR

2) spondylolisthesis is present as above OR
3) there is pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of foraminal joints expected to be resected)

The following interventions are not included on these lines due to lack of evidence of effectiveness for the treatment of conditions on these lines, including cervical, thoracic, lumbar, and sacral conditions:

- ~~facet joint corticosteroid injection~~
- prolotherapy
- ~~intradiscal corticosteroid injection~~
- local injections
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- ~~sacroiliac joint steroid injection~~
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- radiofrequency denervation
- ~~epidural steroid injections~~
- ~~•~~ corticosteroid injections for cervical pain

Corticosteroid injections for low back pain with or without radiculopathy are only included on Line 532.

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/herc/Pages/blog-LBP-EpiduralSteroid.aspx.

GUIDELINE NOTE 100, SMOKING AND SPINAL FUSION

Lines 51,154,205,259,351,366,406,482,532,561

Non-emergent spinal arthrodesis (CPT 22532-22634) is limited to patients who are non-smoking and abstinent from ~~any~~all nicotine products for 6 months prior to the planned procedure, as shown by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date. Patients should be given access to appropriate smoking cessation therapy. Non-emergent spinal arthrodesis is defined as surgery for a patient with a lack of myelopathy or rapidly declining neurological exam.

Appendix A
Revised Guideline Notes

GUIDELINE NOTE 104, VISCOSUPPLEMENTATION OF THE KNEE

Lines 436,467

CPT 20610 and 20611 are ~~is~~ included on these lines only for interventions other than viscosupplementation for osteoarthritis of the knee.

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/herc/Pages/blog-viscosupplementation-knee.aspx

GUIDELINE NOTE 112, LUNG VOLUME REDUCTION SURGERY

Line 288

Lung volume reduction surgery (LVRS, CPT 32491, 32672) is included on Line 288 only for treatment of patients with radiological evidence of severe bilateral upper lobe predominant emphysema (ICD-10-CM J43.9) and all of the following:

A) BMI ≤31.1 kg/m2 (men) or ≤32.3 kg/m 2 (women)
B) Stable with ≤20 mg prednisone (or equivalent) dose a day
C) Pulmonary function testing showing
    1) Forced expiratory volume in one second (FEV 1) ≤ 45% predicted and, if age 70 or older, FEV 1≥ 15% predicted value
    2) Total lung capacity (TLC) ≥ 100% predicted post-bronchodilator
    3) Residual volume (RV) ≥ 150% predicted post-bronchodilator
D) PCO_2, ≤ 60 mm Hg (PCO 2, ≤ 55 mm Hg if 1-mile above sea level)
E) PO_2, ≥ 45 mm Hg on room air (PO 2, ≥ 30 mm Hg if 1-mile above sea level)
F) Post-rehabilitation 6-min walk of ≥ 140 m
G) Non-smoking and abstinence from ~~any~~all nicotine products for 6 months prior to surgery, as shown by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date.

The procedure must be performed at an approved facility (1) certified by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) under the LVRS Disease Specific Care Certification Program or (2) approved as Medicare lung or heart-lung transplantation hospitals. The patient must have approval for surgery by pulmonary physician, thoracic surgeon, and anesthesiologist post-rehabilitation. The patient must have approval for surgery by cardiologist if any of the following are present: unstable angina; left-ventricular ejection fraction (LVEF) cannot be estimated from the echocardiogram; LVEF <45%; dobutamine-radionuclide cardiac scan indicates coronary artery disease or ventricular dysfunction; arrhythmia (>5 premature ventricular contractions per minute; cardiac rhythm other than sinus; premature ventricular contractions on EKG at rest).

Appendix A
Revised Guideline Notes

GUIDELINE NOTE 159, SMOKING AND SURGICAL TREATMENT OF ERECTILE DYSFUNCTION

Line 526

Surgical treatment of erectile dysfunction is only included on this line when patients are non-smoking and abstinent from ~~any~~all nicotine products for 6 months prior to surgery, as shown by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date.

GUIDELINE NOTE 161, SACROILIAC JOINT FUSION

Line 532

Sacroiliac (SI) joint fusion (CPT 27279) is included on this line for patients who have all of the following:

A) Baseline score of at least 30% on the Oswestry Disability Index (ODI)
B) Undergone and failed a minimum six months of intensive non-operative treatment that must include non-opioid medication optimization and active therapy. Active therapy is defined as activity modification, chiropractic/osteopathic manipulative therapy, bracing, and/or active therapeutic exercise targeted at the lumbar spine, pelvis, SI joint and hip including a home exercise program. Failure of conservative therapy is defined as less than a 50% improvement on the ODI.
C) Typically unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SI joint, and consistent with SI joint pain.
D) Thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, i.e. at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine) in the absence of tenderness of similar severity elsewhere (e.g. greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist.
E) Positive response to at least three of six provocative tests (e.g. thigh thrust test, compression test, Gaenslen's test, distraction test, Patrick's sign, posterior provocation test).
F) Absence of generalized pain behavior (e.g. somatoform disorder) and generalized pain disorders (e.g. fibromyalgia).
G) Diagnostic imaging studies that include ALL of the following:
    1) Imaging (plain radiographs and a CT or MRI) of the SI joint that excludes the presence of destructive lesions (e.g. tumor, infection), fracture, traumatic SI joint instability, or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion
    2) Imaging of the pelvis (AP plain radiograph) to rule out concomitant hip pathology
    3) Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain
    4) Imaging of the SI joint that indicates evidence of injury and/or degeneration

Appendix A
Revised Guideline Notes

At least 75 percent reduction of pain for the expected duration of two anesthetics (on separate visits each with a different duration of action), and the ability to perform previously painful maneuvers, following an image-guided, contrast-enhanced intra-articular SI joint injection. SI joint injections (CPT 20610 and 27096, and HCPCS G0260) are included on this line for diagnostic SI joint injections with anesthetic only, but not for therapeutic injections or corticosteroid injections. Injections are only included on this line for patients for whom SI joint fusion surgery is being considered.

Appendix B
New Guideline Notes

GUIDELINE NOTE XXX, CHOLECYSTECTOMY FOR CHOLECYSTITIS AND BILIARY COLIC

Lines 59, 645

Cholecystectomy for cholecystitis and biliary colic are including on line 59 when meeting the following criteria:

A. For cholecystitis, with

1) The presence of right upper quadrant abdominal pain, mass, tenderness or a positive Murphy's sign, AND
2) Evidence of inflammation (e.g. fever, elevated white blood cell count, elevated C reactive protein), OR
3) Ultrasound findings characteristic of acute cholecystitis or non-visualization of the gall bladder on oral cholecystegram or HIDA scan, or gallbladder ejection fraction of < 35%

B. For biliary colic (i.e. documented clinical encounter for right upper quadrant or epigastric pain with gallstones seen on imaging during each episode) without evidence of cholecystitis or other complications is included on line 59 only when

1) recurrent (i.e. 2 or more episodes in a one year period), or
2) a single episode in a patient at high risk for complications with emergent cholecystitis (e.g. immunocompromised patients, morbidly obese patients, diabetic patients), or
3) when any of the following are present: elevated pancreatic enzymes, elevated liver enzymes or dilated common bile duct on ultrasound.

Otherwise, biliary colic is included on line 645.

GUIDELINE NOTE XXX, INTRASTROMAL CORNEAL RING SEGMENTS

Line 315

Insertion of intrastromal corneal ring segments (CPT 65785) is included on this line only for reduction or elimination of myopia or astigmatism in adults age 19 and older with keratoconus who are no longer able to achieve adequate functional vision to perform ADLs with best correction using contact lenses or spectacles, who have a corneal thickness of 450 microns or greater at proposed incision site, and for whom corneal transplant is the only remaining option to improve their functional vision.

Appendix C
Coding Specifications

Add a new coding specification to lines 59 and 645 as follows:

> ICD-10 K82.8 (Other specified diseases of gallbladder) is included on line 59 when the patient has porcelain gallbladder or gallbladder dyskinesia with a gallbladder ejection fraction <35%. Otherwise, K82.8 is included on line 645.

Add a new coding specification to lines 75 and 297 as follows:

> CPT codes 62320-3 are only included on lines 75 and 297 for trials of antispasmodics in preparation for placement of a baclofen pump.

Section 2.0

Staff Report

Errata
August 2017

1) M67.0 (Short Achilles tendon (acquired)) was moved to line 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS from line 382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
    a. This corrects an ICD-10 code placement error; the ICD-10 code will now be on the same line as the equivalent ICD-9 code [727.81 Contracture of tendon (sheath)] and will pair with all appropriate treatment CPT codes.
2) G56.23 (Lesion of ulnar nerve, bilateral upper limbs) was added to line 421 PERIPHERAL NERVE ENTRAPMENT; PALMAR FASCIAL FIBROMATOSIS and removed from lines 512 PERIPHERAL NERVE DISORDERS, 539 PERIPHERAL NERVE DISORDERS to match the placement of lesion of right ulnar nerve (G56.21) and left ulnar nerve (G56.22).

Psoriasis Errata for August 2017

Question:

1) Should further errata changes for psoriasis be completed?

Question source:

1) HERC staff

Issue: Changes regarding psoriasis and psoriatic arthropathy were done as errata and presented at the May, 2017 VBBS/HERC meeting. HERC staff have identified further changes which should be made. The changes presented in May included adding psoriasis ICD-10 codes to the lower line 564 MILD PSORIASIS; DERMATOPHYTOSIS: SCALP, HAND, BODY, DEEP-SEATED and moving psoriatic arthropathy codes to the rheumatoid arthritis line.

The ICD-10 Dermatology group created a new line for moderate/severe psoriasis with a guideline for what defines moderate/severe and what treatments are covered. Prior to the ICD-10 review, moderate/severe psoriasis was on line 134 PYODERMA; MODERATE/SEVERE PSORIASIS and mild psoriasis was on line 564 MILD PSORIASIS ; DERMATOPHYTOSIS: SCALP, HAND, BODY, DEEP-SEATED. There are no specific ICD-10 codes that specify severity of psoriasis; the codes are generic.

Current Prioritized List
Line 430 SEVERE INFLAMMATORY SKIN DISEASE
Line 544 MILD PSORIASIS; DERMATOPHYTOSIS: SCALP, HAND, BODY, DEEP-SEATED

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

Line 430, 544

Severe inflammatory skin disease is 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; and/or
B) Hand, foot or mucous membrane involvement.

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.

GUIDELINE NOTE 57, MILD PSORIASIS

Line 430, 544

Mild psoriasis is defined as uncomplicated, having:

- No functional impairment; and/or,

Involving less than 10% of body surface area and no involvement of the hand, foot, or mucous membranes

Psoriasis Errata for August 2017

Errata for correction:

1) Append the following to GN21 SEVERE INFLAMMATORY SKIN DISEASE
   a) "See Guideline Note 57 for the definition of mild psoriasis included on line 544."
2) Append the following to GN57 MILD PSORIASIS
   a) "See Guideline Note 21 for the definition of moderate/severe psoriasis included on line 430"
3) Remove dermatophytosis other than that specified in title of line 493 DERMATOPHYTOSIS OF NAIL, GROIN, AND FOOT AND OTHER DERMATOMYCOSIS from line 493
   a) These codes already appear on line 544 MILD PSORIASIS; DERMATOPHYTOSIS: SCALP, HAND, BODY, DEEP-SEATED
   b) B35.0 Tinea barbae and tinea capitis
   c) B35.2 Tinea manuum
   d) B35.4 Tinea corporis
   e) B35.5 Tinea imbricata
4) Remove B35.8 (Other dermatophytosis, including disseminated), unspecified) from line 544 MILD PSORIASIS; DERMATOPHYTOSIS: SCALP, HAND, BODY, DEEP-SEATED,
   a) Already appears on line 493 DERMATOPHYTOSIS OF NAIL, GROIN, AND FOOT AND OTHER DERMATOMYCOSIS
5) Remove B35.9 (Dermatophytosis, unspecified) from line 493 DERMATOPHYTOSIS OF NAIL, GROIN, AND FOOT AND OTHER DERMATOMYCOSIS and add to line 544 MILD PSORIASIS; DERMATOPHYTOSIS: SCALP, HAND, BODY, DEEP-SEATED
6) Change title of line 544 to MILD PSORIASIS; DERMATOPHYTOSIS: SCALP, HAND, BODY~~, DEEP-SEATED~~

Section 3.0

Consent Agenda-

Straightforward Items

Consent Agenda Issues—August, 2017

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
44310	Ileostomy or jejunostomy, non-tube	220 CANCER OF STOMACH	HSD requested that 44310 pair with C16.2 (Malignant neoplasm of body of stomach). 44310 is on lines 32,46,51,75,92,105,158,161. Many similar codes appear on line	Add 44310 to line 220
35251 35281 64680	Repair blood vessel with vein graft; intra-abdominal Repair blood vessel with graft other than vein; intra-abdominal Destruction by neurolytic agent, with or without radiologic monitoring; celiac plexus	321 CANCER OF PANCREAS	HSD requested that 35251 and 35281 pair with C25 (Malignant neoplasm of pancreas). 35255281 are 1 and 3 only on line 285 BUDD-CHIARI SYNDROME, AND OTHER VENOUS EMBOLISM AND THROMBOSIS. HSD also requested 63680 pair with cancer of the pancreas. This code appears on lines 60,368.	Add 35251 and 35281 and 64680 to line 321
38542	Dissection, deep jugular node(s)	280 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA	HSD requested that 38542 pair with C44.3 (Basal cell carcinoma). 38542 is on lines 162,267,319,408,427,574. Other lymph node dissection codes appear on this line.	Add 38542 to line 280
49255	Omentectomy, epiploectomy, resection of omentum	243 CANCER OF OVARY	HSD requested that 49255 pair with C56.1 (Malignant neoplasm of right ovary). 49255 is on line 266 CANCER OF RETROPERITONEUM, PERITONEUM, OMENTUM AND MESENTERY	Add 49255 to line 243
67840	Excision of lesion of eyelid (except chalazion) without closure or with simple direct closure	280 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA	HSD requested that 67840 pair with D48.5 (Neoplasm of uncertain behavior of skin). 67840 is on lines 372,499.	Add 67840 to line 280

Consent Agenda Issues—August, 2017

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
92002-92014 92081-92083	Ophthalmological services: medical examination and evaluation Visual field examination	130 BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD	HSD requested that several ophthalmology codes be paired with pituitary gland tumors (D35.2). These tumors frequently affect vision due to mass effect on the visual nerves.	Add 92002-92014 and 92081-92083 to line 130
65435 65450	Removal of corneal epithelium; with or without chemocauterization (abrasion, curettage) Destruction of lesion of cornea by cryotherapy, photocoagulation or thermocauterization	117 CANCER OF EYE AND ORBIT	HSD requested that 65435 and 65450 pair with D48.7 (Neoplasm of uncertain behavior of other specified sites). 65435 is on line 441 RECURRENT EROSION OF THE CORNEA hwile 65450 is on line 315 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA.	Add 65435 and 65450 to line 117
99356 99357	Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour each additional 30 minutes	Approximately 80 inpatient lines	HERC staff found that 99356 and 99357 are missing from approximately 80 lines which contain other prolonged E&M inpatient CPT codes (i.e. 99358 and 99359).	Add 99356 and 99357 to all lines containing 99358/99359 on which that do not already appear
99468-99480	Initial/subsequent inpatient neonatal critical care	152 ACQUIRED HEMOLYTIC ANEMIAS	HSD requested that inpatient neonatal critical care codes be paired with D62 (Acute posthemorrhagic anemia). All other inpatient codes appear on this line.	Add 99468-99480 to line 152
49424	Contrast injection for assessment of abscess or cyst via previously placed drainage catheter or tube	51,105,368,427,570,574	HSD requested that 49424 be paired with cutaneous abscess. On review, this CPT code appears diagnostic and could be used for a variety of other diagnoses other than those currently paired.	Remove 49424 from lines 51,105,368,427,570,574 Advise HSD to place 49424 on the Diagnostic Procedures File

Consent Agenda Issues—August, 2017

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
13133	Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; each additional 5 cm or less	1 PREGNANCY	HSD requested pairing of 13133 with second degree perineal laceration after delivery. The smaller repair codes (13131 and 13132) already appear on line 1)	Add 13133 to line 1
99406 99407	Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes Greater than 10 minutes	1 PREGNANCY	HSD requested that 99406 pair with various tobacco use in pregnancy diagnoses. Currently, 99406 and 99407 are only on line 5 TOBACCO DEPENDENCE. Generally, pregnancy series codes are used for smoking in pregnancy rather than nicotine dependence codes	Add 99406 and 99407 to line 1
99460 99461 99462 99463	Initial hospital or birthing center care, per day, for evaluation and management of normal newborn infant Initial care, per day, for evaluation and management of normal newborn infant seen in other than hospital or birthing center Subsequent hospital care, per day, for evaluation and management of normal newborn Initial hospital or birthing center care, per day, for evaluation and management of normal newborn infant admitted and discharged on the same date	23 LOW BIRTH WEIGHT (1500-2500 GRAMS) 105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 146 CONDITIONS INVOLVING THE TEMPERATURE REGULATION OF NEWBORNS	HSD requested that 99460 be paired with low birth weight. Recently, 99460 and similar codes were added to a variety of newborn lines. Many of these lines contain diagnoses which are considered minor and are appropriately paired with “normal newborn” CPT codes	Add 99460-99463 to lines 23, 105, and 146

Consent Agenda Issues—August, 2017

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes	353 MILD/MODERATE BIRTH TRAUMA FOR BABY	HSD requested that 97530 be paired with P14.0 (Erb's paralysis). The other PT/OT CPT codes appear on line 353. 97530 appears on 60+ lines.	Add 97530 to line 353
31290 31291	Nasal/sinus endoscopy, surgical, with repair of cerebrospinal fluid leak; ethmoid region sphenoid region	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	CareOregon requested that 31291 pair with G96.0 (Cerebrospinal fluid leak). 31290 is a similar procedure. 31290 and 31291 are currently on lines 200,469,509. Other CSF leak repair codes (63707 and 63709) are on line 290	Add 31290 and 31291 to line 290
96150-96155	Health and behavior assessment	111 GIANT CELL ARTERITIS, POLYMYALGIA RHEUMATICA AND KAWASAKI DISEASE 210 SUPERFICIAL ABSCESSES AND CELLULITIS	HSD requested that 96150 pair with abscess diagnoses and with Polymyalgia rheumatica. These CPT codes are on approximately 170 lines	Add 97150-96155 to lines 111 and 210
29075	Application, cast; elbow to finger (short arm)	467 OSTEOARTHRITIS AND ALLIED DISORDERS	HSD requested that 29075 pair with M12.5 (Traumatic arthropathy). 29075 is on 9 lines	Add 29075 to line 467
25230	Radial styloidectomy	361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE	HSD requested that 25230 pair with M19.03 (Primary osteoarthritis, wrist), 25230 is on lines 136, 188, 205, 259, 360, 406, 561	Add 25230 to line 361
28304	Osteotomy, tarsal bones, other than calcaneus or talus;	530 DEFORMITIES OF UPPER BODY AND ALL LIMBS	HSD requested that 28304 pair with M21.07 (Valgus deformity, ankle). 28304 is on lines 297,364,392,545	Add 28304 to line 530

Consent Agenda Issues—August, 2017

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
27033	Arthrotomy, hip, including exploration or removal of loose or foreign body	364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS	HSD requested that 27033 be paired with M24.05 (Loose body in hip). 27033 is on line 187 FRACTURE OF PELVIS, OPEN AND CLOSED	Add 27033 to line 364
29822 29823	Arthroscopy, shoulder, surgical; debridement, limited Extensive	364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS	HSD requested pairing of 29822 with M24.41 (Recurrent dislocation, shoulder). 29822 and 29833 are on line 157,361,423. Similar codes for other joints and other shoulder arthroscopy codes are on line 364	Add 29822 and 29823 to line 364
20610 20611	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance with ultrasound guidance	361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE	HSD requested that 20610 pair with various hemarthrosis diagnoses. 20610 currently appears on 13 lines	Add 20610 and 26011 to line 361
21198	Osteotomy, mandible, segmental	561 BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE INCLUDING OSTEOID OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE	HSD requested that 21198 pair with M27.8 (Other specified diseases of jaws). 21198 is currently on lines 207,620.	Add 21198 to line 561
M35.01	Sicca syndrome with keratoconjunctivitis	476 KERATOCONJUNCTIVITIS	HSD requested that Sicca Syndrome with keratoconjunctivitis be paired with ophthalmology visits. In 2011, HSC approved adding Sicca syndrome to an ophthalmology line but it appears to have not followed with the ICD-10 conversion	Add M35.01 to line 476

Consent Agenda Issues—August, 2017

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
27360 27460	Partial excision (craterization, saucerization, or diaphysectomy) bone, femur, proximal tibia and/or fibula (eg, osteomyelitis or bone abscess) Partial excision (craterization, saucerization, or diaphysectomy), bone (eg, osteomyelitis); tibia	188 ACUTE OSTEOMYELITIS	HSD requested that 27360 and 27460 pair with osteomyelitis diagnoses. Many other amputation codes appear on this line. 27360 and 27460 are on the chronic osteomyelitis line	Add 27360 and 27460 to line 188
26910	Amputation, metacarpal, with finger or thumb (ray amputation), single, with or without interosseous transfer	136 OPEN FRACTURE/DISLOCATION OF EXTREMITIES	HSD requested that 26910 be paired with S62.310B (Displaced fracture of base of second metacarpal bone, right hand, initial encounter for open fracture). 26910 is on lines 61,164,188,205,240,290,327,333	Add 26910 to line 136
26735	Open treatment of phalangeal shaft fracture, proximal or middle phalanx, finger or thumb, includes internal fixation, when performed, each	447 MALUNION AND NONUNION OF FRACTURE	HSD requested that 26735 pair with S62.614P (Displaced fracture of proximal phalanx of right ring finger, subsequent encounter for fracture with nonunion). 26735 is currently on lines 136,290,360	Add 26735 to line 447
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft	447 MALUNION AND NONUNION OF FRACTURE	HSD requested that 27132 pair with S72.001K (Fracture of unspecified part of neck of right femur, subsequent encounter for open fracture type IIIA, IIIB, or IIIC with delayed healing). 27132 is currently on lines 85,290,361,428. Other total hip arthroplasty CPT codes are on line 447	Add 27132 to line 447

Consent Agenda Issues—August, 2017

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
27236	Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement	447 MALUNION AND NONUNION OF FRACTURE	HSD requested the 27236 pair with S72.002K (Fracture of unspecified part of neck of left femur, subsequent encounter for closed fracture with nonunion). 27236 is on lines 85,290	Add 27236 to line 447
27254 27269	Open treatment of hip dislocation, traumatic, with acetabular wall and femoral head fracture, with or without internal or external fixation Open treatment of femoral fracture, proximal end, head, includes internal fixation, when performed	85 FRACTURE OF HIP	HSD requested that 27254 and 27269 pair with hip fracture diagnosis codes. 27269 is on lines 364,392	Add 27254 and 27269 to line 85
27360	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with intramedullary implant, with or without interlocking screws and/or cerclage	360 CLOSED FRACTURE OF EXTREMITIES (EXCEPT MINOR TOES)	HSD requested that 27360 pair with several femur fracture diagnoses on line 360. 27360 is on line 85 FRACTURE OF HIP. 27360 includes fractures of the femur up to 5 mm below the trochanter	Add 27245 to line 360
27570 29882	Manipulation of knee joint under general anesthesia (includes application of traction or other fixation devices) Arthroscopy, knee, surgical; with meniscus repair (medial OR lateral)	360 CLOSED FRACTURE OF EXTREMITIES (EXCEPT MINOR TOES)	HSD requested that 29882 pair with condylar tibial fractures. 29882 is on lines 136,364,392,436,601. 27570 is on lines 364,392,428,436	Add 27570 and 29882 to line 360

Consent Agenda Issues—August, 2017

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
27620 29899	Arthrotomy, ankle, with joint exploration, with or without biopsy, with or without removal of loose or foreign body Arthroscopy, ankle (tibiotalar and fibulotalar joints), surgical; with ankle arthrodesis	360 CLOSED FRACTURE OF EXTREMITIES (EXCEPT MINOR TOES)	HSD requested that 27620 and 29899 pair with malleolar fractures. 27620 is on lines 259,361,364,392. 29899 is on line 361 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE	Add 27620 and 29899 to line 360
92978 92979	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel (List separately in addition to code for primary procedure) each additional vessel	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	HSD requested that 92978 and 92979 pair with various coronary artery stent restenosis diagnosis codes found on line 290. These CPT codes are found on 40+ lines.	Add 92978 and 92979 to line 290
34001-34203	Embolectomy or thrombectomy, with or without catheter	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	HSD requested that embolectomy codes be paired with diagnosis codes for thrombosis of vascular devices, implants and grafts.	Add 34001-34203 to line 290

Consent Agenda Issues—August, 2017

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
37220- 37235 37236 37237 37238 37239	Revascularization, endovascular, open or percutaneous, various arteries of the leg Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery each additional artery Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel; initial vein Each additional vein	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	HSD requested that a variety of procedures for treating vascular graft stenosis be paired with the vascular graft stenosis procedure codes on line 290.	Add 37220-37239 to line 290
L60.0	Ingrowing nail	588 DISEASE OF NAILS, HAIR AND HAIR FOLLICLES	Currently, L60.0 is only on line 210 SUPERFICIAL ABSCESSES AND CELLULITIS. It needs to be on the lower line for pairing with removal with cellulitis is not present. Similar nail conditions are on line 588	Add L60.0 to line 588 and keep on line 210

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
			GN 67 ENZYME REPLACEMENT THERAPY needs to be added to line 64 METABOLIC DISORDERS which contains most of the conditions treated by enzyme replacement therapy.	Add line 64 to GN67
26200	Excision or curettage of bone cyst or benign tumor of metacarpal;	205 CANCER OF BONES	Benign bone tumors are prioritized to lines 406 BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS and 561 BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE INCLUDING OSTEOID OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE with GN 137 governing placement. 26200 is the only excision of a benign tumor appearing on line 205, which is reserved for malignant tumors. 26200 appears on lines 406 and 561, appropriately	Remove 26200 from line 205

Cardiac Graft Occlusion Consent

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	HSD requested that 92928 and 92937 pair with various coronary artery stent restenosis diagnosis codes found on line 290. These CPT codes are generally found on lines 49,73,102,193. There are other similar codes which are also appropriate to pair with stent restenosis.	Add 92928, 92929, 92933, 92934, 92937, 92938, 92943 and 92944 to line 290
92929	each additional branch			
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch			
92934	each additional branch			
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel			
92938	each additional branch subtended by the bypass graft			
92943	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel			
	each additional coronary artery, coronary artery branch, or bypass graft			
92944	each additional coronary artery, coronary artery branch, or bypass graft			

Lower Extremity Amputations for Severe Pressure Ulcers

Issue: Severe (stage 3 and 4) pressure ulcers involve damage to muscles, bones, and other deep structures. At times, amputation of the affected area is appropriate. The pressure ulcer line (line 384 CHRONIC ULCER OF SKIN) has two codes for lower extremity amputation (CPT 27598 Disarticulation at knee, 28810 Amputation, metatarsal, with toe, single) but not a complete series. HSD has received multiple requests for amputation CPT codes that are not currently on line 384. Amputation would not be an abused procedure, as it would be a last effort to treat a patient after wound care, grafts, and other less extreme procedures have been attempted and have failed.

HERC staff recommendation:

1) Add the following lower extremity amputation CPT codes to line 384 CHRONIC ULCER OF SKIN
    a. 27880-27886 Amputation, leg, through tibia and fibula; various techniques
    b. 27888 Amputation, ankle, through malleoli of tibia and fibula (eg, Syme, Pirogoff type procedures), with plastic closure and resection of nerves
    c. 28800 Amputation, foot; midtarsal (eg, Chopart type procedure)
    d. 28804 Amputation, foot; transmetatarsal
    e. 28805 Amputation, foot; transmetatarsal
    f. 28820 Amputation, toe; metatarsophalangeal joint
    g. 28825 Amputation, toe; interphalangeal joint

Medical Treatment of Missed Abortion

Issue: Missed abortion is defined as a pregnancy in which there is a fetal demise but no uterine activity to expel the products of conception. Traditionally, missed abortions have been treated with either expectant management or surgical treatment with either D&C or vacuum aspiration. In recent years, medical management of missed abortions has become much more common. Generally, medical management consists of intravaginal misoprostol, which is effective in approximately 80% of cases. Oral medications may be used as well.

Currently, there are no CPT codes for medical management of missed abortions on line 67 SPONTANEOUS ABORTION; MISSED ABORTION, although there are a variety of surgical treatment codes on that line. There are 3 CPT codes for use of vaginal prostaglandin for medical treatment of missed abortion. Two of these codes are specific for the surgical treatment after a failed medical management. There is also a HCPCS code for medical management of missed abortion.

HERC staff recommendations:

1) Add the following CPT codes to line 67 SPONTANEOUS ABORTION; MISSED ABORTION
    a. 59855 Induced abortion, by 1 or more vaginal suppositories (eg, prostaglandin) with or without cervical dilation (eg, laminaria), including hospital admission and visits, delivery of fetus and secundines;
    b. 59856 …with dilation and curettage and/or evacuation
    c. 59857 …with hysterotomy (failed medical evacuation)
2) Add the following HCPCS code to line 67 SPONTANEOUS ABORTION; MISSED ABORTION
    a. S0199 Medically induced abortion by oral ingestion of medication including all associated services and supplies (e.g., patient counseling, office visits, confirmation of pregnancy by hcg, ultrasound to confirm duration of pregnancy, ultrasound to confirm complete

Non-Major Neonatal Infections

Issue: Several ICD-10 codes for neonatal infectious conditions appear only on the dysfunction lines and therefore do not pair with newborn hospital care CPT codes. Major neonatal infections such as sepsis are on lines such as 186 SEPTICEMIA. Other infections, such as neonatal conjunctivitis, have their own specific lines. Many diagnoses which are minor but require treatment appear on line 2 BIRTH OF INFANT, such as neonatal bradycardia or certain newborn birth injuries. Conditions which occur in the neonatal period and which result in long term dysfunction should be coded with the sequalae causing that dysfunction (i.e. joint contracture, developmental delay, etc.).

HERC staff recommendations:

1) Remove the following ICD-10 codes from the dysfunction lines (lines 75,297,350,382) and add to line 2 BIRTH OF INFANT:
    a. P39.3 Neonatal urinary tract infection
    b. P39.4 Neonatal skin infection
    c. P39.8 Other specified infections specific to the perinatal period
    d. P39.9 Infection specific to the perinatal period, unspecified
        i. Additionally, remove P39.9 from line 186 Septicemia

Surgical Treatment of Bone/Joint Prostheses with Infection or Inflammatory Reaction

Question: should various orthopedic procedures be paired with joint prostheses with infection or inflammatory reactions?

Question source: HSD claims reconsideration

Issue: when a joint prostheses becomes infected, frequently, bone or other tissue in the area of the prostheses needs to be removed as well as the prosthesis itself. There are many requests for pairing of various bone removal surgeries with diagnosis codes for joint prostheses with infection/inflammatory reactions. These diagnoses are on line 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT. There are many orthopedic procedures already on line 290. The procedures proposed for addition are unlikely to be abused.

CPT Code	Code Description	Current Line(s)
20650	Insertion of wire or pin with application of skeletal traction, including removal (separate procedure)	136,360
27703	Arthroplasty, ankle; revision, total ankle	361,580
27704	Removal of ankle implant	361,428
27125	Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)	85,361,447
27448	Osteotomy, femur, shaft or supracondylar; without fixation	361,364,392,431,508,530
27556	Open treatment of knee dislocation, includes internal fixation, when performed; without primary ligamentous repair or augmentation/reconstruction	136,364,392
27882	Amputation, leg, through tibia and fibula; open, circular (guillotine)	140,188,205,240,259,327,333,447 Other leg amputation codes on 290
29819	Arthroscopy, shoulder, surgical; with removal of loose body or foreign body	157,361,364,392,423

HERC staff recommendation:

1) Add codes in table above to line 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT

Section 4.0

New Discussion Items

Lattice Degeneration, Asymptomatic Retinal Breaks and Round Holes

Questions:

1) Should lattice degeneration be moved to a higher priority line with a guideline?
2) Should limitations be placed on treatment of asymptomatic retinal breaks and round holes?

Question Sources:

1) Dr. Andreas Lauer, OHSU ophthalmology
2) HERC staff

Issue:

Lattice degeneration is a condition of the eye in which the peripheral retina becomes atrophic in a lattice pattern and may develop tears, breaks, or holes, which may further progress to retinal detachment. It is an important cause of retinal detachment in young myopic individuals. The cause is unknown, but pathology reveals inadequate blood flow resulting in ischemia and fibrosis. Lattice degeneration occurs in approximately 6–8% of the general population.

Lattice degeneration itself is not treated. Asymptomatic retinal breaks resulting from lattice degeneration also rarely require treatment. Asymptomatic horseshoe retinal tears lead to retinal detachment in about 5% of patients. Some retinal breaks can lead to retinal detachment, which is generally symptomatic with flashers or loss of vision, and requires treatment. Symptomatic retinal breaks lead to retinal detachment about 50% of the time and require treatment.

From the American Academy of Ophthalmology Practice Guideline (2014) on lattice degeneration:

> Lattice degeneration can result in atrophic round holes. One study of 423 eyes found that 10 had subclinical retinal detachment on initial exam. 6 additional patients developed new subclinical retinal detachments during follow up. Clinically symptomatic retinal detachment occurred in 3 of the 423 eyes over 11 years (0.7%). Two of these detachments were in patients in their mid-20's with retinal holes and one was due to a symptomatic retinal tear. Therefore patients with or without round holes are at very low risk for progression to clinical retinal detachment without a previous retinal detachment in the fellow eye.

Currently, lattice degeneration (ICD-10 H35.41) is on line 658 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY. Dr. Lauer is requesting that lattice degeneration be paired with ophthalmology visits and dilated eye exams. He states that asymptomatic patients with lattice degeneration require dilated eye exams once per year. Dr. Lauer is concerned that OHP patients do not have access to the recommended yearly eye exams.

Complications of lattice degeneration, such as retinal tears and retinal detachment are on covered lines on the Prioritized List and have various treatments paired with them.

In reviewing this topic, HERC staff identified that asymptomatic retinal breaks and round holes, which are generally not recommended for treatment, are on a covered line with no limitations on treatment.

Lattice Degeneration, Asymptomatic Retinal Breaks and Round Holes

Current Prioritized List status

ICD-10 H35.41 (Lattice degeneration) is on line 658 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

ICD-10 Z86.69 (Personal history of other diseases of the nervous system and sense organs—includes personal history of retinal detachment) is on the HSD Informational Diagnosis File

Ophthalmologic visit CPT codes (92002-92014) are on approximately 70 lines. HSD is working on allowing use for diagnostic purposes.

Line 379 RETINAL TEAR contains CPT codes for laser prophylactic treatment, and includes such diagnoses as unspecified retinal tears (ICD-10 H33.30—unspecified as to presence of retinal detachment), horseshoe breaks (ICD-10 H33.31), and round holes (ICD-10 H33.32). This line was reviewed as part of the ICD-10 Ophthalmology review and the only change recommended was moving round holes from the retinal detachment line to this line.

Evidence

1) **Wilkinson 2014,** Cochrane review of interventions for asymptomatic retinal breaks and lattice degeneration for preventing retinal detachment (http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003170.pub4/full)
    a. No trials found meeting inclusion criteria
    b. Author's conclusions: No conclusions could be reached about the effectiveness of surgical interventions to prevent retinal detachment in eyes with asymptomatic retinal breaks or lattice degeneration, or both. Current recommendations for treatment, based upon a consensus of expert opinion should be assessed in a randomized controlled trial.
2) **Wilkinson 2016,** review to evaluate the effectiveness of interventions for asymptomatic retinal breaks and lattice degeneration
    a. No randomized controlled trials found in which one treatment for asymptomatic retinal breaks and lattice degeneration was compared to another treatment or to no treatment.
    b. The chances of a retinal detachment developing in an eye with lattice degeneration were less than one per cent over an average of 11 years if retinal detachment had not occurred in the other eye
    c. The chances of retinal detachment due to an asymptomatic retinal break in people in which a retinal detachment has not occurred in either eye were approximately 0.5 per cent over a follow-up period averaging 11 years. If a retinal detachment has occurred in one eye of a person with an asymptomatic retinal break in the second eye, the chances of retinal detachment in the latter eye appear to be higher, with incidence figures ranging from 0 to 15 per cent
    d. The primary limitation of prophylactic therapy is related to the fact that most retinal detachments are due to retinal tears that develop in areas of the retina that appear normal prior to vitreous detachment
    e. Authors' conclusions—No conclusions could be reached about the effectiveness of surgical interventions to prevent retinal detachment in eyes with asymptomatic retinal breaks and/or lattice degeneration. Some current recommendations for treatment, based upon a consensus of expert opinion, are contradicted by the best available evidence.

3) **Wilkinson 2000**, systematic review of prophylactic treatment of asymptomatic retinal breaks and lattice degeneration
    a. Total number of articles and patients unclear
    b. No prospective randomized clinical trials regarding the prevention of retinal detachment have been published.
    c. Level I (strong evidence base) found for
        i. Treatment of symptomatic flap (horseshoe) tears
            1. Based on retrospective studies demonstrating untreated flap tears frequently progress to clinical retinal detachment, whereas treatment of similar cases is usually effective in preventing this complication
    d. Level II (substantial evidence base) found for
        i. Non-treatment of asymptomatic lattice degeneration in myopic and phakic eyes
        ii. Rarely treat symptomatic lattice degeneration, asymptomatic lattice degeneration in aphakic eyes, or symptomatic atrophic holes
        iii. Sometimes treat lattice degeneration in eyes in which the patients has had a retinal detachment in the other eye
    e. Level III (expert consensus) found for
        i. Rarely treating asymptomatic retinal tears
        ii. Sometimes treat asymptomatic flap tears
    f. Author conclusions: The current literature regarding prevention of retinal detachment does not provide sufficient information to support strongly prophylactic treatment of lesions other than symptomatic flap tears. Prospective randomized trials of prophylactic therapy are indicated

<u>Expert guidelines:</u>

1) American Academy of Ophthalmology 2014
    a. Asymptomatic round holes rarely lead to retinal detachment
        i. 74 eyes followed for 5-11 yrs in 2 studies, with no retinal detachments
    b. Approximately 5% of eyes with asymptomatic horseshoe tears progress to retinal detachment. Asymptomatic horseshoe tears are less likely to lead to progression than symptomatic horseshoe tears
    c. At least ½ of symptomatic retinal breaks lead to retinal detachment unless treated
        i. Symptoms include new onset flashers or floaters
    d. Myopic patients with lattice degeneration and round holes need close follow up. Treatment of holes should be considered when holes are documented to increase in size and show signs of progression
    e. 1 study with 423 eyes with lattice degeneration followed for 11 years found 150 (35%) had atrophic holes in the lattice. 10 of these 150 had subclinical retinal detachment. 6 additional eyes developed subclinical retinal detachment during follow up. Clinical retinal detachment developed in a total of 3 of these 423 eyes in 11 yrs. Two of these clinical retinal tears developed in myopic patients in their 20's with round retinal holes and a third was due to a symptomatic tractional tear. Patients with lattice degeneration with or without round holes are at *very low* risk for progression to clinical retinal detachment without a previous retinal detachment in the fellow eye.
    f. More commonly, retinal detachment occurs in eyes with lattice degeneration with horseshoe tears, and such tears should be repaired

g. Treatment is only recommended for symptomatic horseshoe tears and operculated holes
h. Recommend follow up dilated eye exams annually for patients with asymptomatic lattice degeneration with or without round holes

Expert opinion

From Dr. Lauer:

Not all retinal detachments or retinal tears are symptomatic. Typically, but not invariably, asymptomatic retinal tears do not require treatment. Retinal detachments, however, almost always require treatment. In particular, inferior retinal detachments, such as those associated with lattice degeneration in teens and young adults are notorious for being asymptomatic. When retina specialists take such referrals, the patient is typically being seen by an optometrist or ophthalmologist for a glasses or contact lens examination and these asymptomatic retinal detachments are detected by a dilated eye exam, ultra-wide field photography or visual field testing. Detection and treatment at this opportune stage is essential for prevention of irreversible vision loss. Since the condition affects young adults, there are significant implications in terms of their productivity if their condition goes undetected until after vision loss occurs. Although we are able to recover lost vision with retinal detachment repair, most often the recovery is partial and it is infrequent to get the vision back to normal. It is better to detect and treat asymptomatic retinal detachment early (before vision loss). This scenario is one of the reasons for the importance of dilated eye examinations and detecting lattice degeneration. Lattice degeneration is the retinal lesion that predisposes such patients to retinal detachment, therefore patients with lattice degeneration require periodic eye examinations.

Dr. Lauer agreed with the staff guideline proposal, with the addition of family members with a history of retinal tears or detachment as an additional high risk criteria.

HERC staff summary:

Lattice degeneration is a predisposing factor to retinal detachment; however, the risk of symptomatic retinal detachment with lattice degeneration is very low (<1% over 11 yrs). Treatment of asymptomatic retinal holes or tears are not generally recommended, except for expert recommendation to occasionally treat horseshoe tears, usually in young, myopic eyes. Patients with lattice degeneration who have had retinal detachment in the other eye are at higher risk for retinal detachment in the previously non-affected eye. Overall, the evidence for treatment of asymptomatic lattice degeneration and asymptomatic retinal tears or breaks is very poor.

Round holes rarely require treatment unless symptomatic or the result of trauma. Retinal tears also only appear to require treatment when symptomatic, the result of trauma or are horseshoe tears.

HERC staff recommendations:

1) Allow limited coverage of eye exams for patients with lattice degeneration at high risk for retinal detachment
    a. Add ICD-10 H35.41 (Lattice degeneration) to line 379 RETINAL TEAR and keep on line 658 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
    b. Adopt the new guideline below for lines 379 and 658
2) Limit treatment of retinal breaks and round holes to those most likely to progress to retinal detachment and/or which are recommended for treatment by expert groups
    a. Add unspecified retinal tears (ICD-10 H33.30) and round holes (ICD-10 H33.32) to line 658 and keep on line 379
    b. See guideline wording below

GUIDELINE NOTE XXX LATTICE DEGENERATION, ASYMPTOMATIC RETINAL BREAKS AND ROUND HOLES
Lines 379,658
Lattice degeneration is included on line 379 only for pairing with ophthalmologic visits and dilated eye exams, and only for patients at high risk of retinal detachment:

1) Young patients with round holes and myopic vision
2) Patients with a history of retinal detachment in the other eye
3) Patients with biologic family member with history of retinal tear or retinal detachment

Otherwise, lattice degeneration is included on line 658.

Retinal breaks and round holes are only included for pairing with treatment (other than ophthalmologic visits and dilated eye exams) on line 379 when they are symptomatic, the result of trauma, or are horseshoe breaks. Otherwise, these diagnoses are included on line 658.

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February 23, 2017

Darren D. Coffman
Director, Health Services Commission
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RE: Prioritized List Addition Request

Dear Mr. Coffman:

We occasionally notice that the condition and treatment pairs list is either missing ocular diagnoses or their corresponding treatments. We concluded that there may be a lack of understanding of ocular disease processes or their therapy, including surgical repair. We also feel that many conditions/treatments missing, or below-the-line, meet medical necessity criteria and are considered standard of care, not experimental.

Please consider Lattice Degeneration (H35.41x) for inclusion on the Prioritized List:
Lattice degeneration is a developmental thinning of the retina that occurs in about 6 percent of the population. It is a risk factor for retinal tears and retinal detachment. The recommendation by the American Academy of Ophthalmology is that people with lattice degeneration should have a yearly dilated examination by an ophthalmologist even if they are asymptomatic. Such people should immediately report any floaters, flashing lights or loss of vision and be provided prompt care. We have major concerns that the Oregonians will not have access to standard of care clinical and diagnostic examinations and, when indicated, necessary treatment for a condition that has the potential to cause retinal detachment and severe irreversible vision loss or blindness. Key references are included in this communication.

Thank you for your consideration. Do not hesitate to contact me if further clarification is needed.

Sincerely,

Andreas K. Lauer, MD
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Interventions for asymptomatic retinal breaks and lattice degeneration for preventing retinal detachment

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Abstract

Background—Asymptomatic retinal breaks and lattice degeneration are visible lesions that are risk factors for later retinal detachment. Retinal detachments occur when fluid in the vitreous cavity passes through tears or holes in the retina and separates the retina from the underlying retinal pigment epithelium. Creation of an adhesion surrounding retinal breaks and lattice degeneration, with laser photocoagulation or cryotherapy, has been recommended as an effective means of preventing retinal detachment. This therapy is of value in the management of retinal tears associated with the symptoms of flashes and floaters and persistent vitreous traction upon the retina in the region of the retinal break, because such symptomatic retinal tears are associated with a high rate of progression to retinal detachment. Retinal tears and holes unassociated with acute symptoms and lattice degeneration are significantly less likely to be the sites of retinal breaks that are responsible for later retinal detachment. Nevertheless, treatment of these problems is frequently recommended, in spite of the fact that the effectiveness of this therapy is unproven.

Objectives—The purpose of this review was to evaluate the effectiveness of interventions for asymptomatic retinal breaks and lattice degeneration.

Search methods—We searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (*The Cochrane Library* 2012, Issue 1), MEDLINE (January 1950 to January 2012), EMBASE (January 1980 to January 2012), the *meta*Register of Controlled Trials (*m*RCT) (www.controlled-trials.com), ClinicalTrials.gov (www.clinicaltrials.gov) and the WHO International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/search/en). There were no date or language restrictions in the electronic searches for trials. The electronic databases were last searched on 28 January 2012. Textbooks regarding retinal detachment and the reference

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CONTRIBUTIONS OF AUTHORS

CPW screened the search results, graded selected trials and wrote the review. CPW is the guarantor for the review.

The Cochrane Eyes and Vision Group editorial team developed the search strategies and undertook the electronic searches. Richard Wormald (Co-ordinating Editor for CEVG) acknowledges financial support for his CEVG research sessions from the Department of Health through the award made by the National Institute for Health Research to Moorfields Eye Hospital NHS Foundation Trust and UCL Institute of Ophthalmology for a Specialist Biomedical Research Centre for Ophthalmology. The views expressed in this publication are those of the authors and not necessarily those of the Department of Health.

DECLARATIONS OF INTEREST

None known.

DATA AND ANALYSES

This review has no analyses.

Article for CME Credit

Evidence-Based Analysis of Prophylactic Treatment of Asymptomatic Retinal Breaks and Lattice Degeneration

C. P. Wilkinson, MD

Purpose: To assess the quality of information in the literature regarding the benefits of prophylactic treatment of asymptomatic retinal tears and lattice degeneration.

Clinical Relevance: Asymptomatic retinal breaks occur in approximately 7% of patients over age 40, and lattice degeneration is present in approximately 8% of the general population. Because retinal breaks cause retinal detachment and lattice degeneration is associated with approximately 30% of retinal detachments, prophylactic treatment of these lesions has sometimes been recommended.

Literature Reviewed: A panel of vitreoretinal experts performed a literature review of all publications regarding prevention of retinal detachment that have been published in English. These articles were then used to prepare recommendations for patient care in an American Academy of Ophthalmology Preferred Practice Pattern (PPP). Each recommendation was rated according to: (1) its importance in the care process and (2) the strength of evidence supporting the given recommendation.

Results: Most recommendations were rated as A (most important to patient care). Only a single publication was graded as I (providing strong evidence in support of a recommendation), and this was not a prospective trial. Of the few publications rated as II (substantial evidence), most were studies documenting a lack of treatment benefit. Because of an absence of level I and level II studies in the literature, level III (consensus of expert opinion) was the basis for most recommendations in the PPP.

Conclusions: The current literature regarding prevention of retinal detachment does not provide sufficient information to support strongly prophylactic treatment of lesions other than symptomatic flap tears. Prospective randomized trials of prophylactic therapy are indicated. Eyes highly predisposed to retinal detachment should be considered for such studies. *Ophthalmology 2000;107:12–18 © 2000 by the American Academy of Ophthalmology.*

Evidence-based medicine represents an effort to use the best current scientific evidence in formulating management decisions regarding the care of individual patients. The development of practice guidelines such as the American Academy of Ophthalmology's (AAO) Preferred Practice Patterns (PPP) is also dependent on the identification of optimal research results, because the quality of such publications is a function of the strength of the evidence supporting the recommendations contained in the documents.

O'Day et al[1] described negative realities of ophthalmology literature searches of the subject *cataract*. However, a large number of prospective, multicenter, randomized trials of posterior segment disorders, including diabetic retinopathy, age-related macular degeneration, and retinal venous occlusive disease, have been published, and there is evidence that selected retinal practice guidelines based on these research data have been implemented in the ophthalmologic community.[2]

The AAO mandates a periodic review and update of the topics discussed in its PPPs. The most recently modified versions contain a description of both the newest evidence used to prepare recommendations and a specific rating of each recommendation.[3] During the latest revision of the PPP devoted to prevention of retinal detachment, the quality and weaknesses of the current literature became evident, and these deficiencies are the subject of this report.

Methods

With the dedicated assistance of the AAO PPP Retina Panel,[3] the author conducted a MEDLINE literature search of articles published in English from 1966 to the present. Search words included *retinal detachment, posterior vitreous detachment, lattice degeneration, retinal tear, retinal hole, retinal break, vitreoretinal degeneration*, and *prophylactic therapy*. Additional pertinent articles

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from a variety of textbooks and older journals had previously been collected by the author.[4] These publications were initially reviewed and rated by two members of the Retina Panel and ultimately by all members, including a skilled methodologist who reviewed the group's consensus ratings. Ultimately, each recommendation in the PPP was rated in two ways.

The first concerned the importance of the specific recommendation to the care process. This "importance to the care process" rating represented care that the Panel believed would improve quality in a meaningful way. The ratings were divided into three levels:[3]

Level A, defined as most important

Level B, defined as moderately important

Level C, defined as relevant but not critical.

The second rating concerned the strength of evidence in the available literature that was referenced and used to support each recommendation. The ratings of "strength of evidence" were also divided into three levels:[3]

Level I, defined as data that provided strong evidence in support of the recommendation. The design of the study addressed the issue in question, and the study was performed in the population of interest and executed in a manner that assured production of accurate and reliable data using appropriate statistical methods.

Level II, defined as data that provided substantial evidence in support of the recommendation. The study had selected attributes of level I support but lacked one or more of the components of level I.

Level III, defined as a consensus of expert opinion in the absence of evidence that met Levels I and II.

Ratings of importance to care and strength of evidence were provided after each recommendation. For instance, a rating of A:II indicated a recommendation with high importance to clinical care (A) supported by meaningful published evidence (II) but not by a randomized controlled trial or a retrospective study with a highly significant statistical outcome.

Results

All recommendations regarding therapy were considered to be level A, most important to the quality of the patients' care. However, the strength of the evidence used to support the recommendations was surprisingly weak. No prospective randomized clinical trials regarding the prevention of retinal detachment have been published. Of the 25 recommendations regarding treatment that were published in the new PPP,[3] a rating of I was applied to a single recommendation for therapy, to treat symptomatic flap (horseshoe) tears. This rating was based on a number of primarily retrospective studies demonstrating that untreated flap tears frequently progress to clinical retinal detachment, whereas treatment of similar cases is usually effective in preventing this complication (Table 1).[5–9]

A level II rating (substantial evidence) was applied to eight recommendations regarding therapy (Table 2). These included a recommendation of "rarely treat" in four instances, "don't treat" in three situations, and "sometimes treat" in a single setting.

Neither strong (level I) nor substantial (level II) evidence was available to support 16 of the 25 recommendations. Therefore, these 16 were rated as level III, consensus of opinion (Table 2). These included a recommendation to "rarely treat" in six situations, "sometimes treat" in five instances, and "almost always treat" in five additional settings.

Table 1. Outcomes Associated with Symptomatic Flap Tears[4]

Senior Author	No. Cases	Subsequent Retinal Detachment
Treated eyes		
Shea[5]	48	4.2%
Robertson[6]	88	7.8%
Verdaguer[7]	74	5.4%
Pollack[8]	74	1.4%
Untreated eyes		
Colyear[9]	20	55%
Shea[5]	21	48%

Discussion

Current management of many posterior segment disorders, including diabetic retinopathy, age-related macular degeneration, and venous occlusive disease, is based on results of prospective randomized collaborative trials. However, our review of the ophthalmologic literature devoted to prevention of retinal detachment revealed that optimal trials re-

Table 2. Grading of Recommendations for Therapy*

Evidence Base	Recommendation	Type of Case**
I (Strong)	Always treat	Symp flap tears
II (Substantial)	No treat	Asymp operc tears
		Asymp L.D. in phakic eyes
		Asymp L.D. in myopic eyes
	Rarely treat	Asymp at. holes in phakic eyes
		Asymp L.D. in aphakic eyes
		Symp atrophic holes
		Symp L.D.
	Sometimes treat	L.D. in F.E.
III (Consensus)	Rarely treat	Asymp operc tears in myopic eyes
		Asymp operc tears in F.E.
		Asymp operc tears in aphakic eyes
		Asymp at. breaks in myopic eyes
		Asymp at. breaks in F.E.
		Asymp at. breaks in aphakic eyes
	Sometimes treat	Asymp flap tears in phakic eyes
		Asymp flap tears in myopic eyes
		Asymp flap tears in F.E.
		Asymp flap tears in aphakic eyes
		Symp operc tears
	Almost always treat	Asymp dialysis in phakic eyes
		Asymp dialysis in myopic eyes
		Asymp dialysis in F.E.
		Asymp dialysis in aphakic eyes
		Symp dialysis

*Modified from the American Academy of Ophthalmology Preferred Practice Pattern.[3]

**Asymp = eyes asymptomatic for posterior vitreous detachment; At = atrophic; F.E. = eyes of patients who have had retinal detachments in their other eye; L.D. = lattice degeneration, with or without holes; operc = operculated retinal tears; Symp = eyes symptomatic for posterior vitreous detachment. Aphakic eyes includes eyes that are pseudophakic.

garding prophylactic treatment are unavailable. Prospective randomized trials of therapy to prevent retinal detachment have not been performed. Our search for the best available evidence indicated that only a single recommendation, to treat symptomatic flap tears promptly, was supported with data of significant strength. Seven of the eight recommendations that were based on level II data were for no prophylactic therapy or for its "rare" use. Only one level II recommendation was worded somewhat more enthusiastically, to "sometimes" treat lattice degeneration, with or without retinal holes, in fellow eyes of patients with a history of detachment in the first eye.

All of the remaining 16 recommendations were based on a rating of level III, consensus of expert opinion. Although these included a recommendation to "almost always treat" in five instances and to "sometimes treat" in five additional situations, the genuine value of this level of support is both lower than levels I and II and questionable in many instances. Analyses of selected examples of a "consensus of expert opinion" regarding the management of specific vitreoretinal pathologic conditions reveals major contradictions with the evidence contained in the best available literature regarding the lesions in question.

For instance, Freeman (written communication, 1998) recently conducted a poll of 138 members of vitreoretinal subspecialty societies. These individuals were asked if they would treat a number of specific vitreoretinal lesions before cataract surgery. An analysis of the responses demonstrates remarkable contrast with evidence in the literature that was used in the PPP. Four percent of poll responders recommended treatment of lattice degeneration without holes, but 17% recommended therapy for lattice degeneration with holes, despite evidence that the course of lattice degeneration is usually not influenced by the presence of holes within lattice lesions.[10] Moreover, 51% recommended treatment of lattice in eyes with 8 diopters (D) or more of myopia, and 83% recommended therapy if the other eye had experienced a prior retinal detachment. These polled recommendations contradict the best published evidence, which indicates that the value of treatment of fellow eyes with lattice degeneration is modest at best, and that treatment is of no value in eyes with more than 6 D of myopia or with more than 6 clock-hours of lattice degeneration.[11]

Another frequently cited study[12] indicated that treatment of peripheral vitreoretinal pathologic conditions, before or after cataract surgery, was valuable in fellow eyes of patients with a history of retinal detachment in their first eye. Later retinal detachment occurred in 19% of 100 untreated eyes but in only 8.3% of 24 treated cases. However, further analysis of these data reveals that the breaks responsible for later detachment occurred in areas of the retina previously considered normal in 89% of the untreated eyes and in all treated cases, so the treatment of all visible lesions in all eyes in the series would have prevented only two of 21 detachments.

Perhaps the most obvious example of the paucity of meaningful evidence supporting treatment to prevent retinal detachment regards data obtained in a prospective trial[13] of aphakic eyes in patients who had a history of retinal detachment surgery in their other eye. Eighty-three such cases were followed. Forty-three of these had evidence of a posterior vitreous detachment (PVD) at the time of entry into the study, and 40 did not have a PVD. In only a single patient in the former group (2.3%) did a subsequent retinal detachment develop. However, PVDs developed in 11 cases that did not initially exhibit this change, and retinal detachments developed in eight of these, representing 20% of the original 40 eyes without PVD. In spite of the dramatic importance of the state of the vitreous gel on the likelihood of future retinal detachment, the PVD variable has not been included in any other published study known to the Panel regarding preventative therapy!

Myopia, lattice degeneration, cataract surgery, and a history of retinal detachment in a fellow eye are clearly risk factors for retinal detachment.[3,4] However, a demonstration that vitreoretinal lesions increase risk does not justify the treatment of these disorders in the absence of scientific evidence that the therapy genuinely lowers the rate of subsequent retinal detachment.[14]

As evidence-based medicine becomes increasingly important as a method of improving many aspects of medical care, better studies of therapy to prevent retinal detachment clearly are necessary. Prospective randomized trials of treatment for eyes with a relatively high risk of later detachment should offer the best opportunity to provide outcome data that are statistically meaningful. Such cases may include highly myopic fellow eyes with lattice degeneration and no PVD, which are also pseudophakic or scheduled for cataract surgery. Such a prospective trial should include an appropriate number of cases observed over a lengthy follow-up period to assure that the questions regarding outcomes of therapy versus no therapy are answered in a satisfactory statistical fashion.

Acknowledgments. The author thanks Dennis Robertson, MD, and the additional members of the AAO PPP Retina Panel: Richard K. Bernstein, MD, FACE, FACN, Michael A. Bloom, MD, Emily Y. Chew, MD, Paul P. Lee, MD, Louis A. Lobes, MD, Flora C. Lum, MD, David W. Parke II, MD, and Marco A. Zarbin, MD, PhD.

References

1. O'Day DM, Steinberg EP, Dickersin K. Systematic literature review for clinical practice guideline development. Trans Am Ophthalmol Soc 1993;91:421–36; discussion 437–8. (I)
2. Hall-Moller J, Albrecht K, Lee P. Conformance with the preferred practice pattern for diabetic eye care. Retina 1998; 18:160–3. (I)
3. American Academy of Ophthalmology. Management of posterior vitreous detachment, retinal breaks, and lattice degeneration. Preferred Practice Pattern. San Francisco, CA: American Academy of Ophthalmology, 1998. (I)
4. Wilkinson CP, Rice TA. Michels Retinal Detachment, 2nd ed. St. Louis: Mosby, 1997;1082–117. (II)
5. Shea M, Davis MD, Kamel I. Retinal breaks without detachment, treated and untreated. Mod Probl Ophthalmol 1974;12: 97–102. (II)
6. Robertson DM, Norton EWD. Long-term follow-up of treated retinal breaks. Am J Ophthalmol 1973;75:395–404. (II)

7. Verdaguer J, Vaisman M. Treatment of symptomatic retinal breaks. Am J Ophthalmol 1979;87:783–8. (II)
8. Pollak A, Oliver M. Argon laser photocoagulation of symptomatic flap tears and retinal breaks of fellow eyes. Br J Ophthalmol 1981;65:469–72. (II)
9. Colyear BH Jr, Pischel DK. Preventive treatment of retinal detachment by means of light coagulation. Trans Pac Coast Otoophthalmol Soc 1960;41:193–217. (II)
10. Byer NE. Long-term natural history of lattice degeneration of the retina. Ophthalmology 1989;96:1396–402. (II)
11. Folk JC, Arrindell EL, Klugman MR. The fellow eye of patients with phakic lattice retinal detachment. Ophthalmology 1989;96:72–9. (II)
12. Benson WE, Grand MG, Okun E. Aphakic retinal detachment. Management of the fellow eye. Arch Ophthalmol 1975;93: 245–9. (II)
13. Hovland KR. Vitreous findings in fellow eyes of aphakic retinal detachment. Am J Ophthalmol 1978;86:350–3. (II)
14. Byer NE. Rethinking prophylactic therapy of retinal detachment. In: Stirpe, M, ed, Advances in Vitreoretinal Surgery. New York: Ophthalmic Communications Society 1992;399–411. (II)

Invited Commentary: For Treatment

The evidence-based approach to medicine is a very desirable evolving tool for clinical care. We are still learning how to use it effectively. when combined with a careful evaluation of the patient's history, findings on examination, and psychosocial and economic status, it adds greatly to the integrity of a physician's recommendations for management. The paucity of the A:I prospective prevention studies of retinal tears and lattice degeneration reinforces the need for thoughtful, caring, competent, and artfully individualized medicine, especially in the asymptomatic patient. The creation of the rating systems of Importance to Care and Strength of Evidence is a brilliant innovation for focusing on current reality. I believe my care has improved over the years directly as a result of Dr. Byer's work, but we differ on some important details.

My management principles are strongly influenced by 32 years of careful preoperative drawing for all scleral buckles. These record the details of the retina, alterations of the retinal pigment epithelium, and the location of nearly every hole in over 1500 detachments. Many patients demonstrated subtle but definite evidence of causative asymptomatic flap tears with either demarcation lines, retinal thinning from long standing subclinical retinal detachments, or both. These eventually had extended and become symptomatic. Some of these tears were exquisitely small and could be confirmed only by a diathermy mark. It is unreasonable to expect a patient to perceive and report, or to remember and lateralize accurately the symptoms of new floaters in every instance. Because the risks of prophylactic laser are so slight and my experience with untreated and asymptomatic detachment causing lesions is so extensive, I choose to treat all tears that have definite residual focal traction. As soon as the treatment heals, the patient is essentially at prelesion status and does not need special or even regular retinal follow up. The marks are 500 mu, 0.2 second, creamy white and tangent to each other. I prefer the slit lamp with a three mirror lens for laser delivery, although anterior marks may require the indirect laser or an Eisner cone for indentation. Two or three rows of laser marks are placed posteriorly and laterally, increasing to three or four at the lateral horns, and five or six anteriorly (or to the ora). Occasionally cryo is needed. I always leave at least ½ cryo width of normal retina between the freeze and the hole. Cryo breaks down the RPF pump effect for 3–5 days.

A number of retinal detachments are caused by old nondetectable traumatic tears of the pars plana, as evidenced by a detachment, multiple demarcation lines, and a focally detached ora. These were cured by a localized anterior buckle placed where the ora was abnormal or "funny looking." Armed with this experience, I prophylactically treat every case where I find a "funny ora" after trauma and, of course, treat any asymptomatic dialysis. Two or three rows of laser, again tangential to each other, are delivered to make a new ora posterior to any abnormality, and extend ½ clock hour at the ends to connect with normal ora. Cryo is used only when laser is not feasible, and ½ cryo mark of untreated retina is left between the marks. The treatment also connects with the ora at the ends of the lesion and behind adjacent normal ora.

I almost never treat any fully operculated tears, unless the patient is at high risk for other reasons and there is definite proximal vitreous traction proven with a three-mirror contact lens.

I infrequently treat lattice in a fellow eye, regardless of lens status, and then only after a careful examination demonstrates residual vitreous traction on the lesions and the symptomatic eye had a detachment related to lattice with a horseshoe tear. Large areas of treatment are avoided. However, I will treat a similar fellow eye prophylactically 6 to 8 weeks before cataract removal. The ends of the lattice are treated with a C-shaped laser distribution as if treating a horseshoe tear, but not treating the lattice itself.

For all other asymptomatic eyes with lattice, with or without atrophic holes, and eyes with isolated atrophic holes, I prefer to re-examine in 12 to 18 months and to give the patient clear instructions regarding the sudden onset of new floaters as a signal to have a complete indirect retinal exam within 48 hours. An explanation of the pathologic condition sensitizes the patient to become an effective partner in the management of all asymptomatic cases.

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Invited Commentary: Against Treatment

Dr. Wilkinson's report discusses perceived deficiencies that have become evident in searching the literature pertaining to prophylactic treatment of asymptomatic retinal breaks and lattice degeneration. This kind of systematic effort is highly laudable and is a long overdue development in ophthalmology. There is a remarkable and painful realization that over a period of more than 40 years, since the beginning of the worldwide popularization of so-called "prophylactic" treatment to prevent retinal detachment, there has been relatively little progress in understanding or change in attitudes about this subject. Although the PPP panel must be

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RETINA/VITREOUS PREFERRED PRACTICE PATTERN® DEVELOPMENT PROCESS AND PARTICIPANTS

The **Retina/Vitreous Preferred Practice Pattern® Panel** members wrote the Posterior Vitreous Detachment, Retinal Breaks, and Lattice Degeneration Preferred Practice Pattern® (PPP) guidelines. The PPP Panel members discussed and reviewed successive drafts of the document, meeting in person twice and conducting other review by e-mail discussion, to develop a consensus over the final version of the document.

Retina/Vitreous Preferred Practice Pattern Panel 2013–2014
Timothy W. Olsen, MD, Chair
Ron A. Adelman, MD, MPH, MBA, FACS, Retina Society Representative
Christina J. Flaxel, MD
James C. Folk, MD, American Society of Retina Specialists Representative
Jose S. Pulido, MD, MS, Macula Society Representative
Carl D. Regillo, MD, FACS
Leslie Hyman, PhD, Methodologist

The **Preferred Practice Patterns Committee** members reviewed and discussed the document during a meeting in March 2014. The document was edited in response to the discussion and comments.

Preferred Practice Patterns Committee 2014
Stephen D. McLeod, MD, Chair
Robert S. Feder, MD
Timothy W. Olsen, MD
Bruce E. Prum, Jr., MD
C. Gail Summers, MD
Ruth D. Williams, MD
David C. Musch, PhD, MPH, Methodologist

The Posterior Vitreous Detachment, Retinal Breaks, and Lattice Degeneration PPP was then sent for review to additional internal and external groups and individuals in June 2014. All those returning comments were required to provide disclosure of relevant relationships with industry to have their comments considered. Members of the Retina/Vitreous Preferred Practice Pattern Panel reviewed and discussed these comments and determined revisions to the document.

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Retina/Vitreous Panel
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The Retina Society
Thai Retina Society
H. Culver Boldt, MD

INTRODUCTION

DISEASE DEFINITION

Posterior vitreous detachment (PVD) is a separation of the posterior vitreous cortex from the internal limiting membrane of the retina.[4] (See Glossary.) Vitreous traction at sites of significant vitreoretinal adhesion is responsible for most retinal breaks that lead to retinal detachment. Retinal breaks are defined as full-thickness defects in the retina. Lattice degeneration is a peripheral vitreoretinal condition characterized by retinal thinning, overlying vitreous liquefaction, and firm vitreoretinal adhesions at the margins of thinning. Most lesions are ovoid, with the long axes of lattice running parallel to the ora serrata. Round holes occur frequently within areas of lattice degeneration. Lattice degeneration is a vitreoretinal degenerative process that predisposes to retinal tears and detachment. Vitreomacular traction may develop when the vitreous partially separates from the macula, potentially leading to mechanical distortion of the macula that may correspond to visual symptoms.[4] (See Glossary.)

PATIENT POPULATION

Individuals may present with symptoms or signs suggestive of PVD, retinal breaks, vitreous hemorrhage, retinal detachment, or vitreomacular traction. Other individuals may not be symptomatic and, based on clinical examination findings, may have an increased risk of retinal detachment as the vitreous separates.

CLINICAL OBJECTIVES

- Identify patients at risk of developing a rhegmatogenous retinal detachment (RRD)
- Examine symptomatic patients with an acute PVD to detect and treat associated retinal breaks or tears
- Recognize the evolution of retinal breaks and lattice degeneration
- Manage patients at high risk of developing retinal detachment
- Educate high-risk patients about symptoms of PVD, retinal breaks, and retinal detachments as well as the need for periodic follow-up

BACKGROUND

POSTERIOR VITREOUS DETACHMENT

Population-based studies that evaluate incidence and prevalence of PVD are difficult to conduct due to the lack of definite clinical signs and unreliable clinical tests. A PVD typically occurs between the ages of 45 and 65 in the general population; however, the posterior vitreous may detach earlier in myopic patients.[5] Posterior vitreous detachment leads to vitreous traction at the vitreous base and in areas of lattice degeneration, and thereby, secondarily, is thought to cause most symptomatic retinal breaks that may lead to a RRD. The symptoms of a PVD include light flashes and floaters, and patients with such symptoms are at a higher risk for retinal detachment.[6-10] The stages of a PVD are described in Table 1.[4] Patients typically report the light flashes characteristic of a PVD as being most noticeable in the dark. Such photopsias are likely the result of vitreous traction on the peripheral retina as the vitreous separates from the posterior retina toward the vitreous base. The floaters may be due to blood from a torn or avulsed retinal vessel, condensations of vitreous collagen, or the epipapillary glial tissue (Weiss ring) that is torn from the optic nerve head and area adjacent to the optic nerve head. Between 8% and 26% of patients with acute PVD symptoms have a retinal tear at the time of the initial examination.[8,11-14] There is a direct correlation between the amount of vitreous hemorrhage and the likelihood of a retinal tear.[15] Patients with an acute PVD who have no reported retinal breaks on presentation have a 2% to 5% chance of experiencing a detected (missed or new) break in the weeks that follow.[9,12,16]

Section 5.0

OHAP report

Orthodontics for Craniofacial Anomalies

Question: Should orthodontics be covered for treatment of craniofacial anomalies other than cleft lip/palate?

Question sources: Dr. Bruce Austin from HSD; Dr. Gary Allen from VBBS/HERC; Dr. Garfinkle, orthodontist; the Oregon Dental Association; Ms. Olivia Brandon, the mother of two children with cleidocranial dysostosis, and their orthodontist, Dr. Juliana Panchura.

Issue: A new Oregon law was passed a few years ago to require medical insurance carriers to include orthodontia coverage for craniofacial disorders; however, this legislation did not apply to OHP. Multiple stakeholders are requesting consideration of coverage of orthodontics for conditions involving craniofacial deformities. Currently, only cleft lip/palate diagnoses are paired with orthodontia CDT codes on a covered line; malocclusion is paired with orthodontia on an uncovered line.

Most non-cleft lip facial deformities are on line 261 DEFORMITIES OF HEAD Treatment: CRANIOTOMY/CRANIECTOMY. Line 261 contains a limited series of procedure codes for reconstruction but is missing many codes required for reconstruction of some of the types of craniofacial anomalies included on that line.

The legislation requiring private insurance coverage of orthodontia for craniofacial anomaly is shown below:

> 76th OREGON LEGISLATIVE ASSEMBLY--2012 Regular Session
> House Bill 4128
> SECTION 2. (1) As used in this section, "craniofacial anomaly" includes any congenital anomaly affecting the face or head, including but not limited to cleft palate, cleft lip, craniosynostosis, craniofacial microsomia and Treacher Collins syndrome.
> (2) All health benefit plans, as defined in ORS 743.730, providing coverage of hospital, surgical or dental services, shall provide coverage for dental and orthodontic services for the treatment of craniofacial anomalies if the services are medically necessary to improve or restore function.

This topic was discussed at the June, 2017 OHAP meeting. There was considerable discussion about this topic. The OHAP members felt unanimously that reconstruction including orthodontics should be covered for craniofacial anomalies other than cleft lip/palate due to medical necessity and fairness/morality. The members recognized that such coverage would involve a possible significant increase in cost for both the medical and dental plans, and acknowledged that actuarial review and possible rate adjustment would be required. However, these anomalies are rare, and treatment with orthodontia may save on future surgical costs. The DCO representatives who attended the OHAP meeting requested that they continue to be involved in the process of determining coverage as they feel that this is part of the ongoing process of integrating oral and physical health.

During the OHAP discussion, the advisory panel became aware that current OAR does not allow coverage of orthodontics for cleft lip alone, despite the pairing on the Prioritized List and the intent of the HERC to cover this. HERC staff have been working with HSD staff to ensure OAR is changed to allow coverage.

Dr. Judah Garfinkle, a Portland area orthodontist/oral surgeon provided expert testimony to OHAP and has been working with HERC staff to ensure correct codes are identified for coverage and has given input on the proposed guideline wording. He has consulted with various specialists, who have given

input on the diagnoses and CDT codes that should be included in the new pairings. The codes and guideline have been reviewed by OHAP via email and they concur with the recommendations.

Note that the oral surgeons proposed more codes than are proposed for addition by HERC staff. These codes were for implants, crowns, or other non-covered services. Currently, dentures are covered for similar conditions. Surgeons/orthodontists will need to work directly with the DCOs to negotiate coverage for such services if they are truly required for the reconstruction of a particular patient's condition for function (not aesthetics). Dental implants are going to be discussed as part of the next biennial review cycle for all dental conditions.

Orthodontics for Craniofacial Anomalies

HERC staff recommendations:

All of the following changes are effective January 1, 2018:

1) Add CPT 21110 (Application of interdental fixation device for conditions other than fracture or dislocation, includes removal) to line 305 CLEFT PALATE AND/OR CLEFT LIP
2) Add ICD-10 Q67.4 (Other congenital deformities of skull, face and jaw) and Q74.0 (Other congenital malformations of upper limb(s), including shoulder girdle) to line 261 DEFORMITIES OF HEAD
3) Add orthodontic CDT codes to line 261 DEFORMITIES OF HEAD
    a. See table below
4) Add craniofacial surgery CDT codes to line 261 DEFORMITIES OF HEAD
    a. See table below
5) Add craniofacial surgery CPT codes (21110, 21120-21123, 21193-21199, 21206, 21210, 21215) to line 261 DEFORMITIES OF HEAD
    a. Similar codes CPT 21141-21188 (midface reconstruction) are already on line 261
6) Add advanced imaging CDT (D0364-D0367) codes to line 261 DEFORMITIES OF HEAD
    a. Note: these codes are currently on Services Recommended for Non-Coverage, but the orthodontic/craniofacial surgeons state they are essential for evaluation and surgical planning for these patients
7) Adopt a new guideline note for line 261 as shown below

GUIDELINE NOTE XXX ORTHODONTICS AND CRANIOFACIAL SURGERY FOR CRANIOFACIAL ANOMALIES

Line 261

Orthodontics and craniofacial surgery are included on this line only for pairing with craniofacial anomaly diagnoses when there is significant malocclusion expected to result in difficulty with mastication, speech, or other oral function. Advanced dental imaging is included on this line only when required for surgical planning for repair of craniofacial anomalies.

Orthodontics for Craniofacial Anomalies

Proposed conditions to pair with orthodontics on line 261:

ICD-10 code	Code description	Current line(s)
Q67.4	Other congenital deformities of skull, face and jaw [used for craniofacial macrosomia and hemifacial macrosomia]	665 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
Q74.0	Other congenital malformations of upper limb(s), including shoulder girdle [includes Cleidocranial dysostosis]	364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS
Q75.0	Craniosynostosis	261 DEFORMITIES OF HEAD
Q75.1	Craniofacial dysostosis (includes Crouzon's syndrome)	261 DEFORMITIES OF HEAD
Q75.4	Mandibulofacial dysostosis [Treacher-Collins syndrome)	261 DEFORMITIES OF HEAD
Q87.0	Congenital malformation syndromes predominantly affecting facial appearance [used for Aperts and Pfeiffer's syndromes and frontonasal dysplasia]	261 DEFORMITIES OF HEAD

Orthodontic and craniofacial repair CDT codes to add to line 261:

CDT code	Code description	Current line(s)
D0354	Cone beam CT capture and interpretation with limited field of view less than one whole jaw	Services recommended for non-coverage
D0365	Cone beam CT capture and interpretation with field of view of one full dental arch - mandible	Services recommended for non-coverage
D0366	Cone beam CT capture and interpretation with field of view one full dental arch – maxilla with or without cranium	Services recommended for non-coverage
D0367	Cone beam CT capture and interpretation with field of view of both jaws with or without cranium	Services recommended for non-coverage
D7111	EXTRACTION, CORONAL REMNANTS - DECIDUOUS TOOTH	271 DENTAL CONDITIONS (TIME SENSITIVE EVENTS) 305 CLEFT PALATE AND/OR CLEFT LIP
D7140	EXTRACTION, ERUPTED TOOTH OR EXPOSED ROOT (ELEVATION AND/OR FORCEPS REMOVAL)	58 DENTAL CONDITIONS (EG. INFECTION, PAIN, TRAUMA) 305
D7210	SURGICAL REMOVAL OF ERUPTED TOOTH REQUIRING REMOVAL OF BONE AND/OR SECTIONING OF TOOTH, AND INCLUDING ELEVATION OF MUCOPERIOSTEAL FLAP IF INDICATED	58,305, 349 DENTAL CONDITIONS (EG. SEVERE CARIES, INFECTION)
D7220	REMOVAL OF IMPACTED TOOTH-SOFT TISSUE	349

Orthodontics for Craniofacial Anomalies

CDT code	Code description	Current line(s)
D7230	REMOVAL OF IMPACTED TOOTH-PARTIALLY BONY	349
D7240	REMOVAL OF IMPACTED TOOTH-COMPLETELY BONY	349
D7280	SURGICAL ACCESS OF AN UNERUPTED TOOTH	621 DENTAL CONDITIONS (EG. MALOCCLUSION)
D7283	PLACEMENT OF DEVICE TO FACILITATE ERUPTION OF IMPACTED TOOTH	621
D7940	OSTEOPLASTY-FOR ORTHOGNATHIC DEFORMITIES	620 ANOMALIES OF RELATIONSHIP OF JAW TO CRANIAL BASE, MAJOR ANOMALIES OF JAW SIZE, OTHER SPECIFIED AND UNSPECIFIED DENTOFACIAL ANOMALIES
D7941	OSTEOTOMY - MANDIBULAR RAMI	620
D7943	OSTEOTOMY - MANDIBULAR RAMI WITH BONE GRAFT; INCLUDES OBTAINING THE GRAFT	620
D7944	OSTEOTOMY-SEGMENTED OR SUBAPICAL	620
D7945	OSTEOTOMY-BODY OF MANDIBLE	620
D7946	LEFORT I (MAXILLA-TOTAL)	620
D7947	LEFORT I (MAXILLA-SEGMENTED)	620
D7948	LEFORT II OR LEFORT III (OSTEOPLASTY OF FACIAL BONES FOR MIDFACE HYPOPLASIA OR RETRUSION)-WITHOUT BONE GRAFT	620
D7949	LEFORT II OR LEFORT III-WITH BONE GRAFT	620
D7950	OSSEOUS, OSTEOPERIOSTEAL, OR CARTILAGE GRAFT OF THE MANDIBLE OR MAXILLA - AUTOGENOUS OR NONAUTOGENOUS, BY REPORT	650 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT
D7951	Sinus augmentation with bone or bone substitutes via a lateral open approach	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D7952	Sinus augmentation via a vertical approach	622
D7953	BONE REPLACEMENT GRAFT FOR RIDGE PRESERVATION - PER SITE	650 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT
D7955	REPAIR OF MAXILLOFACIAL SOFT AND/OR HARD TISSUE DEFECT	647 TMJ DISORDERS
D8010	LIMITED ORTHODONTIC TREATMENT OF THE PRIMARY DENTITION	47 CLEFT PALATE WITH AIRWAY OBSTRUCTION 305 CLEFT PALATE AND/OR CLEFT LIP 621
D8020	LIMITED ORTHODONTIC TREATMENT OF THE TRANSITIONAL DENTITION	47,305,621
D8030	LIMITED ORTHODONTIC TREATMENT OF THE ADOLESCENT DENTITION	47,305,621

Orthodontics for Craniofacial Anomalies

CDT code	Code description	Current line(s)
D8040	LIMITED ORTHODONTIC TREATMENT OF THE ADULT DENTITION	47,305,621
D8050	INTERCEPTIVE ORTHODONTIC TREATMENT OF THE PRIMARY DENTITION	305,621
D8060	INTERCEPTIVE ORTHODONTIC TREATMENT OF THE TRANSITIONAL DENTITION	47,305,621
D8070	COMPREHENSIVE ORTHODONTIC TREATMENT OF THE TRANSITIONAL DENTITION	47,305,621
D8080	COMPREHENSIVE ORTHODONTIC TREATMENT OF THE ADOLESCENT DENTITION	47,305,621
D8090	COMPREHENSIVE ORTHODONTIC TREATMENT OF THE ADULT DENTITION	47,305,621
D8210	REMOVABLE APPLIANCE THERAPY	47,305,621
D8220	FIXED APPLIANCE THERAPY	47,305,621
D8660	PRE-ORTHODONTIC EXAMINATION TO MONITOR GROWTH AND DEVELOPMENT	47,305,621
D8670	PERIODIC ORTHODONTIC TREATMENT VISIT	47,305,621
D8680	ORTHODONTIC RETENTION (REMOVAL OF APPLIANCES, CONSTRUCTION AND PLACEMENT OF RETAINER(S))	47,305,621
D8681	Removable orthodontic retainer adjustment	47,305,621
D8690	ORTHODONTIC TREATMENT (ALTERNATIVE BILLING TO A CONTRACT FEE)	47,305,621
D8691	REPAIR OF ORTHODONTIC APPLIANCE	47,305,621
D8692	REPLACEMENT OF LOST OR BROKEN RETAINER	47,305,621
D8693	RE-CEMENT OR RE-BOND FIXED RETAINERS	47,305,621
D8694	Repair of fixed retainers, includes reattachment	47,305,621

Orthodontic and craniofacial repair CPT codes to add to line 261:

CPT code	Code description	Current line(s)
21110	Application of interdental fixation device for conditions other than fracture or dislocation, includes removal	96 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 428 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT 620 ANOMALIES OF RELATIONSHIP OF JAW TO CRANIAL BASE, MAJOR ANOMALIES OF JAW SIZE, OTHER SPECIFIED AND UNSPECIFIED DENTOFACIAL ANOMALIES

Orthodontics for Craniofacial Anomalies

CPT code	Code description	Current line(s)
21121	Genioplasty; sliding osteotomy, single piece	204 CANCER OF SOFT TISSUE 620
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies	620
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)	620
21193	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft	207 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER 620
21194	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; with bone graft (includes obtaining graft)	207,620
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation	207,620
21196	with internal rigid fixation	207,620
21198	Osteotomy, mandible, segmental;	207,620
21199	Osteotomy, mandible, segmental; with genioglossus advancement	207,620
21206	Osteotomy, maxilla, segmental (eg, Wassmund or Schuchard)	207,620
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)	207 233 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES 587 ATROPHY OF EDENTULOUS ALVEOLAR RIDGE 647
21215	Graft, bone; mandible (includes obtaining graft)	207,233,587,647

Frenulectomy

Question: Should the breastfeeding difficulties in infants be added as a covered condition for frenulectomy?

Question source: Gary Allen, DMD

Issue: Coverage frenulectomy (treatment of "lip tie") for infants with breastfeeding difficulties was discussed at the June, 2017 OHAP meeting. The OHAP members unanimously felt that frenulectomy does not have adequate evidence for coverage for infant breastfeeding difficulties.

During the OHAP review, it was noted that the CDT code for frenotomy (treatment of tongue tie) was not included on the infant breast feeding line. Only the equivalent CPT code was included. This procedure is frequently done by dentists, who use CDT coding rather than CPT coding.

OHAP/HERC staff recommendations:

1) Housekeeping changes required due to inaccurate code placement
    a. Remove CPT 40806 (Incision of labial frenum (frenotomy)) from line 599 TONGUE TIE AND OTHER ANOMALIES OF TONGUE and add to line 665 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY.
        i. Lip-Tie diagnosis is on line 665 not 599
    b. Add D7960 (FRENULECTOMY - ALSO KNOWN AS FRENECTOMY OR FRENOTOMY - SEPARATE PROCEDURE NOT INCIDENTAL TO ANOTHER PROCEDURE) to line 19 and modify GN139 as shown below

GUIDELINE NOTE 139, FRENOTOMY FOR TONGUE-TIE IN NEWBORNS

Lines 19,599

ICD-10-CM Q38.1 (Ankyloglossia) is included on Line 19 for pairing with CPT 41010 (Frenotomy) and CDT D7960 only when the ankyloglossia interferes with breastfeeding. Otherwise, Q38.1 and CPT 41010 are included on Line 599.

MINUTES

Health Evidence Review Commission's
Oral Health Advisory Panel (OHAP)

Clackamas Community College
Wilsonville Training Center, Room 211
June 26, 2017
9:00 AM – 12:00 PM

Members Present: Gary Allen, DMD, Chair; Bruce Austin, DMD (via phone); Gary Allen, DMD; Eli Schwarz, DDS, MPH, PhD; Len Barozzini, DDS; Karen Nolan (via phone); Patricia Parker, DMD; Deborah Loy

Members Absent: Lynn Ironside

Staff Present: Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Jason Gingerich

Also Attending: Cathleeen Olesitse, CareOregon; Kathleen Klemann, Family Care; Laura McKeane, AllCare CCO, Kellie Skenandore, OHA; Judah Garfinkle DMD; Olivia Brandon (via phone)

Roll Call/Minutes Approval/Staff Report

The meeting was called to order at 9:05 am and roll was called. The November, 2016 OHAP minutes were reviewed and no changes were recommended.

- **Topic:** Orthodontics for non-cleft lip craniofacial anomalies

Smits introduced the staff summary of this topic. Allen noted that the treatment pairings proposed are medically necessary. It is unfair that such treatments are covered for cleft lip/palate but not similar conditions. He did not that the proposed coverage Involves surgical costs for medical plans as well as dental costs. Schwartz are about the prevalence of these conditions, which would help determine the possible cost impact of implementation. Garfinkle testified that cleft lip and palate occur in about 1 in 700 births; the other craniofacial anomalies are much more rare (1 in 5,000 or fewer births).

Garfinkle raised a concern that cleft lip alone (without cleft palate) is currently being denied for orthodontic coverage. He explained that a cleft lip may extend into the mouth and affect the teeth without actually affecting the palate. Smits noted that orthodontia CPT/CDT codes paired with the ICD-10 codes for cleft lip alone. However, Nolan noted that current OHP rule does not

include cleft lip for coverage of orthodontia. HERC staff will work with HSD staff to change OAR to ensure that cleft lip is allowed to pair with orthodontia.

Garfinkle testified that these conditions are rare, but serious. OHP reimbursement is so low, he can't treat in his private office. But clinics that do provide these services are getting orthodontia denied. He wrote the bill that added the coverage for orthodontia for these conditions for commercial carriers. He noted that patients need supportive dental care services as well. Smits noted that supportive dental care services may not be among the proposed CPT/CDT codes for addition to the craniofacial anomalies line; she will work with Garfinkle to ensure all the CPT/CDT codes are included on line 261

Allen noted that adding orthodontia for these conditions adds considerable expense. Loy noted that the DCOs have only a very small rate to cover orthodontia because of current very limited coverage. Smits indicated that the additional cost of the proposed coverage would require actuarial review of the cost and possibly delay in implementation until such actuarial analysis could be done and rates can be adjusted. Garfinkle noted that not covering the orthodontia might actually increase costs overall for OHP because the covered reconstructive surgeries will fail if the orthodontia that is used with them is not covered/done.

Loy noted that extractions are not included in the proposed CPT/CDT codes. Garfinkle indicated that extractions needs to be covered for these conditions in many cases. Garfinkle also noted that Q74.0 (Other congenital malformations of upper limb(s), including shoulder girdle) which codes for cleidocranial dysostosis is not included for addition to line 261 and should. Smits reviewed the subdiagnoses of Q74.0 and oral/dental conditions are included. Q74.0 should also be added to line 261.

Allen stressed again that it was a moral and medical necessity to cover these treatments.

Ms. Brandon gave public testimony about the difficulty in obtaining coverage for her two daughters with cleidocranial dysotosis. They have been denied both medical and dental benefits for their condition. They are currently getting coverage currently through pro bono work of a local orthodontic.

Livingston noted that very rare conditions could be eligible for treatment thought the exceptions process.

Loy raised that concern that Medicaid only covers dental/orthodontia through age 20. HSD staff thought that coverage for cleft lip/palate had no age restrictions; staff will look into the rules on this.

McKeane requested that the HERC/HSD keep CCOs involved in the process. She stressed the need for integration between CCOs and dental plans.

Garfinkle noted that he has a non-profit which can provide coverage/payment for patients called Smile Oregon.

Overall, the OHAP felt that coverage should be added for orthodontia and related craniofacial surgeries for craniofacial anomalies other than cleft lip palate. They felt that a guideline was required, and generally approved the staff suggested guideline wording. HERC staff will work with Dr. Garfinkle to ensure that all appropriate ICD-10, CPT and CDT codes are identified and added to line 261, and will work with him on finalizing guideline wording. Once this is done, staff will send the final proposed codes and guideline to the OHAP members via email for final approval. Dr. Garfinkle will be invited to come to the August VBBS/HERC meeting to provide expert input into any discussion on this topic.

Actions:

1) HERC staff will work with HSD staff to change OAR to ensure that cleft lip alone is allowed to pair with orthodontia.
2) HERC staff will work with Garfinkle to ensure all necessary ICD-10.CPT/CDT codes are included on line 261
3) HERC staff will work with Garfinkle to finalize the guideline wording
4) Once the coding and guideline wording are finalized, staff will send via email to OHAP members for final approval
5) Dr. Garfinkle will be invited to provide expert testimony at the August VBBS/HERC meeting
6) HERC staff will work with HSD leadership to ensure actuarial input on the cost impact of the proposed changes

- **Topic:** GUIDELINE NOTE 48, FRENULECTOMY/FRENULOTOMY

Smits introduced the staff summary of this topic. There was limited discussion regarding treatment of lip tie. The group unanimously felt the evidence did not support coverage. The housekeeping items were approved with minimal discussion. It was noted that D7960 (FRENULECTOMY - ALSO KNOWN AS FRENECTOMY OR FRENOTOMY - SEPARATE PROCEDURE NOT INCIDENTAL TO ANOTHER PROCEDURE) is the code used by dentists, rather than CPT 41010 (Frenotomy). Adding this code was considered to be a beneficial change to clarify coverage for dentists.

Actions:

1) Remove CPT 40806 (Incision of labial frenum (frenotomy)) from line 599 TONGUE TIE AND OTHER ANOMALIES OF TONGUE and add to line 665 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY.
    i. Lip-Tie diagnosis is on line 665 not line 599

2) Add D7960 (FRENULECTOMY - ALSO KNOWN AS FRENECTOMY OR FRENOTOMY - SEPARATE PROCEDURE NOT INCIDENTAL TO ANOTHER PROCEDURE) to line 19 FEEDING PROBLEMS IN NEWBORNS
    i. Dental code equivalent to CPT 41010
3) Modify GN139 as shown below

GUIDELINE NOTE 139, FRENOTOMY FOR TONGUE-TIE IN NEWBORNS

Lines 19,599

ICD-10-CM Q38.1 (Ankyloglossia) is included on Line 19 for pairing with CPT 41010 (Frenotomy) and CDT D7960 only when the ankyloglossia interferes with breastfeeding. Otherwise, Q38.1 and CPT 41010 are included on Line 599.

- **TOPIC:** MULTISECTOR INTERVENTION: EARLY CHILDHOOD CARIES PREVENTION

Livingston presented a discussion of the draft Multisector Interventions Report for the Prevention of Early Childhood Caries. Barozzoni queried about the impact on coverage for the evidence statements. Livingston clarified that those that have specific odes and coverage implication will be addressed on the Prioritized List if not aligned, but for noncoverage items, these would be added at the end of the Prioritized List and be informational. The group expressed appreciation for the extensive evidence summary.

The group discussed specific concerns about the evidence statement. Barozonni suggested clarifying that oral fluoride supplementation should also be done in primary care settings, and that this is widely done in the County. Schwarz discussed that overall rates of primary care prescribing of oral fluoride are very low. Dental hygienists are also able to prescribe oral fluoride supplementation, and the group discussed the importance of increased prescribing of oral fluoride supplementation in multiple settings. Members decided to add clarification that oral fluoride supplementation could also occur in a primary care setting.

Next the group moved onto oral health risk assessment. It was clarified that the codes are in the funded region, but there is not a separate fee. Schwartz talked about a concern assuming the child is high risk just because the child is poor. Loy and Schwarz talked about disagreement in the dental community about risk assessment tools. Most panelists felt that it was important to do risk assessment but noted the lack of consistent evidence or a single standard tool.

For dental sealants, when risk assessment is used it creates a difference. Only children at elevated or high risk should have dental sealants. Allen discussed a strategy for identifying high risk children and engaging them in case management to help get them into dental care.

Livingston discussed xylitol and the lack of evidence found in the 0-5 year old population. Schwarz discussed iodine and xylitol and members raised the question of xylitol in pregnant women. Livingston clarified she did not identify much evidence for caries outcomes with xylitol in infants or in pregnant mothers.

Next the panel discussed silver diamine fluoride. Livingston clarified that this evidence search was focused on prevention rather than treatment of caries. The group agreed the statement needed to be modified to specify there was insufficient evidence for prevention. Allen discussed that they use silver diamine fluoride primarily for prevention. It does not stain intact enamel. Schwarz compared silver diamine fluoride and sealant and fluoride varnish and found similar outcomes. Loy raised the issue of SDF being used at a population level, there may be active caries that would not be discerned. All agreed that in primary care settings and settings without careful discernment, that varnish was more appropriate, and SDF is appropriate for dental settings. Opt out programs for SDF would need to be different than with fluoride varnish. Allen's DCO is actively doing research on SDF. Schwarz mentioned a new systematic review coming out soon, and the group agreed on the need to watch SDF for prevention carefully over the next couple of years.

For risk assessment, Barozzoni recommended clarifying that it was caries risk assessment (as opposed to periodontal risk assessment). The group agreed.

The group clarified next steps for the multisector intervention report on prevention of early childhood caries. Loy suggested that a more detailed discussion at QHOC occur discussing the multisector interventions for prevention of early childhood caries. Others agreed on the importance of presenting this to the medical plans.

Actions:

1) Recommend to VbBS to approve the Multisector Intervention Report on the Prevention of Early Childhood Caries with minor amendments
2) Recommend that HERC staff highlight this report at QHOC

- **Public Comment:**

No further public comment was heard.

- **Issues for next meeting:**

-2018 CDT code placement

- **Next meeting:**
  - TBD

Early Childhood Caries - Multisector Interventions

Question: How should the new Multisector Intervention Report on the Prevention of Early Childhood Caries be incorporated into the Prioritized List?

Question source: Oral Health Advisory Panel (OHAP)

Issue: OHAP reviewed the evidence on preventing early childhood caries, examining interventions in a variety of settings. They recommended VbBS and HERC approve a new Multisector Interventions statement.

Prioritized List Status

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: 76706,77067,90378,90460-90472,90620,90621,90630-90674,90680-90688, 90696-90716,90723-90736,90739-90748,92002-92014,92551,92552,92567, 96110,96150-96155,98966-98969,99051,99060,99070,99078,99173,99188, 99201-99215,99281-99285,99341-99355,99358-99378,99381-99404, 99408-99449,99487-99498,99605-99607

HCPCS: D0191,D1206,G0008-G0010,G0296,G0297,G0396,G0397,G0438-G0445, G0463-G0468,G0490,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: 57

Condition: PREVENTIVE DENTAL SERVICES (See Guideline Notes 17,64,65)

Treatment: CLEANING, FLUORIDE AND SEALANTS

ICD-10: K00.4,K08.55,Z01.20-Z01.21,Z29.3

CPT: 98966-98969,99051,99060,99070,99078,99188,99201-99215,99281-99285, 99341-99355,99358-99378,99381-99404,99408-99449,99487-99498, 99605-99607

HCPCS: D0120,D0145,D0150,D0180,D0191,D0601-D0603,D1110-D1310,D1330, D1351,D1510-D1575,D4346,D4355,D5986,D9920,G0396,G0397,G0463-G0467,G0490

Line: 348

Condition: DENTAL CONDITIONS (EG. CARIES, FRACTURED TOOTH) (See Guideline Notes 91,123)

Treatment: BASIC RESTORATIVE (E.G. COMPOSITE RESTORATIONS FOR ANTERIOR TEETH, AMALGAM RESTORATIONS FOR POSTERIOR TEETH)

ICD-10: K02.3,K02.51-K02.9,K03.2,K03.89,K08.530-K08.539

HCPCS: D1354,D2140-D2394,D2930-D2933,D2941,D2950,D2951,D2954,D2957, D2980,D6980

GUIDELINE NOTE 17, PREVENTIVE DENTAL CARE

Lines 3,57

Dental cleaning is limited to once per 12 months for adults and twice per 12 months for children up to age 19 (D1110, D1120). More frequent dental cleanings may be required for certain higher risk populations. Additionally, assessment (D0191) may be performed once per 12 months for adults and twice per 12 months for children up to age 19.

Fluoride varnish (D1206) is included on Line 3 for use with children 18 and younger during well child preventive care visits. Fluoride treatments (D1206 and D1208) are included on Line 57 PREVENTIVE DENTAL SERVICES for use with adults and children during dental visits. The total number of fluoride applications provided in all settings is not to exceed four per twelve months for a child at high risk for dental caries and two per twelve months for a child not at high risk. The number of fluoride treatments is limited to once per 12 months for average risk adults and up to four times per 12 months for high risk adults.

GUIDELINE NOTE 91, CARIES ARRESTING MEDICAMENT APPLICATION

Line 348

D1354 is limited to silver diamine fluoride applications, with a maximum of two applications per year.

CPT	Code Description	Line Placement
99188	Application of topical fluoride varnish by a physician or other qualified health care professional	3,57

HERC Staff Assessment

Fluoride varnish and oral fluoride supplementation are already included on Line 3 PREVENTIVE DENTAL SERVICES.

Silver diamine fluoride is currently on a dental treatment line (348), rather than a preventive line (for which there is insufficient evidence), which is appropriate.

Risk assessment is included in the funded region, and frequency is delineated in guideline note 17, although this has insufficient evidence to support its use. OHAP felt strongly it was important and there is not evidence of inefficacy at this time. There is not a specific additional payment available for risk assessment at this time. Removing the specific mention of risk assessment given nonpayment and insufficient evidence seems appropriate.

HERC staff recommendations:

1) Adopt a new Multisector Interventions statement:

Multisector Interventions: Prevention of Early Childhood Caries

Evidence supports

- Community water fluoridation
- Fluoride varnish, including applied in a primary care setting
- Fluoride gel
- Oral fluoride supplementation
- Community-based programs that combine oral health education with supervised toothbrushing

Limited evidence supports

- Motivational interviewing towards caregivers

Insufficient or conflicting evidence on:

- Anticipatory guidance/oral health education alone
- Encouragement of preventive dental visits
- Risk assessment
- Xylitol products
- Chlorhexidine
- Silver diamine fluoride
- School-based behavioral interventions
- Breastfeeding interventions

2) Modify Guideline Note 17 as follows:

GUIDELINE NOTE 17, PREVENTIVE DENTAL CARE

Lines 3,57

Dental cleaning is limited to once per 12 months for adults and twice per 12 months for children up to age 19 (D1110, D1120). More frequent dental cleanings may be required for certain higher risk populations. ~~Additionally, assessment (D0191) may be performed once per 12 months for adults and twice per 12 months for children up to age 19.~~

Fluoride varnish (~~D1206,~~99188) is included on Line 3 for use with children 18 and younger during well child preventive care visits. Fluoride treatments (D1206 and D1208) are included on Line 57 PREVENTIVE DENTAL SERVICES for use with adults and children during dental visits. The total number of fluoride applications provided in all settings is not to exceed four per twelve months for a child at high risk for dental caries and two per twelve months for a child not at high risk. The number of fluoride treatments is limited to once per 12 months for average risk adults and up to four times per 12 months for high risk adults.

3) Consider whether or not to clarify guideline note 91

GUIDELINE NOTE 91, CARIES ARRESTING MEDICAMENT APPLICATION

Line 348

D1354 is limited to silver diamine fluoride applications for the treatment (rather than prevention) of caries, with a maximum of two applications per year.

Health Evidence Review Commission (HERC)

Multisector Interventions:

Prevention of Early Childhood Caries

DRAFT for VbBS/HERC Meeting 8/10/2017

Multisector Interventions

To prevent early childhood caries, the evidence supports the following interventions:

- Community water fluoridation
- Fluoride varnish, including applied in a primary care setting
- Fluoride gel
- Oral fluoride supplementation
- Community-based programs that combine oral health education with supervised toothbrushing

Limited evidence supports:

- Motivational interviewing towards caregivers

Insufficient or conflicting evidence is available for:

- Anticipatory guidance/oral health education alone
- Encouragement of preventive dental visits
- Risk assessment
- Xylitol products
- Chlorhexidine
- Silver diamine fluoride
- School-based behavioral interventions
- Breastfeeding interventions

Table of Contents

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. Multisector intervention reports will be developed to address these population-based health interventions or other types of interventions that occur outside of the typical clinical setting.

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.

Evidence Summary Table

Intervention	Outcomes	Strength of evidence	References	HERC Staff Assessment
Anticipatory guidance/ encourage-ment of preventive dental visits	Preventive dental visits associated with higher need for restorative care, emergency visits Oral health education alone appears ineffective Multicomponent strategies can increase dental visits	Very low Low	Sen, 2016 USPSTF, 2014 (document not included due to length) Douglass, 2015 De Silva, 2016	Mixed evidence. Widely endorsed by professional bodies.
Risk assessment	No specific tool. A variety or risk factors have been identified. Impact of risk assessment on improved outcomes unknown.	Very low	USPSTF, 2014 Fontana, 2015	Insufficient evidence
Water fluoridation	Median decrease of 15.2 percentage points in caries. Children having 35% fewer decayed, missing and filled baby teeth and 26% fewer decayed, missing and filled permanent teeth. Fluoridation led to a 15% increase in children with no decay in their baby teeth and a 14% increase in children with no decay in their permanent teeth. Cost-saving	Strong according to Community Preventive Services Task Force	Community Preventive Services Task Force, 2013 Cochrane systematic review, 2015	Highly effective and cost-saving. Possible harm of cosmetic fluorosis.

Topical fluoride	Varnish Primary teeth - 37% reduction in decayed, missing and filled tooth surfaces (dmfs). Percent reduction in caries increment, 18 to 59% Gel – 20% reduction in decayed, missing and filled tooth surfaces (dmfs)	Moderate for varnish Low for gel	Cochrane systematic review, 2013; USPSTF, 2014 Cochrane systematic review, 2015	Highly effective without harms.
Fluoride supplement-ation	32% to 72% reduction in decayed, missing, and filled teeth and from 38% to 81% for decayed, missing, and filled tooth surfaces	Adequate evidence of at least moderate benefit	USPSTF, 2014	Effective. Small risk of enamel fluorosis
Xylitol products	Caries prevention	Insufficient evidence	Cochrane systematic review, 2015	Insufficient evidence
Chlorhexidine	Caries prevention	Insufficient evidence	Cochrane systematic review	Insufficient evidence
Silver diamine fluoride	Caries prevention	Insufficient evidence	MED, 2015	Insufficient evidence and known cosmetic harms
School-based behavioral interventions	Prevented fraction (PF) = 0.65 (95% CI 0.12 to 1.18)	Insufficient evidence	Cochrane systematic review, 2013	Insufficient evidence
Maternal interventions	Motivational interviewing (MI) toward caregivers has mixed but somewhat positive evidence to support its use	Very low	Gao, 2014 Borrelli, 2015 Tham, 2015	For MI, Mixed but favors benefit

	Conflicting evidence on breastfeeding and caries (protective association for less than 12 months of breastfeeding, increased association beyond 12 months). No direct evidence about breastfeeding interventions and caries outcomes was identified			
Community targeted programs	Decline in decayed teeth but not reaching clinical significance Improved access to multiple preventive services	Very low	Ricks, 2015	Insufficient
Toothbrushing programs & oral health education	Decrease dmfs caries index (three studies, MD -1.59, 95% CI -2.67 to -0.52, low-quality evidence) and dmft (two studies, MD -0.97, 95% CI -1.06 to -0.89, low-quality evidence)	Low quality	De Silva, 2016	Low quality

Abbreviations

dfms: An index of decayed, missing or filled surfaces in primary teeth. Each tooth surface is examined separately. dfmt: An index of decayed, missing or filled teeth in primary teeth.

Note: Lower case is used for primary teeth. All capital letters (e.g., DMFS, DMFT) is used for permanent teeth.

Background

Dental caries are largely preventable yet they continue to pose a significant burden on young children. Early childhood caries are defined as the presence of 1 or more decayed (noncavitated or cavitated lesions), missing (due to caries), or filled tooth surfaces in any primary tooth in a child 71 months of age or younger (AAPD, 2008). Caries disproportionately affect low-income children. A recent study found that 0.5% of children age 1-20 enrolled in Medicaid required dental surgeries in operating rooms or ambulatory surgical centers, and 71% of these were children ages 1-5 (Bruen, 2016).

Evidence Review

Anticipatory guidance

USPSTF, 2014
https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/dental-caries-in-children-from-birth-through-age-5-years-screening?ds=1&s=dental

- Evidence on the effectiveness of primary care educational or counseling interventions to reduce dental caries remains sparse or unavailable

Blackburn, 2017 doi:10.1001/jamapediatrics.2016.4514

- Retrospective cohort study using claims data for 19,658 Alabama Medicaid children
- Used high-dimensional-propensity scores to reduce selection bias
- Results: 25.8% (n = 3658) received early preventive dental care, of whom 44%were black, 37.6%were white, and 16.3%were Hispanic. Compared matched children without early preventive dental care, children with dentist-delivered preventive dental care more frequently had a subsequent caries-related treatment (20.6%vs 11.3%, *P* < .001), higher rate of visits (0.29 vs 0.15 per child-year, *P* < .001), and greater dental expenditures ($168 vs $87 per year, *P* < .001). Dentist-delivered preventive dental care was with an increase in the expected number of caries-related treatment visits by 0.14 per child per year (95%CI, 0.11-0.16) and caries-related treatment expenditures by $40.77 child per year (95%CI, $30.48-$51.07). Primary care provider–delivered preventive dental care did not significantly affect caries-related treatment use or expenditures.
- Author conclusions: Children with early preventive care visits from dentists were more likely to have subsequent dental care, including caries-related treatment, and greater expenditures than children without preventive dental care. There was no association with subsequent caries-related treatment and preventive dental care from PCPs.We observed no evidence of a benefit of early preventive dental care, regardless of the provider.

Sen, 2016

- Retrospective cohort study using claims data for all Alabama Medicaid children
- N=4,774 continuously enrolled children
- Evaluating effectiveness of preventive dental visits and 4 year outcomes
- Analyses are conducted separately for children 0–4 years, 4–9 years, and >9 years. For 0–4 years, the intervention of interest is whether they have at least one preventive dental visit before age 3. For the other two age groups, interventions of interest are if they have regular preventive dental visits during each of the first 3 years, and if they have claims for a sealant in the first 3 years.
- Only sealants are associated with a reduced likelihood of using restorative and emergency services and costs.

- Consistent utilization of preventive dental visits is associated with higher probability of restorative visits and higher emergency visits in year 4

Risk assessment

USPSTF, 2014

- Systematic review of prevention of early childhood caries
- No study evaluated the accuracy of risk-assessment tools applied by primary care clinicians to identify children younger than age 5 years at increased risk for future dental caries.
- No randomized trial or observational study compared clinical outcomes between children younger than age 5 years screened and not screened by primary care clinicians for dental caries. One good-quality cohort study found primary care pediatrician examination following 2 hours of training associated with a sensitivity of 0.76 for identifying a child with one or more cavities and 0.63 for identifying children age <36 months in need of a dental referral compared with a pediatric dentist evaluation.

Fontana, 2015

- Included systematic reviews and recommendations on caries risk assessment
- 12 publications
- Many not validated in US populations
- Strongest risk predictors: previous caries experience, multivariate prediction models, low socioeconomic status, high levels of Strep mutans
- The evidence offers no consensus as to the best caries risk assessment tool
- Author Conclusions: Moderate to weak evidence supports the following recommendations:
  (1) Children should have a caries risk assessment done in their first year (or as soon as their first tooth erupts) as part of their overall health assessment, and this should be reassessed periodically over time.
  (2) Multiple clinical, environmental, and behavioral factors should be considered when assessing caries risk in young children, including factors associated with the primary caregiver.
  (3) The use of structured forms, although most may not yet be validated, may aid in systematic assessment of multiple caries risk factors and in objective record-keeping.
  (4) Children from low socioeconomic status groups should be considered at increased risk when developing community preventive programs.

SIGN, 2014 http://www.sign.ac.uk/assets/qrg138.pdf

- Scottish Intercollegiate Guidelines Network guideline on dental interventions to prevent caries in children
  - Obtain a social history. GRADE OF RECOMMENDATION C

- The following factors should be considered when assessing caries risk: GRADE OF RECOMMENDATION C
  - clinical evidence of previous disease
  - dietary habits, especially frequency of sugary food and drink consumption
  - social history, especially socioeconomic status
  - use of fluoride
  - plaque control
  - saliva
  - medical history
- Specialist child healthcare professionals should consider carrying out a caries risk assessment of children in their first year as part of the child's overall health assessment. GRADE OF RECOMMENDATION D
- Children whose families live in a deprived area should be considered as at increased risk of early childhood caries when developing preventive programmes. GRADE OF RECOMMENDATION D

Douglass, 2015

- Nonsystematic review of 69 articles examining integration of oral health into primary care settings
- Screening and risk assessment – no studies evaluate impact on caries outcomes, but they are adoptable by PCPs and increase referral
- Oral health counseling - No studies evaluating PCP counseling on oral health outcomes. Studies in dental health providers doing counseling improves oral hygiene but has no impact on caries increment.
- Motivational interviewing - One study specifically examined the use of MI by PCPs in the absence of fluoride varnish. At the one-year follow-up, the ECC prevalence at the intervention site was 17.7 percent versus 31.7 percent at the control site (*P*=0.086).
- Access to Baby and Child Dentistry (ABCD) program for Washington Medicaid, involved 4144 children. 37% had a visit with a dentist compared to 12% of Medicaid non-ABCD children. Program components involve enrolling Medicaid-eligible children by age 1, educating their families and caregivers about dental hygiene and eating habits; providing outreach and case management to connect families with dental offices; training dentists in the best care practices for young children; and creating referral networks of pediatric dentists for children with more difficult treatment needs.

Table 1. EXISTING POLICIES ON ORAL HEALTH SCREENING, RISK ASSESSMENT, AND ESTABLISHMENT OF A DENTAL HOME
American Academy of Pediatrics policy on risk assessment, timing, and establishment of the dental home[36] • Administer an oral health risk assessment periodically to all children. • Include anticipatory guidance for oral health as an integral part of comprehensive patient counseling. • Recommend that every child has a dental home by 1 year of age.
American Academy of Pediatric Dentistry policy on the dental home[68] • The AAPD encourages parents and other care providers to help every child establish a dental home by 12 months old.
Bright Futures[69] • The first oral examination should occur within six months of the eruption of the first primary tooth, and no later than age 12 months. Thereafter, the child or adolescent should be seen according to a schedule recommended by the dentist, based on the individual needs and susceptibility to disease.

Table 2. RECOMMENDED AGE OF FIRST DENTAL VISIT BASED ON PERIODICITY RECOMMENDATIONS OR STATE MEDICAID PROGRAM RECOMMENDATIONS

Category	Recommended age of first dental visit based on periodicity schedule or state Medicaid recommendations	No. of states
AAPD dental periodicity schedule	By 12 mos old	25
State-specific dental periodicity schedule	By 12 mos old	8
	By 12-18 mos old	1
	6-24 mos for those at risk; age 3 ys otherwise	1
	≤3 ys	1
	3 ys	1
No dental periodicity schedule available (state Medicaid program defines age of first dental visit)	By 12 mos old	5
	3 ys	4
	2 ys	2
	Unknown/information not available	2

Bottom line: Both risk assessment and early establishment with a dental home has insufficient evidence but are widely recommended.

Water fluoridation

Community Preventive Services Task Force, 2013
https://www.thecommunityguide.org/findings/dental-caries-cavities-community-water-fluoridation

- Systematic review and meta-analysis of community water fluoridation (CWF)
- 28 studies about the effect of CWF on caries; 16 about oral health disparities, and 117 about dental fluorosis

- Combined evidence showed a median decrease of 15.2 percentage points in caries after CWF began (12 studies).
- The only harm is dental fluorosis, which is usually mild and not clinically significant. There is no evidence CWF is associated with severe fluorosis.
- CWF is cost-saving: Benefit–cost ratios ranged from 1.1:1 to 135.0:1 (6 studies); Studies that provided benefit and cost information reported a per capita annual benefit of CWF that ranged from $5.49 to $93.19 (6 studies).
- Conclusions: strong evidence that community water fluoridation results in decreased dental caries across populations.

Iheozor-Ejiofor, 2015

- Cochrane systematic review
- Evaluated caries data and fluorosis
- For caries, they included prospective controlled studies; for fluorosis, any type of controlled study design.
- 155 studies met inclusion criteria, 107 included in quantitative synthesis
- Results: initiation of water fluoridation results in reductions in dmft of 1.81 (95% CI 1.31 to 2.31; 9 studies at high risk of bias, 44,268 participants). This translates to a 35% reduction in dmft compared to the median control group mean values.
- Initiation of water fluoridation results in an increase in the percentage of caries free children of 15% (95% CI 11% to 19%; 10 studies, 39,966 participants) in deciduous dentition.
- Limitations: The majority of studies (71%) were conducted prior to 1975 and the widespread introduction of the use of fluoride toothpaste.
- There is insufficient information to determine whether initiation of a water fluoridation program results in a change in disparities in caries across socioeconomic status (SES) levels.
- With regard to dental fluorosis, we estimated that for a fluoride level of 0.7 ppm the percentage of participants with fluorosis of aesthetic concern was approximately 12% (95% CI 8% to 17%; 40 studies, 59,630 participants). This increases to 40% (95% CI 35% to 44%) when considering fluorosis of any level (detected under highly controlled, clinical conditions; 90 studies, 180,530 participants). Over 97% of the studies were at high risk of bias and there was substantial between-study variation.
- **Author's conclusions:** The available data come predominantly from studies conducted prior to 1975, and indicate that water fluoridation is effective at reducing caries levels in both deciduous and permanent dentition in children. Our confidence in the size of the effect estimates is limited by the observational nature of the study designs, the high risk of bias within the studies and, importantly, the applicability of the evidence to current lifestyles. There is a significant association between dental fluorosis (of aesthetic concern or all levels of dental fluorosis) and fluoride level. The evidence is

limited due to high risk of bias within the studies and substantial between-study variation.

Bottom line: Community water fluoridation is effective at caries prevention and is cost-saving.

Topical fluoride (e.g., varnish, rinses)

Marinho, 2013 *http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD002280.pub2/epdf*

- Cochrane systematic review of randomized trials of fluoride varnish
- 22 trials with 12,455 participants (9595 used in analyses)
- For primary teeth (10 trials) The pooled d(e/m)fs prevented fraction estimate was 37% (95% CI 24% to 51%; P < 0.0001).
- No significant association between estimates d(e/m)fs prevented fractions and the pre-specified factors of baseline caries severity, background exposure to fluorides, application features such as prior prophylaxis, concentration of fluoride, or frequency of application were found.
- Limitations: there was substantial heterogeneity, confirmed statistically; however, this body of evidence was assessed as of moderate quality.

USPSTF, 2014
https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/dental-caries-in-children-from-birth-through-age-5-years-screening?ds=1&s=dental

- Three randomized trials published since the prior USPSTF review were consistent with three previous trials in finding fluoride varnish more effective than no fluoride varnish in reducing caries incidence in higher risk children younger than age 5 years (percent reduction in caries increment, 18 to 59%), although in all trials, fluoride varnish was applied by dental personnel.
- The USPSTF recommends that primary care clinicians apply fluoride varnish to the primary teeth of all infants and children starting at the age of primary tooth eruption. GRADE B

SIGN, 2014

- Fluoride varnish should be applied at least twice yearly in all children. LEVEL A

Douglass, 2015

- Fluoride varnish delivered by PCPs in the North Carolina Into the Mouths of Babes (IMB) program
- Children enrolled in the IMB program with at least four visits experienced, on average, a 17 percent reduction in dental-caries-related treatments up to six years of age compared to children with no IMB visits. When data were simulated for initial IMB visits

at 12 and 15 months old, there was a cumulative 49 percent reduction in caries-related treatments at 17 months of age. Data analysis revealed that a one-unit increase in IMB visits resulted in a 0.25 dmft decrease per student.

- An observational study involving American Indian Head Start children demonstrated that four or more fluoride varnish visits at well-child visits between nine and 30 months old significantly decreased caries by 35 percent, from a dmfs of 23.66 to 15.5 among those with fluoride varnish treatments. Less than four fluoride varnish treatments did not have a significant effect on caries rates.
- Parents are satisfied with PCP offered varnish care.
- Oral health services provided in the PCP setting does not decrease dental visits.
- Referrals to dentists are only made in high risk children 70-77% of the time
- Reimbursement for primary care providers for oral health risk assessment and fluoride varnish varies from $4 to $85. The plurality of states reimburse between $10 and $30. It may be considered a barrier when too low ($26 in Massachusetts) compared to $45 in Connecticut where it is infrequently perceived as a barrier).
- PCPs provide more fluoride varnish to 1-2 year olds than dentists. Provider training and increased access to dental care important.
- Fluoride varnish in PCP offices is certainly cost-effective and likely to be cost-saving over a 3 year horizon
- Cost-savings/effectiveness of early dental visits are mixed
- Tailored facilitation of fluoride varnish uptake in PCP practices is the most effective strategy. One-hour trainings are insufficient to encourage widespread adoption. A fluoride varnish office champion and EHR-based reminders are key promoters for success.

Bottom line: Fluoride varnish is effective at reduction of caries in primary teeth, including by primary care providers.

Fluoride gel

Marinho, 2015

- Cochrane systematic review of fluoride gels for prevention of caries in children and adolescents.
- Randomized or quasi-randomized controlled trials of at least 1 year duration.
- 28 trials involving 9140 children and adolescents.
- Most school recruitment-based.
- 20 at high risk of bias.
- The d(e/m)fs pooled prevented fraction estimate for the three trials (1254 participants) that contributed data for the meta-analysis on primary teeth surfaces was 20% (95% CI 1% to 38%; P = 0.04; with no heterogeneity (P = 0.54; I2 = 0%); low quality evidence).

Bottom line: Fluoride gel is likely effective at decreasing caries on primary teeth by around 20%.

Fluoride supplementation

USPSTF, 2014

- Oral fluoride supplementation is effective at reducing caries incidence by 32% to 72% for decayed, missing, and filled teeth and from 38% to 81% for decayed, missing, and filled tooth surfaces in children younger than age 5 years but associated with risk of enamel fluorosis.
- The USPSTF recommends that primary care clinicians prescribe oral fluoride supplementation starting at age 6 months for children whose water supply is deficient in fluoride. GRADE B

Silver diamine fluoride

MED, 2015

- Evidence review on silver diamine fluoride (SDF) for the effectiveness and adverse effects of SDF solution to prevent and arrest caries.
- Results: Two RCTs examined the effectiveness of SDF to prevent dental caries. One cluster RCT in the Philippines of 704 6-8 year old children found comparable increases in caries in both SDF treatment and non-treatment of six to eight year old children and concluded that a onetime application of 38% SDF is not an effective method to prevent dentinal caries lesions. The other RCT, which took place among 501 2nd and 3rd grade children in China, found an annual application of SDF solution (similar to resin sealant placement and semi-annual application of fluoride varnish) to be an effective preventive measure against pit and fissure caries in permanent molars.
- *Adverse Effects:* black discoloration is near universal in treated caries

Bottom line: There is insufficient evidence about the utility of silver diamine fluoride as a caries prevention tool in young children. No RCTs were identified for the 0-5 age group and the two studies found in older children had opposing results and are not applicable to US populations. There are cosmetic harms associated with use of silver diamine fluoride if decay is present.

Maternal interventions (pregnant and postpartum, xylitol, counseling, breastfeeding)

Vamos, 2015

- Systematic review of oral health promotion programs during pregnancy

- All interventions (n = 7) were delivered in prenatal care settings and focused on education.
- Modalities varied, including the use of oral instruction and audiovisual presentations, in both individual and group formats; however, content was directed toward infant oral health.
- Primary outcomes measured included knowledge, beliefs, attitudes, self-efficacy and oral hygiene, and health-seeking behaviors.
- All but one study showed significant improvement in one of these outcomes postintervention.
- Staff conclusions: none evaluated infant or child outcomes

Gao, 2014

- Systematic review of motivational interviewing to improve oral health
- 4 studies included targeted to mothers or caregivers
- Behaviors addressed were infant feeding practice and diet, oral hygiene measures and dental visit.
- Results: in one study combining MI with conventional health education significantly reduced the number of new caries lesions in 1 year (0.71 versus 1.91; P <0.01) and the chance of new caries in 2 years (odds ratio = 0.35, 95% confidence interval [CI] = 0.15 to 0.83; hazard ratio = 0.54, 95% CI = 0.35 to 0.84). However, in additional trials performed by other researchers, significant between-group difference was absent in children's caries increment, although MI seemed to reduce the caries severity (fewer decayed teeth at or beyond the dentin level). Behavior-wise, some positive changes were associated with MI, such as less use of shared utensils, more frequent cleaning of child's teeth, brushing at bedtime, and checking the child for ''precavities.'' But no changes were found in children's use of nursing bottle and snacking habits.
- Author conclusions: Although the effect of MI on preventing caries in infants appears to be encouraging, positive changes in clinical outcomes only existed in some studies.

Borrelli, 2015

- Systematic review and meta-analysis of motivational interviewing on multiple parent-child interactions
- 3 studies were identified for early childhood caries. One had no effect and authors computed a meta-analytic estimate with that study excluded and found an overall weighted mean effect size for dental caries: *d+*=0.36 (95% CI=0.18, 0.55).
- Author conclusions: these results, while promising, should be interpreted with caution

Tham, 2015

- Systematic review of observational and experimental studies
- More versus less breastfeeding (up to 12 months) had a reduced risk of caries (OR 0.50; 95%CI 0.25, 0.99).

- Children breastfed >12 months had an increased risk of caries when compared with children breastfed < 12 months (seven studies (OR 1.99; 1.35, 2.95)
- Amongst children breastfed >12 months, those fed nocturnally or more frequently had a further increased caries risk (five studies, OR 7.14; 3.14-16.23)
- There was a lack of studies on children aged >12 months that evaluated confounders
- Breastfeeding in infancy is associated with a lower caries risk up to 12 months [and a higher risk of caries after 12 months]
- Author conclusions: Breastfeeding in infancy may protect against dental caries. Further research to understand the increased risk of caries in children breastfed after 12 months.

Bottom line: Breastfeeding up to 12 months is associated with a decrease in caries, and beyond 12 months is associated with an increase in caries. There is no direct evidence found connecting advice about breastfeeding and caries risk.

Xylitol

Riley, 2015

- Cochrane systematic review of randomized controlled trials
- 10 studies with 5903 participants
- Over 2.5 to 3 years of use, a fluoride toothpaste containing 10% xylitol may reduce caries by 13% when compared to a fluoride-only toothpaste (PF -0.13, 95% CI -0.18 to -0.08, 4216 children analysed, low-quality evidence). However, the 3 studies that contributed to this were in children 8-13 years of age.
- One study reported that xylitol syrup (8 g per day) reduced caries by 58% (95% CI 33% to 83%, 94 infants analysed, low quality evidence) when compared to a low-dose xylitol syrup (2.67 g per day) consumed for 1 year.
- The following results had 95% CIs that were compatible with both a reduction and an increase in caries associated with xylitol: xylitol lozenges versus no treatment in children (very low quality body of evidence); xylitol sucking tablets versus no treatment in infants (very low quality body of evidence); xylitol tablets versus control (sorbitol) tablets in infants (very low quality body of evidence); xylitol wipes versus control wipes in infants (low quality body of evidence).
- Limitations: most studies at high risk of bias
- Author conclusions: We found some low quality evidence to suggest that fluoride toothpaste containing xylitol may be more effective than fluoride-only toothpaste for preventing caries in the permanent teeth of children, and that there are no associated adverse-effects from such toothpastes. The effect estimate should be interpreted with caution due to high risk of bias and the fact that it results from two studies that were carried out by the same authors in the same population. The remaining evidence we

found is of low to very low quality and is insufficient to determine whether any other xylitol-containing products can prevent caries in infants, older children, or adults.

USPSTF, 2014

- Three trials reported no clear effects of xylitol versus no xylitol on caries incidence in children younger than 5 years.

Bottom line: For the population of 0-5 year olds, there is insufficient evidence of benefit using xylitol products for the prevention of caries.

Antimicrobials

Chlorhexidine

Walsh, 2015

- Cochrane systematic review
- Parallel-group, RCTs that compared the caries preventive effects of chlorhexidine gels, toothpastes, varnishes, mouth rinses, chewing gums or sprays with each other, placebo or no intervention in children and adolescents.
- Two trials compared chlorhexidine gel (0.12% concentration) with no treatment in the primary dentition. The presence of new caries gave rise to a 95% confidence interval that was compatible with either an increase or a decrease in caries incidence (RR 1.00, 95% CI 0.36 to 2.77; 487 participants; very low quality evidence). Similarly, data for the effects of chlorhexidine gel on the prevalence of Strep mutans were inconclusive (RR 1.26, 95% CI 0.95 to 1.66; two trials, 490 participants; very low quality evidence).

Bottom line: Insufficient evidence regarding the effects of chlorhexidine on caries prevention.

Interventions aimed at family members, e.g., at-risk siblings

Nothing found

Community-based interventions

De Silva, 2016 (withdrawn/being updated to extend the evidence search)
https://www.ncbi.nlm.nih.gov/pubmed/27629283

- Cochrane systematic review
- individual- and cluster-(RCTs, controlled before-and-after studies and quasi-experimental and interrupted time series

- 38 studies (total n = 119,789 children, including one national study of 99,071 children, which contributed 80% of total participants) on community-based oral health promotion interventions delivered in a variety of settings and incorporating a range of health promotion strategies (e.g., policy, educational activities, professional oral health care, supervised toothbrushing programmes, motivational interviewing).
- Studies included dietary interventions (n = 3), oral health education (OHE) alone (n = 17), OHE in combination with supervised toothbrushing with fluoridated toothpaste (n = 8) and OHE in combination with a variety of other interventions (including professional preventive oral health care, n = 10).
- Oral health education alone on caries has no effect on dmft (three studies, MD -0.3, 95% CI -1.11 to 0.52, low-quality evidence)
- Oral health education in combination with supervised toothbrushing with fluoridated toothpaste may show a beneficial effect on dmfs (three studies, MD -1.59, 95% CI -2.67 to -0.52, low-quality evidence) and dmft (two studies, MD -0.97, 95% CI -1.06 to -0.89, low-quality evidence)
- Conclusions: Low certainty that community-based oral health promotion interventions that combine oral health education with supervised toothbrushing are effective at reducing caries in primary teeth

Bottom line: Community based oral health promotion that include oral health education and supervised toothbrushing are effective.

School oral health programs

Cooper, 2013 *http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD009378.pub2/full*

- Cochrane systematic review of RCTs in primary school settings
- Included behavioural interventions addressing both toothbrushing and consumption of cariogenic foods or drinks and have a primary school as a focus for delivery of the intervention
- Behaviour change techniques included: information around the consequences of twice daily brushing and controlling sugar snacking; information on consequences
- four studies involving 2302 children; 3 studies at high risk of bias
- Only one included study reported the primary outcome of development of caries. This small study at unclear risk of bias showed a prevented fraction of 0.65 (95% confidence interval (CI) 0.12 to 1.18) in the intervention group of adverse behaviour and instruction and demonstration regarding skill development of relevant oral health behaviours.
- Insufficient evidence for the efficacy of primary school-based behavioural interventions for reducing caries

Ricks, 2015

- Early childhood caries collaborative over 5 years
- Zero- to five-year-old Indian/Alaska Native preschool children
- 4 key targets – increasing access to care, sealants, fluoride varnish, and interim therapeutic restorations (ITRs)
- Methods:
    - A national team was created to promote this initiative in each of the 12 geographic and administrative regions of the IHS, with multiple national, regional, and local presentations given to dental staff and prospective health care collaborators.
    - Educational materials, educational videos, continuing education on caries all on a dedicated website
    - Regular updates on the initiative and progress were reported by the national committee to IHS dentists, dental hygienists, dental assistants, physicians, mid-level providers, community health representatives, nurses, and community health representatives through established HIS electronic mail distribution lists.
- Results:
    - Dental visits increased 7%
    - Dental sealants placed increased 65%
    - Fluoride varnish applications increased 161.2%
    - Between 2010 and 2014, the percentage of one- to two-year-olds with decay experience and untreated decay declined, but the difference was not statistically significant.
- Author conclusions: Early childhood caries prevention strategies, such as early access to dental care, sealants, fluoride varnish, and interim therapeutic restorations, demonstrated some initial improvement in the oral health status of zero- to five-year-old Indian/Alaska Native children.

Policy Landscape

American Academy of Pediatric Dentistry, 2014 Policy on early childhood caries

1. Reducing the parent's/sibling's mutans streptococci (MS) levels to decrease transmission of cariogenic bacteria.
2. Minimizing saliva-sharing activities (e.g., sharing utensils) to decrease the transmission of cariogenic bacteria.
3. Implementing oral hygiene measures no later than the time of eruption of the first primary tooth. Toothbrushing should be performed for children by a parent twice daily, using a soft toothbrush of age-appropriate size. In all children under the age of three, a 'smear' or 'rice-size' amount of fluoridated toothpaste should be used. In all children aged three to six, a 'pea-size' amount of fluoridated toothpaste should be used.
4. Providing professionally-applied fluoride varnish treatments for children at risk for ECC.

5. Establishing a dental home within six months of eruption of the first tooth and no later than 12 months of age to conduct a caries risk assessment and provide parental education including anticipatory guidance for prevention of oral diseases.
6. Avoiding high frequency consumption of liquids and/or solid foods containing sugar. In particular:
   - Sugar-containing beverages (e.g., juices, soft drinks, sweetened tea, milk with sugar added) in a baby bottle or no-spill training cup should be avoided.
   - Infants should not be put to sleep with a bottle filled with milk or liquids containing sugars.
   - Ad libitum breast-feeding should be avoided after the first primary tooth begins to erupt and other dietary carbohydrates are introduced.
   - Parents should be encouraged to have infants drink from a cup as they approach their first birthday. Infants should be weaned from the bottle between 12 to 18 months of age.
7. Working with medical providers to ensure all infants and toddlers have access to dental screenings, counseling, and preventive procedures.

Oral Health Care During Pregnancy Expert Workgroup, 2012

- Convened by Health Resources and Services Administration – Maternal and Child Health Bureau
- Collaboration with ACOG and ADA
- Guidance for prenatal health care professionals
    - During initial prenatal evaluation, take an oral health history and do an oral exam
    - Reassure about safety of dental evaluation and treatment
    - Refer to a dentist if no visit in the prior 6 months
    - Encourage women to seek oral health care, practice good oral hygiene, eat healthy foods, and attend prenatal classes during pregnancy
    - Counsel women to follow oral health professionals recommendations
    - Establish relationships with oral health care professionals, develop a formal referral process (particularly for acute issues) and coordinate care
    - Provide support (insurance, transportation, WIC, etc)
    - Refer to nutrition if guidance on healthy eating would be beneficial
    - Integrate oral health topics into prenatal classes
    - Provide culturally and linguistically appropriate care
- Guidance for oral health care professionals
    - Obtain an oral health history with tailored questions to pregnancy
    - Review medical and social history
    - Perform comprehensive oral exam, including risk assessment
    - Radiographs when clinically indicated
    - Reassure women that oral health care is safe and appropriate during pregnancy
    - Encourage women to seek oral health care, practice good oral hygiene, eat healthy foods, and attend prenatal classes during pregnancy

    - Establish relationships with oral health care professionals, develop a formal referral process (particularly for acute issues) and coordinate care
    - Consult with prenatal health care professionals about comorbidities that may affect management of oral health problems and anesthesia/analgesia
    - Provide acute and emergent dental care
    - Develop comprehensive plan for prevention, treatment, and maintenance throughout pregnancy
    - Help with support social services (transportation, DV, WIC)
    - If does not have a prenatal care provider, explain importance
    - Accept women on Medicaid as patients
    - Refer to nutrition if it would be helpful
- Both include specific advice about healthy eating, brushing twice daily with fluoridated toothpaste, using xylitol after eating, and a nightly fluoridated mouth rinse

Section 6.0

BHAP report

BHAP Code and Guideline Change Recommendations
for August, 2017 VBBS Consideration

1) 2018 ICD-10 diagnosis codes were reviewed and the BHAP recommendations are included in the master 2018 ICD-10 code spreadsheet.
2) Add HCPCS G0443 (Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes) to line 4 SUBSTANCE USE DISORDER
3) Change line 442 title to ~~STEREOTYPY/HABIT DISORDER AND SELF-ABUSIVE BEHAVIOR DUE TO NEUROLOGICAL DYSFUNCTION~~ STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER
4) Remove 96101 (Psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, eg, MMPI, Rorschach, WAIS), 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) from all lines on the Prioritized List
    a. Advise HSD to place 96101 on the Diagnostic Work Up File
5) Advise HSD to move 96102 (Psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, eg, MMPI and WAIS), with qualified health care professional interpretation and report, administered by technician, per hour of technician time, face-to-face) and 96103 (Psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology, eg, MMPI), administered by a computer, with qualified health care professional interpretation and report) from the Ancillary List to the Diagnostic Work Up File
6) Modify GN92 entry on post-stroke depression to soften visit number restrictions as shown below and include the correct line that actually contains this diagnosis

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,5,206,~~208~~,366,407,415,467,543

~~Line 208 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE~~ 206 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.

Supported Employment

Question: Where should the procedure codes for supported employment be placed?

Question source: BHAP, OHA Adult Mental Health Program

Issue: In October, 2016, BHAP removed H2023 (Supported employment, per 15 minutes) from the Prioritized List, where it had been on 27 lines. It was added to the Ancillary List, where similar codes (H2024 Supported employment, per diem; H2025-2026 Ongoing support to maintain employment) were located. This change was made to assist OHA in following federal rules for this program, as there are very strict criteria for who qualifies for this program. These rules govern the diagnosis, severity of illness, exact impact of the diagnosis on functioning, etc. that qualify for supportive employment.

This topic first reached BHAP's attention due to a request to pair H2023 with ADHD. BHAP reviewed the 27 lines where this code appeared at that time, and found most of them to be inappropriate. For example, line 153 FEEDING AND EATING DISORDERS OF INFANCY OR CHILDHOOD was included. BHAP requested a line review, but this was reported to be problematic by HSD.

Wendy Chavez from the OHA Adult Mental Health Services Program came forward and testified about the October, 2016 change which removed supported employment from the Prioritized List and made these codes ancillary. This change is causing difficulties with the Oregon Performance Plan and their compliance with requirements of the US Department of Justice. This type of employment has strict rules from the US DOJ and can only be used by a very limited number of serious mental health disorders. Making these codes ancillary opened them up to any diagnosis, which is in violation of US DOJ rules. As the Ancillary list is not published, it appears that these services are not covered to some CCOs. MHD would like the code for this service (HCPCS H2023) put back on the Prioritized List due to the US DOJ issues. The other codes for similar services can remain ancillary.

Ms. Chavez was asked to provide the lines that HSD would like to have H2023 appear on. She consulted with her division and informed HERC staff that HSD would like H2023 to appear on all 27 lines that it appeared on in 2016.

HERC staff have reviewed these 27 lines and found some of them to be inappropriate, and have no claims for diagnoses on those lines paired with H2023. These lines were considered for not pairing, but the final staff decision was to include all the previous lines and then work with HSD staff and BHAP on any modifications, due to the highly regulated nature of this service and the urgency that HSD feels about making these changes.

Supported Employment

HERC staff recommendation:

1) Add HCPCS H2023 (Supported employment, per 15 minutes) to the following lines and advise HSD to remove H2023 from the Ancillary List.
    a. BHAP/HERC staff will work with HSD to review any lines that might be inappropriate for potential removal at a later date.

Line	Condition	Treatment
7	MAJOR DEPRESSION, RECURRENT; MAJOR DEPRESSION, SINGLE EPISODE, SEVERE	MEDICAL/PSYCHOTHERAPY
26	SCHIZOPHRENIC DISORDERS	MEDICAL/PSYCHOTHERAPY
29	BIPOLAR DISORDERS	MEDICAL/PSYCHOTHERAPY
101	BORDERLINE PERSONALITY DISORDER	MEDICAL/PSYCHOTHERAPY
153	FEEDING AND EATING DISORDERS OF INFANCY OR CHILDHOOD	MEDICAL/PSYCHOTHERAPY
177	POSTTRAUMATIC STRESS DISORDER	MEDICAL/PSYCHOTHERAPY
206	CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS	CONSULTATION/MEDICATION MANAGEMENT/BEHAVIORAL SUPPORT
208	DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE	MEDICAL/PSYCHOTHERAPY
216	NON-SUBSTANCE-RELATED ADDICTIVE BEHAVIORAL DISORDERS	MEDICAL/PSYCHOTHERAPY
257	PSYCHOLOGICAL FACTORS AGGRAVATING PHYSICAL CONDITION (EG. ASTHMA, CHRONIC GI CONDITIONS, HYPERTENSION)	MEDICAL/PSYCHOTHERAPY
282	OTHER PSYCHOTIC DISORDERS	MEDICAL/PSYCHOTHERAPY
287	ANOREXIA NERVOSA	MEDICAL/PSYCHOTHERAPY
295	ACUTE STRESS DISORDER	MEDICAL/PSYCHOTHERAPY
386	BULIMIA NERVOSA AND UNSPECIFIED EATING DISORDERS	MEDICAL/PSYCHOTHERAPY
397	PANIC DISORDER; AGORAPHOBIA	MEDICAL/PSYCHOTHERAPY
412	DISSOCIATIVE DISORDERS	MEDICAL/PSYCHOTHERAPY
417	SCHIZOTYPAL PERSONALITY DISORDERS	MEDICAL/PSYCHOTHERAPY
419	OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED	MEDICAL/PSYCHOTHERAPY
437	PERSISTENT DEPRESSIVE DISORDER	MEDICAL/PSYCHOTHERAPY
442	STEREOTYPY/HABIT DISORDER AND SELF-ABUSIVE BEHAVIOR DUE TO NEUROLOGICAL DYSFUNCTION	CONSULTATION/MEDICATION MANAGEMENT/LIMITED BEHAVIORAL MODIFICATION
449	ADJUSTMENT DISORDERS	MEDICAL/PSYCHOTHERAPY
462	SIMPLE PHOBIAS AND SOCIAL ANXIETY DISORDER	MEDICAL/PSYCHOTHERAPY
466	OBSESSIVE-COMPULSIVE DISORDERS	MEDICAL/PSYCHOTHERAPY
483	CONDUCT DISORDER, AGE 18 OR UNDER	MEDICAL/PSYCHOTHERAPY

Supported Employment

Line	Condition	Treatment
549	IMPULSE DISORDERS	MEDICAL/PSYCHOTHERAPY
554	SOMATIC SYMPTOMS AND RELATED DISORDERS	CONSULTATION
576	PERSONALITY DISORDERS EXCLUDING BORDERLINE AND SCHIZOTYPAL	MEDICAL/PSYCHOTHERAPY

MINUTES

Behavioral Health Advisory Panel
Wilsonville Training Center, Room 210
Wilsonville, OR
August 1, 2017
9:00 am--11:30 am

Members Present: David Pollack, MD, Chair; Kathy Savicki, LCSW; Gary Cobb; Eric Davis, MSW, CADC III, PSS; Lynnea Lindsey, PhD, MSCP; Sheldon Levy, PhD; Mark Bradshaw, MD; Nimisha Gokaldas MD

Members Absent:

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Jason Gingerich; Denise Taray (via phone)

Also Attending: Wendy Chavez, John McIlveen, Laurie Theodorou and Lea Forsman (via phone), OHA; Tamara Bakewell and Shauna Signorini, Oregon Family to Family Health Information Center; Joanie Cosgrove, Legacy; Bennett Garner, Family Care

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1. CALL TO ORDER

David Pollack called the meeting to order at 9:45 AM. Roll was called

The minutes of the October, 2016 BHAP meeting were reviewed and no changes were necessary.

Wendy Chavez from the OHA Adult Mental Health Services Program came forward and testified about the October, 2016 change which removed supported employment from the Prioritized List and made these codes ancillary. This change is causing difficulties with the Oregon Performance Plan and their compliance with requirements of the US Department of Justice. This type of employment has strict rules from the US DOJ and can only be used by a very limited number of serious mental health disorders. Making these codes ancillary opened them up to any diagnosis, which is in violation of US DOJ rules. As the Ancillary list is not published, it appears that these services are not covered to some CCOs. MHD would like the code for this service (HCPCS H2023) put back on the Prioritized List due to the US DOJ issues. The other codes for similar services can remain ancillary. Wendy will work with HERC staff to identify the lines or the diagnoses that this code needs to appear on/pair with. Staff will bring this suggested change to VBBS/HERC next week as a change to the October 1, 2017 Prioritized List.

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2. PRIORITIZED LIST ISSUES

1) 2018 ICD-10 code placement: BHAP members agreed with all the staff recommendations, except for T14.91XS. Taray suggested adding this sequelae code to the Informational List Diagnosis Codes File rather than the Diagnostic Procedure Codes File as the provider should code first the actual sequalae (e.g. anoxic brain injury, liver injury, etc.), and this is how most injury sequalae codes are currently being handled. BHAP agreed with this change.

2) Consent table
    a. BHAP discussed the proposed placement of HCPCS G0443 (Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes) on line 4 SUBSTANCE USE DISORDER. G0443 could be used for SBIRT, and is included in the SBIRT metric for CCOs. The BHAP noted that G0442 is for screening and is appropriately on line 3 PREVENTIVE SERVICES. G0443 is for the brief intervention and is appropriate for line 4.
    b. BHAP discussed the proposed placement of HCPCS H0037 (Community psychiatric supportive treatment program, per diem) and H2012 (Behavioral health day treatment, per hour) on the autism line (line 197). The committee that reviewed treatments for autism specifically left these codes off line 197 in the past due to misuse concerns by both the state and managed care contractors. Members had concern for mild behavioral issues with ASD getting day treatment. There was also concern that individuals may not have had a full evaluation and therefore get a default diagnosis of autism for which these might not be appropriate services. BHAP voted no on the staff recommendation. HERC staff was directed to bring this issue to QHOC for CCO input. If there is further consideration of putting these codes on the autism line in the future, then there will need to be a new guideline added restricting this service to patients with severe behavioral problems.

3) Line 442 renaming. There was no discussion. The BHAP agreed with the recommended line title change.

4) Psychological testing (96101) placement. BHAP discussed the staff proposal to move CPT 96101 from the Prioritized List to the Ancillary File, where similar codes are located. The BHAP discussed the cost of 96101 which would be difficult to control if this test was ancillary. Initially, members discussed keeping 96101 on the Prioritized List due to cost; however, it was then discussed that this test is diagnostic. Additinally, the staff proposal to place 96101 on the Ancillary File would make the code for this testing modality not visible as the Ancillary File is not published. BHAP felt that 96101 and the similar psychological testing codes should all be diagnostic. Cost and utilization can be monitored by the CCOs and the issue brought back to BHAP if found to be highly

expensive. Most CCOs already have prior authorizations in place for this type of testing, which should address the expense issue. This type of testing was suggested to be brought to QHOC to discuss best practices amongst the CCOs for appropriate PAs for this type of testing.

5) Acupuncture guideline revisions for post-stroke depression. There was minimal discussion and the staff recommendation was accepted.

6) Guideline note 86 revisions. The BHAP discussed the question of whether to remove the psychotherapy CPT codes from line 206 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS or whether to modify or delete GN86 ORGANIC MENTAL DISORDERS. Lindsey argued to keep CPT codes on line 206 as they might be appropriate and there can be good value in psychotherapy therapeutic intervention for certain patients in this population. The BHAP members agreed to leave CPT codes online 206. Savicki noted that GN 86 was created in an era when there was more misuse of psychotherapy codes and was also added for education of providers. The BHAP members agreed that GN86 should be deleted as it is not serving any purpose and to keep the psychotherapy CPT codes on line 206.
    a. Note: there was concerns raised after the meeting by HSD about this decision. Staff will delay bringing this suggested change to VBBS/HERC. Staff will bring any suggested guideline edits or other changes back to BHAP to discuss after working with HSD and providers.

7) Implantable buprenorphine for opioid use disorder: BHAP discussed the HERC staff recommendation to add the CPT code for buprenorphine implant insertion to the substance abuse line. There was considerable concern among BHAP members about the relative cost of the implant vs the sublingual formulation. Gokaldas reported that for Multnomah County patients, the cost is $10,000/yr for implant ($5,000 per implant every 6 months) and the sublingual form is $100/month or $1200 per year. It was noted that the P&T PA criteria restricted use to very stable patients, which is probably the group that least needs this type of treatment. Livingston noted that other states are considering using the implants in the prison population at release from prison, but there are no studies on this population regarding outcomes. BHAP members suggested adding buprenorphine implants to line 500 for the studied population (i.e. patients stable on 8mg or less of sublingual buprenorphine for at least 6 months with stable housing, etc.) as it is much less cost-effective that the sublingual formulation. BHAP suggested adding buprenorphine implants to line 660 for all other populations, as it is an unproven therapy for those patients (not studied, no evidence). HERC staff indicated that they would need to have internal conversations with P&T and HSD leadership on this topic, and would likely not bring it to VBBS/HERC until the September meeting.

8) Medication assisted treatment (MAT) in residential treatment programs. Livingston presented the issue summary. Savicki asked McIlveen about the current statewide approaches. McIlveen said that the goal is to increase options and MAT availability.

McIlveen said that some programs have philosophical barriers to MAT. However, addiction is a chronic condition that needs management and needs to be treated as a chronic disease. Engagement in treatment is going to improve outcomes on average. This is adding an evidence-based treatment to that mix.

Cobb discussed support for the guideline. Programs that have philosophical objections should not feel mandated to provide MAT. Additionally, some patients don't want to use MAT and should not feel mandated to use it. McIlveen argued that the diagnosis is a medical condition and patients should not engage in treatment that is ineffective. Lindsey commented that she felt that programs should have to offer access to MAT.

Pollack asked about availability of opioid treatment programs east of the Cascades. McIlveen said it is very limited. Now that nurse practitioners and physician assistants can prescribe buprenorphine, it increases the ability in very rural areas for people to offer it. The state is offering additional addiction support services to rural areas.

Levy felt that if people are going to make an informed decision, they need to have information about what works best for addiction. Information ought to be made available to them. Pollack stated that some people believe that MAT is enabling patients, and that belief needs to be disabused.

Savicki advocated for patients needing access and support for MAT. Treatment facilities need to be able to support MAT use. Bradshaw noted some of these places refuse to allow people on MAT. Pollack felt that MAT is about harm reduction and is really important. Programs have to come to grips with other forms of harm reduction, including safe injection sites.

Garner stated that in the tri-county metro area, there is a meeting being pulled together by Paul Lewis to develop standards of addiction treatment. The draft standards do require that any contracted residential treatment program have people who are knowledgeable and supportive of MAT and provide access. The draft standards include many other things including systems of care and peer mentors but they are still in active development.

Pollack was concerned about putting barriers in between patients and access to MAT. Garner was concerned about not complicating the lives of providers. Savicki stated she did not feel that the proposed guideline was something that could be added to the October 1, 2017 Prioritized List. More provider engagement and consultation will be needed to make sure the guideline can be adopted.

McIlveen noted that Oregon received a SAMSHA grant for expanding access to MAT. Savicki asked if there were training resources as part of that grant. McIlveen said that there are state resources, but residential providers do not utilize state resources much.

There are pragmatic issues that need to be worked through. Savicki talked about the payment requirement.

Garner stated that all providers should be knowledgeable and provide accurate and updated treatment information, including MAT. All providers should provide access to MAT and ensure people with MAT are given equal access to services.

Coffman discussed options for timing of implementation of the draft guideline note on the Prioritized List. Savicki noted there is very limited residential capacity. If there were fewer people recycling through multiple stays, providing MAT might actually lower costs.

Lindsey advocated for a January 1, 2018 change as the most efficacious. There was interest among the BHAP members in aligning with an active workgroup in the tri-county area. Livingston was directed to work with Garner to wordsmith a guideline revision, based on the tri-county workgroup guidelines being drafted.

Decision: HERC staff are to work on revised guideline language that captures issues of ensuring residential treatment providers inform patients of all treatment options and offer access to MAT, and send it to BHAP members for review. Once agreed upon by BHAP members via email discussion, then the topic will be sent to VBBS/HERC for discussion and possible January 1, 2018 implementation.

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3. OTHER BUSINESS

Dr. Pollack announced he is retiring and will no longer be part of BHAP. Staff will identify a new chair for BHAP.

Public testimony: Tamara Bakewell testified regarding representation of children by HERC. She is the parent of a child with special health needs, and works with other families of children with special needs. She wanted to thank the BHAP members for their service. She asked that BHAP work to make sure that HERC policies work for children as well as adults. She requested that BHAP actively involve pediatric providers in their deliberations and for assistance in identifying evidence. She also wanted to remind BHAP that Oregon families and children are mobile, particularly foster children. She wanted CCO policies aligned around the state for treatment of mental health disorders and other disorders of children.

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4. ADJOURNMENT

The meeting was adjourned at 11:30am.

Section 7.0

New Codes

2018 ICD-10 Code Placement Issues

1) **F50.82** (Avoidant/restrictive food intake disorder)
    a. Definition: Avoidant/restrictive food intake disorder (ARFID) also previously known as selective eating disorder (SED), is a type of eating disorder, as well as feeding disorder, where the consumption of certain foods is limited based on the food's appearance, smell, taste, texture, brand, presentation, or a past negative experience with the food
    b. Previous BHAP/VBBS/HERC actions
        i. Reviewed in November, 2016, at which time only ICD-10 F50.89 (Other specified eating disorder) was available for coding this condition. F50.89 was added to lines 153 FEEDING AND EATING DISORDERS OF INFANCY OR CHILDHOOD and line 635 PICA; it was kept on line 386 BULIMIA NERVOSA AND UNSPECIFIED EATING DISORDERS. A coding specification was added to lines 153 and 635: "ICD-10 F50.89 is included on lines 153 for avoidant/restrictive food intake disorder and on line 386 for psychogenic loss of appetite. ICD-10 F50.89 is included on line 635 for pica in adults and for all other diagnoses using this code."
    c. BHAP reviewed August 1, 2017 and agreed with the staff recommendations.
    d. <u>HERC staff recommendations:</u>
        i. Add ICD-10 F50.82 (Avoidant/restrictive food intake disorder) to line 153 FEEDING AND EATING DISORDERS OF INFANCY OR CHILDHOOD
        ii. Add the following coding specification to line 386, delete from line 153, and keep on line 635 in the modified form shown below:
            1. "ICD-10 F50.89 is included ~~on Line 153 for avoidant/ restrictive food intake disorder and~~ on Line 386 for psychogenic loss of appetite. ICD-10 F50.89 is included on Line 635 for pica in adults and for all other diagnoses using this code."

2) **P83.81** (Umbilical granuloma)
    a. Definition: Umbilical granuloma (UG) is the most common umbilical abnormality in neonates, causing inflammation and drainage. Present as a moist, pink mass 1-10 mm in size which appears a few days after cord separation. Most fail to epithelialize and persist for more than 2 months. The common treatment is application of a 75% silver nitrate stick, usually repeated two to three times over a number of clinic visits.
    b. Similar code placement:
        i. The previous less specific code P83.8 (Other specified conditions of integument specific to newborn) was on line 648 EDEMA AND OTHER CONDITIONS INVOLVING THE SKIN OF THE FETUS AND NEWBORN

ii. Similar code L92.9 (Granulomatous disorder of the skin and subcutaneous tissue, unspecified) is on line 606 KELOID SCAR; OTHER ABNORMAL GRANULATION TISSUE

c. HERC staff recommendation:
   i. Place P83.81 (Umbilical granuloma) on line 648 EDEMA AND OTHER CONDITIONS INVOLVING THE SKIN OF THE FETUS AND NEWBORN
      1. Would still require primary care office visits

3) **Q53.13** (Unilateral high scrotal testis) and **Q53.23** (Bilateral high scrotal testes)
   a. Definition: a form of undescended testes in which the testes can still be brought through the scrotal entrance into a high scrotal (unstable) position. Generally treated with surgery, but in some cases may spontaneously descend during puberty
   b. Expert input:
      i. Dr. Stephen Skoog, pediatric urology at OHSU:
         1. [High scrotal testis are sometimes] called "ASCENDED TESTES". A rare cause for surgical correction. We fix them when they are diagnosed.
   c. HERC staff recommendation:
      i. Place Q53.13 and Q53.23 (High scrotal testes) on line 98 UNDESCENDED TESTICLE

4) **Z40.03** (Encounter for prophylactic removal of fallopian tube(s))
   a. Definition: the removal of one or both fallopian tubes with the intent of reducing the risk of ovarian cancer. Women with elevated hereditary risk for ovarian cancer also have an elevated risk for fallopian tube cancer. For this reason, when their ovaries are removed prophylactically, the fallopian tubes must also be removed. In women at increased risk for ovarian cancer, bilateral risk-reducing salpingo-oophorectomy has been shown to be a highly effective tool to lower the risk for both ovarian cancer and breast cancer.
   b. Current Prioritized List status: prophylactic oophorectomy for genetically high risk women (for example, BRCA+ women) is on line 195 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
   c. NOTE: this topic is currently being reviewed as part of a coverage guidance. This procedure may be expanded to average risk women in certain situations.
   d. HERC staff recommendation:
      i. Place Z40.03 (Encounter for prophylactic removal of fallopian tube(s)) on line 195 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER

1. Reassess placement once the coverage guidance on this topic is completed

ii. Alternative placement: Informational File. Then reassess placement with coverage guidance input

5) **Z71.82** (Exercise counseling)
   a. Definition: counseling that can be intensive or simply encouragement to exercise more often
   b. This topic was reviewed as part of the Obesity Taskforce
   c. Current Prioritized List status:
      i. intensive exercise counseling is included on line 325 OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95TH PERCENTILE) AND OVERWEIGHT IN ADULTS (BMI >25) WITH CARDIOVASCULAR RISK FACTORS Treatment INTENSIVE NUTRITIONAL/PHYSICAL ACTIVITY COUNSELING AND BEHAVIORAL INTERVENTIONS
      ii. non-intensive exercise counseling is included on line 589 OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95TH PERCENTILE) AND OVERWEIGHT IN ADULTS (BMI >25) WITH CARDIOVASCULAR RISK FACTORS Treatment: NON-INTENSIVE NUTRITIONAL/PHYSICAL ACTIVITY COUNSELING AND BEHAVIORAL INTERVENTIONS; BARIATRIC SURGERY FOR OBESITY WITH A SIGNIFICANT COMORBIDITY OTHER THAN TYPE II DIABETES & BMI >=35 OR BMI>=40 WITHOUT A SIGNIFICANT COMORBIDITY OTHER THAN TYPE II DIABETES & BMI >=35 OR BMI>=40 WITHOUT A SIGNIFICANT COMORBIDITY
      iii. The two obesity lines are merging into one line with the 2018 Biennial review: 325 OBESITY IN ADULTS AND CHILDREN; OVERWEIGHT STATUS IN ADULTS WITH CARDIOVASCULAR RISK FACTORS Treatment: MEDICAL THERAPY
      iv. Guideline note 5 is applied to line 325. The wording of this guideline was revised with the obesity taskforce and the wording that will be in place on January 1, 2018 is shown below:

GUIDELINE NOTE 5, OBESITY AND OVERWEIGHT

Line 325

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.

d. <u>HERC staff recommendation</u>:
    i. Add Z71.82 (Exercise counseling) to lines
        1. 325 OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95TH PERCENTILE) AND OVERWEIGHT IN ADULTS (BMI >25) WITH CARDIOVASCULAR RISK FACTORS
            a. Guideline Note 5 will apply to Z71.82 on line 325
        2. 589 OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95TH PERCENTILE) AND OVERWEIGHT IN ADULTS (BMI >25) WITH CARDIOVASCULAR RISK FACTORS
            a. Line 589 will be deleted with the January 1, 2018 Prioritized List.
        3. 625 PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS
            a. Placement on line 625 will match the placement of nutrition counseling and will be for use in exercise counseling for non-overweight/obese patients.

2018 ICD-10-CM Codes

Code	Description	Notes	Recommended Placement
A04.71	Enterocolitis due to Clostridium difficile, recurrent	A04.7 (Enterocolitis due to Clostridium difficile) was on line 150	150 ENTERIC INFECTIONS AND OTHER BACTERIAL FOOD POISONING
A04.72	Enterocolitis due to Clostridium difficile, not specified as recurrent		150 ENTERIC INFECTIONS AND OTHER BACTERIAL FOOD POISONING
C96.20	Malignant mast cell neoplasm, unspecified	C96.2 (Malignant mast cell tumor) was on line 162	162 NON-HODGKIN'S LYMPHOMAS
C96.21	Aggressive systemic mastocytosis		162 NON-HODGKIN'S LYMPHOMAS
C96.22	Mast cell sarcoma		162 NON-HODGKIN'S LYMPHOMAS
C96.29	Other malignant mast cell neoplasm		162 NON-HODGKIN'S LYMPHOMAS
D47.01	Cutaneous mastocytosis	D47.0 (Histiocytic and mast cell tumors of uncertain behavior) was on line 162	162 NON-HODGKIN'S LYMPHOMAS
D47.02	Systemic mastocytosis		162 NON-HODGKIN'S LYMPHOMAS
D47.09	Other mast cell neoplasms of uncertain behavior		162 NON-HODGKIN'S LYMPHOMAS
E11.10	Type 2 diabetes mellitus with ketoacidosis without coma		30 TYPE 2 DIABETES MELLITUS
E11.11	Type 2 diabetes mellitus with ketoacidosis with coma		30 TYPE 2 DIABETES MELLITUS
E85.81	Light chain (AL) amyloidosis	E85.8 (Other amyloidosis) was on lines 239,265	239 ACUTE LYMPHOCYTIC LEUKEMIAS (ADULT) AND MULTIPLE MYELOMA 265 MULTIPLE MYELOMA
E85.82	Wild-type transthyretin-related (ATTR) amyloidosis		239 ACUTE LYMPHOCYTIC LEUKEMIAS (ADULT) AND MULTIPLE MYELOMA 265 MULTIPLE MYELOMA
E85.89	Other amyloidosis		239 ACUTE LYMPHOCYTIC LEUKEMIAS (ADULT) AND MULTIPLE MYELOMA 265 MULTIPLE MYELOMA
F10.11	Alcohol abuse, in remission	BHAP review	4 SUBSTANCE USE DISORDER
F11.11	Opioid abuse, in remission	BHAP review	4 SUBSTANCE USE DISORDER
F12.11	Cannabis abuse, in remission	BHAP review	4 SUBSTANCE USE DISORDER
F13.11	Sedative, hypnotic or anxiolytic abuse, in remission	BHAP review	4 SUBSTANCE USE DISORDER
F14.11	Cocaine abuse, in remission	BHAP review	4 SUBSTANCE USE DISORDER

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Code	Description	Notes	Recommended Placement
F15.11	Other stimulant abuse, in remission	BHAP review	4 SUBSTANCE USE DISORDER
F16.11	Hallucinogen abuse, in remission	BHAP review	4 SUBSTANCE USE DISORDER
F18.11	Inhalant abuse, in remission	BHAP review	4 SUBSTANCE USE DISORDER
F19.11	Other psychoactive substance abuse, in remission	BHAP review	4 SUBSTANCE USE DISORDER
F50.82	Avoidant/restrictive food intake disorder	See issues document	153 FEEDING AND EATING DISORDERS OF INFANCY OR CHILDHOOD
G12.23	Primary lateral sclerosis	G12.2 series are on the dysfunction lines	75,297,350,382
G12.24	Familial motor neuron disease		75,297,350,382
G12.25	Progressive spinal muscle atrophy		75,297,350,382
H44.2A1	Degenerative myopia with choroidal neovascularization, right eye	H44.2 (Degenerative myopia) is on line 453. Most choroidal conditions are on line 453	453 DEGENERATION OF MACULA AND POSTERIOR POLE
H44.2A2	Degenerative myopia with choroidal neovascularization, left eye		453 DEGENERATION OF MACULA AND POSTERIOR POLE
H44.2A3	Degenerative myopia with choroidal neovascularization, bilateral eye		453 DEGENERATION OF MACULA AND POSTERIOR POLE
H44.2A9	Degenerative myopia with choroidal neovascularization, unspecified eye		453 DEGENERATION OF MACULA AND POSTERIOR POLE
H44.2B1	Degenerative myopia with macular hole, right eye	H44.2 (Degenerative myopia) is on line 453. H35.34 (Macular cyst, hole, or pseudohole) is also on line 453	453 DEGENERATION OF MACULA AND POSTERIOR POLE
H44.2B2	Degenerative myopia with macular hole, left eye		453 DEGENERATION OF MACULA AND POSTERIOR POLE
H44.2B3	Degenerative myopia with macular hole, bilateral eye		453 DEGENERATION OF MACULA AND POSTERIOR POLE
H44.2B9	Degenerative myopia with macular hole, unspecified eye		453 DEGENERATION OF MACULA AND POSTERIOR POLE
H44.2C1	Degenerative myopia with retinal detachment, right eye	Retinal detachment is on line 284	284 RETINAL DETACHMENT AND OTHER RETINAL DISORDERS

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Code	Description	Notes	Recommended Placement
H44.2C2	Degenerative myopia with retinal detachment, left eye		284 RETINAL DETACHMENT AND OTHER RETINAL DISORDERS
H44.2C3	Degenerative myopia with retinal detachment, bilateral eye		284 RETINAL DETACHMENT AND OTHER RETINAL DISORDERS
H44.2C9	Degenerative myopia with retinal detachment, unspecified eye		284 RETINAL DETACHMENT AND OTHER RETINAL DISORDERS
H44.2D1	Degenerative myopia with foveoschisis, right eye	Foveoschisis is a thickening of the macula which may involve macular holes	453 DEGENERATION OF MACULA AND POSTERIOR POLE
H44.2D2	Degenerative myopia with foveoschisis, left eye		453 DEGENERATION OF MACULA AND POSTERIOR POLE
H44.2D3	Degenerative myopia with foveoschisis, bilateral eye		453 DEGENERATION OF MACULA AND POSTERIOR POLE
H44.2D9	Degenerative myopia with foveoschisis, unspecified eye		453 DEGENERATION OF MACULA AND POSTERIOR POLE
H44.2E1	Degenerative myopia with other maculopathy, right eye		453 DEGENERATION OF MACULA AND POSTERIOR POLE
H44.2E2	Degenerative myopia with other maculopathy, left eye		453 DEGENERATION OF MACULA AND POSTERIOR POLE
H44.2E3	Degenerative myopia with other maculopathy, bilateral eye		453 DEGENERATION OF MACULA AND POSTERIOR POLE
H44.2E9	Degenerative myopia with other maculopathy, unspecified eye		453 DEGENERATION OF MACULA AND POSTERIOR POLE
H54.0X33	Blindness right eye category 3, blindness left eye category 3	H54 (blindness) is on line 382	382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.0X34	Blindness right eye category 3, blindness left eye category 4		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION

Code	Description	Notes	Recommended Placement
H54.0X35	Blindness right eye category 3, blindness left eye category 5		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.0X43	Blindness right eye category 4, blindness left eye category 3		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.0X44	Blindness right eye category 4, blindness left eye category 4		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.0X45	Blindness right eye category 4, blindness left eye category 5		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.0X53	Blindness right eye category 5, blindness left eye category 3		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.0X54	Blindness right eye category 5, blindness left eye category 4		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION

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Code	Description	Notes	Recommended Placement
H54.0X55	Blindness right eye category 5, blindness left eye category 5		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.1131	Blindness right eye category 3, low vision left eye category 1		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.1132	Blindness right eye category 3, low vision left eye category 2		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.1141	Blindness right eye category 4, low vision left eye category 1		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.1142	Blindness right eye category 4, low vision left eye category 2		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.1151	Blindness right eye category 5, low vision left eye category 1		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION

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Code	Description	Notes	Recommended Placement
H54.1152	Blindness right eye category 5, low vision left eye category 2		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.1213	Low vision right eye category 1, blindness left eye category 3	Low vision is on line 382	382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.1214	Low vision right eye category 1, blindness left eye category 4		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.1215	Low vision right eye category 1, blindness left eye category 5		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.1223	Low vision right eye category 2, blindness left eye category 3		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.1224	Low vision right eye category 2, blindness left eye category 4		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION

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Code	Description	Notes	Recommended Placement
H54.1225	Low vision right eye category 2, blindness left eye category 5		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.2X11	Low vision right eye category 1, low vision left eye category 1		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.2X12	Low vision right eye category 1, low vision left eye category 2		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.2X21	Low vision right eye category 2, low vision left eye category 1		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.2X22	Low vision right eye category 2, low vision left eye category 2		382 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
H54.413A	Blindness right eye category 3, normal vision left eye	H54.4 (Blindness, one eye) is on line 658	658 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
H54.414A	Blindness right eye category 4, normal vision left eye		658 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

Code	Description	Notes	Recommended Placement
H54.415A	Blindness right eye category 5, normal vision left eye		658 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
H54.42A3	Blindness left eye category 3, normal vision right eye		658 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
H54.42A4	Blindness left eye category 4, normal vision right eye		658 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
H54.42A5	Blindness left eye category 5, normal vision right eye		658 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
H54.511A	Low vision right eye category 1, normal vision left eye		658 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
H54.512A	Low vision right eye category 2, normal vision left eye		658 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
H54.52A1	Low vision left eye category 1, normal vision right eye		658 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
H54.52A2	Low vision left eye category 2, normal vision right eye		658 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
I21.9	Acute myocardial infarction, unspecified	I21 (MI) is on line 73	73 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION
I21.A1	Myocardial infarction type 2		73 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION
I21.A9	Other myocardial infarction type		73 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION
I27.20	Pulmonary hypertension, unspecified	I27.2 (Other secondary pulmonary hypertension) is on line 102	102 HEART FAILURE

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Code	Description	Notes	Recommended Placement
I27.21	Secondary pulmonary arterial hypertension		102 HEART FAILURE
I27.22	Pulmonary hypertension due to left heart disease		102 HEART FAILURE
I27.23	Pulmonary hypertension due to lung diseases and hypoxia		102 HEART FAILURE
I27.24	Chronic thromboembolic pulmonary hypertension		102 HEART FAILURE
I27.29	Other secondary pulmonary hypertension		102 HEART FAILURE
I27.83	Eisenmenger's syndrome	congential heart condition resulting in heart failure and pulmonary hypertention	102 HEART FAILURE
I50.810	Right heart failure, unspecified		102 HEART FAILURE
I50.811	Acute right heart failure		102 HEART FAILURE
I50.812	Chronic right heart failure		102 HEART FAILURE
I50.813	Acute on chronic right heart failure		102 HEART FAILURE
I50.814	Right heart failure due to left heart failure		102 HEART FAILURE
I50.82	Biventricular heart failure		102 HEART FAILURE
I50.83	High output heart failure		102 HEART FAILURE
I50.84	End stage heart failure		102 HEART FAILURE
I50.89	Other heart failure		102 HEART FAILURE
K06.010	Localized gingival recession, unspecified	K06.0 (Gingival recession) is on line 223	223 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
K06.011	Localized gingival recession, minimal	Bruce Austin DMD, agrees with placement	223 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
K06.012	Localized gingival recession, moderate		223 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
K06.013	Localized gingival recession, severe		223 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
K06.020	Generalized gingival recession, unspecified		223 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
K06.021	Generalized gingival recession, minimal		223 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)

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Code	Description	Notes	Recommended Placement
K06.022	Generalized gingival recession, moderate		223 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
K06.023	Generalized gingival recession, severe		223 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
K56.50	Intestinal adhesions [bands], unspecified as to partial versus complete obstruction	K65.5 (Intestinal adhesions [bands] with obstruction) is on line 46	46 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION
K56.51	Intestinal adhesions [bands], with partial obstruction		46 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION
K56.52	Intestinal adhesions [bands] with complete obstruction		46 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION
K56.600	Partial intestinal obstruction, unspecified as to cause	K56.60 (Unspecified intestinal obstruction) is on line 46	46 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION
K56.601	Complete intestinal obstruction, unspecified as to cause		46 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION
K56.609	Unspecified intestinal obstruction, unspecified as to partial versus complete obstruction		46 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION
K56.690	Other partial intestinal obstruction	K56.69 (Other intestinal obstruction) is on line 46	46 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION

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Code	Description	Notes	Recommended Placement
K56.691	Other complete intestinal obstruction		46 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION
K56.699	Other intestinal obstruction unspecified as to partial versus complete obstruction		46 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION
K91.30	Postprocedural intestinal obstruction, unspecified as to partial versus complete	K91.3 (Postprocedural intestinal obstruction) is on line 290	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
K91.31	Postprocedural partial intestinal obstruction		290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
K91.32	Postprocedural complete intestinal obstruction		290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
L97.105	Non-pressure chronic ulcer of unspecified thigh with muscle involvement without evidence of necrosis	Similar non-pressure chronic ulcer codes are on line 384	384 CHRONIC ULCER OF SKIN
L97.106	Non-pressure chronic ulcer of unspecified thigh with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.108	Non-pressure chronic ulcer of unspecified thigh with other specified severity		384 CHRONIC ULCER OF SKIN
L97.115	Non-pressure chronic ulcer of right thigh with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.116	Non-pressure chronic ulcer of right thigh with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.118	Non-pressure chronic ulcer of right thigh with other specified severity		384 CHRONIC ULCER OF SKIN
L97.125	Non-pressure chronic ulcer of left thigh with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN

Code	Description	Notes	Recommended Placement
L97.126	Non-pressure chronic ulcer of left thigh with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.128	Non-pressure chronic ulcer of left thigh with other specified severity		384 CHRONIC ULCER OF SKIN
L97.205	Non-pressure chronic ulcer of unspecified calf with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.206	Non-pressure chronic ulcer of unspecified calf with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.208	Non-pressure chronic ulcer of unspecified calf with other specified severity		384 CHRONIC ULCER OF SKIN
L97.215	Non-pressure chronic ulcer of right calf with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.216	Non-pressure chronic ulcer of right calf with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.218	Non-pressure chronic ulcer of right calf with other specified severity		384 CHRONIC ULCER OF SKIN
L97.225	Non-pressure chronic ulcer of left calf with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.226	Non-pressure chronic ulcer of left calf with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.228	Non-pressure chronic ulcer of left calf with other specified severity		384 CHRONIC ULCER OF SKIN
L97.305	Non-pressure chronic ulcer of unspecified ankle with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN

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Code	Description	Notes	Recommended Placement
L97.306	Non-pressure chronic ulcer of unspecified ankle with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.308	Non-pressure chronic ulcer of unspecified ankle with other specified severity		384 CHRONIC ULCER OF SKIN
L97.315	Non-pressure chronic ulcer of right ankle with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.316	Non-pressure chronic ulcer of right ankle with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.318	Non-pressure chronic ulcer of right ankle with other specified severity		384 CHRONIC ULCER OF SKIN
L97.325	Non-pressure chronic ulcer of left ankle with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.326	Non-pressure chronic ulcer of left ankle with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.328	Non-pressure chronic ulcer of left ankle with other specified severity		384 CHRONIC ULCER OF SKIN
L97.405	Non-pressure chronic ulcer of unspecified heel and midfoot with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.406	Non-pressure chronic ulcer of unspecified heel and midfoot with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.408	Non-pressure chronic ulcer of unspecified heel and midfoot with other specified severity		384 CHRONIC ULCER OF SKIN
L97.415	Non-pressure chronic ulcer of right heel and midfoot with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN

Code	Description	Notes	Recommended Placement
L97.416	Non-pressure chronic ulcer of right heel and midfoot with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.418	Non-pressure chronic ulcer of right heel and midfoot with other specified severity		384 CHRONIC ULCER OF SKIN
L97.425	Non-pressure chronic ulcer of left heel and midfoot with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.426	Non-pressure chronic ulcer of left heel and midfoot with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.428	Non-pressure chronic ulcer of left heel and midfoot with other specified severity		384 CHRONIC ULCER OF SKIN
L97.505	Non-pressure chronic ulcer of other part of unspecified foot with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.506	Non-pressure chronic ulcer of other part of unspecified foot with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.508	Non-pressure chronic ulcer of other part of unspecified foot with other specified severity		384 CHRONIC ULCER OF SKIN
L97.515	Non-pressure chronic ulcer of other part of right foot with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.516	Non-pressure chronic ulcer of other part of right foot with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.518	Non-pressure chronic ulcer of other part of right foot with other specified severity		384 CHRONIC ULCER OF SKIN
L97.525	Non-pressure chronic ulcer of other part of left foot with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN

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Code	Description	Notes	Recommended Placement
L97.526	Non-pressure chronic ulcer of other part of left foot with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.528	Non-pressure chronic ulcer of other part of left foot with other specified severity		384 CHRONIC ULCER OF SKIN
L97.805	Non-pressure chronic ulcer of other part of unspecified lower leg with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.806	Non-pressure chronic ulcer of other part of unspecified lower leg with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.808	Non-pressure chronic ulcer of other part of unspecified lower leg with other specified severity		384 CHRONIC ULCER OF SKIN
L97.815	Non-pressure chronic ulcer of other part of right lower leg with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.816	Non-pressure chronic ulcer of other part of right lower leg with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.818	Non-pressure chronic ulcer of other part of right lower leg with other specified severity		384 CHRONIC ULCER OF SKIN
L97.825	Non-pressure chronic ulcer of other part of left lower leg with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.826	Non-pressure chronic ulcer of other part of left lower leg with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.828	Non-pressure chronic ulcer of other part of left lower leg with other specified severity		384 CHRONIC ULCER OF SKIN

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Code	Description	Notes	Recommended Placement
L97.905	Non-pressure chronic ulcer of unspecified part of unspecified lower leg with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.906	Non-pressure chronic ulcer of unspecified part of unspecified lower leg with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.908	Non-pressure chronic ulcer of unspecified part of unspecified lower leg with other specified severity		384 CHRONIC ULCER OF SKIN
L97.915	Non-pressure chronic ulcer of unspecified part of right lower leg with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.916	Non-pressure chronic ulcer of unspecified part of right lower leg with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.918	Non-pressure chronic ulcer of unspecified part of right lower leg with other specified severity		384 CHRONIC ULCER OF SKIN
L97.925	Non-pressure chronic ulcer of unspecified part of left lower leg with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.926	Non-pressure chronic ulcer of unspecified part of left lower leg with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L97.928	Non-pressure chronic ulcer of unspecified part of left lower leg with other specified severity		384 CHRONIC ULCER OF SKIN
L98.415	Non-pressure chronic ulcer of buttock with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L98.416	Non-pressure chronic ulcer of buttock with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN

Code	Description	Notes	Recommended Placement
L98.418	Non-pressure chronic ulcer of buttock with other specified severity		384 CHRONIC ULCER OF SKIN
L98.425	Non-pressure chronic ulcer of back with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L98.426	Non-pressure chronic ulcer of back with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L98.428	Non-pressure chronic ulcer of back with other specified severity		384 CHRONIC ULCER OF SKIN
L98.495	Non-pressure chronic ulcer of other sites with muscle involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L98.496	Non-pressure chronic ulcer of other sites with bone involvement without evidence of necrosis		384 CHRONIC ULCER OF SKIN
L98.498	Non-pressure chronic ulcer of other sites with other specified severity		384 CHRONIC ULCER OF SKIN
M33.03	Juvenile dermatomyositis without myopathy	M33.0 (Juvenile dermatopolymyositis) is on line 78	78 DERMATOMYOSITIS, POLYMYOSITIS
M33.13	Other dermatomyositis without myopathy		78 DERMATOMYOSITIS, POLYMYOSITIS
M33.93	Dermatopolymyositis, unspecified without myopathy		78 DERMATOMYOSITIS, POLYMYOSITIS
M48.061	Spinal stenosis, lumbar region without neurogenic claudication	M48.06 (Spinal stenosis, lumbar region) is on lines 351, 407 and 532	351 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS 407 CONDITIONS OF THE BACK AND SPINE 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
M48.062	Spinal stenosis, lumbar region with neurogenic claudication		351 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS 407 CONDITIONS OF THE BACK AND SPINE 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS

2018 ICD-10-CM Codes

Code	Description	Notes	Recommended Placement
N63.0	Unspecified lump in unspecified breast	N63 (Unspecified lump in breast) is DWF	Diagnostic Workup File (DWF)
N63.10	Unspecified lump in the right breast, unspecified quadrant		Diagnostic Workup File (DWF)
N63.11	Unspecified lump in the right breast, upper outer quadrant		Diagnostic Workup File (DWF)
N63.12	Unspecified lump in the right breast, upper inner quadrant		Diagnostic Workup File (DWF)
N63.13	Unspecified lump in the right breast, lower outer quadrant		Diagnostic Workup File (DWF)
N63.14	Unspecified lump in the right breast, lower inner quadrant		Diagnostic Workup File (DWF)
N63.20	Unspecified lump in the left breast, unspecified quadrant		Diagnostic Workup File (DWF)
N63.21	Unspecified lump in the left breast, upper outer quadrant		Diagnostic Workup File (DWF)
N63.22	Unspecified lump in the left breast, upper inner quadrant		Diagnostic Workup File (DWF)
N63.23	Unspecified lump in the left breast, lower outer quadrant		Diagnostic Workup File (DWF)
N63.24	Unspecified lump in the left breast, lower inner quadrant		Diagnostic Workup File (DWF)
N63.31	Unspecified lump in axillary tail of the right breast		Diagnostic Workup File (DWF)
N63.32	Unspecified lump in axillary tail of the left breast		Diagnostic Workup File (DWF)
N63.41	Unspecified lump in right breast, subareolar		Diagnostic Workup File (DWF)
N63.42	Unspecified lump in left breast, subareolar		Diagnostic Workup File (DWF)
O00.101	Right tubal pregnancy without intrauterine pregnancy	O00.1 (Tubal pregnancy) is on line 41	41 ECTOPIC PREGNANCY; HYDATIDIFORM MOLE; CHORIOCARCINOMA
O00.102	Left tubal pregnancy without intrauterine pregnancy		41 ECTOPIC PREGNANCY; HYDATIDIFORM MOLE; CHORIOCARCINOMA

Code	Description	Notes	Recommended Placement
O00.109	Unspecified tubal pregnancy without intrauterine pregnancy		41 ECTOPIC PREGNANCY; HYDATIDIFORM MOLE; CHORIOCARCINOMA
O00.111	Right tubal pregnancy with intrauterine pregnancy		41 ECTOPIC PREGNANCY; HYDATIDIFORM MOLE; CHORIOCARCINOMA
O00.112	Left tubal pregnancy with intrauterine pregnancy		41 ECTOPIC PREGNANCY; HYDATIDIFORM MOLE; CHORIOCARCINOMA
O00.119	Unspecified tubal pregnancy with intrauterine pregnancy		41 ECTOPIC PREGNANCY; HYDATIDIFORM MOLE; CHORIOCARCINOMA
O00.201	Right ovarian pregnancy without intrauterine pregnancy		41 ECTOPIC PREGNANCY; HYDATIDIFORM MOLE; CHORIOCARCINOMA
O00.202	Left ovarian pregnancy without intrauterine pregnancy		41 ECTOPIC PREGNANCY; HYDATIDIFORM MOLE; CHORIOCARCINOMA
O00.209	Unspecified ovarian pregnancy without intrauterine pregnancy		41 ECTOPIC PREGNANCY; HYDATIDIFORM MOLE; CHORIOCARCINOMA
O00.211	Right ovarian pregnancy with intrauterine pregnancy		41 ECTOPIC PREGNANCY; HYDATIDIFORM MOLE; CHORIOCARCINOMA
O00.212	Left ovarian pregnancy without intrauterine pregnancy		41 ECTOPIC PREGNANCY; HYDATIDIFORM MOLE; CHORIOCARCINOMA
O00.219	Unspecified ovarian pregnancy with intrauterine pregnancy		41 ECTOPIC PREGNANCY; HYDATIDIFORM MOLE; CHORIOCARCINOMA
O36.8310	Maternal care for abnormalities of the fetal heart rate or rhythm, first trimester, not applicable or unspecified		1 PREGNANCY
O36.8311	Maternal care for abnormalities of the fetal heart rate or rhythm, first trimester, fetus 1		1 PREGNANCY
O36.8312	Maternal care for abnormalities of the fetal heart rate or rhythm, first trimester, fetus 2		1 PREGNANCY
O36.8313	Maternal care for abnormalities of the fetal heart rate or rhythm, first trimester, fetus 3		1 PREGNANCY

Code	Description	Notes	Recommended Placement
O36.8314	Maternal care for abnormalities of the fetal heart rate or rhythm, first trimester, fetus 4		1 PREGNANCY
O36.8315	Maternal care for abnormalities of the fetal heart rate or rhythm, first trimester, fetus 5		1 PREGNANCY
O36.8319	Maternal care for abnormalities of the fetal heart rate or rhythm, first trimester, other fetus		1 PREGNANCY
O36.8320	Maternal care for abnormalities of the fetal heart rate or rhythm, second trimester, not applicable or unspecified		1 PREGNANCY
O36.8321	Maternal care for abnormalities of the fetal heart rate or rhythm, second trimester, fetus 1		1 PREGNANCY
O36.8322	Maternal care for abnormalities of the fetal heart rate or rhythm, second trimester, fetus 2		1 PREGNANCY
O36.8323	Maternal care for abnormalities of the fetal heart rate or rhythm, second trimester, fetus 3		1 PREGNANCY
O36.8324	Maternal care for abnormalities of the fetal heart rate or rhythm, second trimester, fetus 4		1 PREGNANCY
O36.8325	Maternal care for abnormalities of the fetal heart rate or rhythm, second trimester, fetus 5		1 PREGNANCY
O36.8329	Maternal care for abnormalities of the fetal heart rate or rhythm, second trimester, other fetus		1 PREGNANCY
O36.8330	Maternal care for abnormalities of the fetal heart rate or rhythm, third trimester, not applicable or unspecified		1 PREGNANCY

2018 ICD-10-CM Codes

Code	Description	Notes	Recommended Placement
O36.8331	Maternal care for abnormalities of the fetal heart rate or rhythm, third trimester, fetus 1		1 PREGNANCY
O36.8332	Maternal care for abnormalities of the fetal heart rate or rhythm, third trimester, fetus 2		1 PREGNANCY
O36.8333	Maternal care for abnormalities of the fetal heart rate or rhythm, third trimester, fetus 3		1 PREGNANCY
O36.8334	Maternal care for abnormalities of the fetal heart rate or rhythm, third trimester, fetus 4		1 PREGNANCY
O36.8335	Maternal care for abnormalities of the fetal heart rate or rhythm, third trimester, fetus 5		1 PREGNANCY
O36.8339	Maternal care for abnormalities of the fetal heart rate or rhythm, third trimester, other fetus		1 PREGNANCY
O36.8390	Maternal care for abnormalities of the fetal heart rate or rhythm, unspecified trimester, not applicable or unspecified		1 PREGNANCY
O36.8391	Maternal care for abnormalities of the fetal heart rate or rhythm, unspecified trimester, fetus 1		1 PREGNANCY
O36.8392	Maternal care for abnormalities of the fetal heart rate or rhythm, unspecified trimester, fetus 2		1 PREGNANCY
O36.8393	Maternal care for abnormalities of the fetal heart rate or rhythm, unspecified trimester, fetus 3		1 PREGNANCY
O36.8394	Maternal care for abnormalities of the fetal heart rate or rhythm, unspecified trimester, fetus 4		1 PREGNANCY

2018 ICD-10-CM Codes

Code	Description	Notes	Recommended Placement
O36.8395	Maternal care for abnormalities of the fetal heart rate or rhythm, unspecified trimester, fetus 5		1 PREGNANCY
O36.8399	Maternal care for abnormalities of the fetal heart rate or rhythm, unspecified trimester, other fetus		1 PREGNANCY
P29.30	Pulmonary hypertension of newborn	P29.3 (Persistent fetal circulation) is on line 81	81 PATENT DUCTUS ARTERIOSUS; AORTIC PULMONARY FISTULA/WINDOW
P29.38	Other persistent fetal circulation		81 PATENT DUCTUS ARTERIOSUS; AORTIC PULMONARY FISTULA/WINDOW
P78.84	Gestational alloimmune liver disease	A rare form of profound liver failure in newborns. A similar condition, P78.81 (Congenital cirrhosis (of liver)) is on lines 105 and 312	105 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION 312 CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR MALFORMATIONS; CAROLI'S DISEASE Tx: Liver transplant
P83.81	Umbilical granuloma	See issues document	648 EDEMA AND OTHER CONDITIONS INVOLVING THE SKIN OF THE FETUS AND NEWBORN
P83.88	Other specified conditions of integument specific to newborn	P83.8 (Other specified conditions of integument specific to newborn) is on line 648	648 EDEMA AND OTHER CONDITIONS INVOLVING THE SKIN OF THE FETUS AND NEWBORN
P91.811	Neonatal encephalopathy in diseases classified elsewhere	Parent code P91.8 (Other specified disturbances of cerebral status of newborn) was on line 27	27 INTRACRANIAL HEMORRHAGES; CEREBRAL CONVULSIONS, DEPRESSION, COMA, AND OTHER ABNORMAL CERERAL SIGNS OF THE NEWBORN
P91.819	Neonatal encephalopathy, unspecified		27 INTRACRANIAL HEMORRHAGES; CEREBRAL CONVULSIONS, DEPRESSION, COMA, AND OTHER ABNORMAL CERERAL SIGNS OF THE NEWBORN

2018 ICD-10-CM Codes

Code	Description	Notes	Recommended Placement
P91.88	Other specified disturbances of cerebral status of newborn		27 INTRACRANIAL HEMORRHAGES; CEREBRAL CONVULSIONS, DEPRESSION, COMA, AND OTHER ABNORMAL CERERAL SIGNS OF THE NEWBORN
Q53.111	Unilateral intraabdominal testis	Other intraabdominal and inguidnal testes codes are on line 98	98 UNDESCENDED TESTICLE
Q53.112	Unilateral inguinal testis		98 UNDESCENDED TESTICLE
Q53.13	Unilateral high scrotal testis	See issues document	98 UNDESCENDED TESTICLE
Q53.211	Bilateral intraabdominal testes		98 UNDESCENDED TESTICLE
Q53.212	Bilateral inguinal testes		98 UNDESCENDED TESTICLE
Q53.23	Bilateral high scrotal testes	See issues document	98 UNDESCENDED TESTICLE
R06.03	Acute respiratory distress	Similar codes are DWF	Diagnostic Workup File (DWF)
R39.83	Unilateral non-palpable testicle	inability to palpate one or both testes on clinical exam. The generally recommended work up includes ultrasound, MRI and/or laparoscopy. These infants are generally referred to a pediatric urologist for such a work up	Diagnostic Workup File (DWF)
R39.84	Bilateral non-palpable testicles	See above	Diagnostic Workup File (DWF)
T07.XXXA	Unspecified multiple injuries, initial encounter	Parent code T07 (Unspecified multiple injuries) is on line 638	638 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS
T07.XXXD	Unspecified multiple injuries, subsequent encounter		638 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS
T07.XXXS	Unspecified multiple injuries, sequela		638 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS
T14.8XXA	Other injury of unspecified body region, initial encounter	Parent code T14.8 (Other injury of unspecified body region) is on line 607	607 DISORDERS OF SOFT TISSUE
T14.8XXD	Other injury of unspecified body region, subsequent encounter		607 DISORDERS OF SOFT TISSUE
T14.8XXS	Other injury of unspecified body region, sequela		607 DISORDERS OF SOFT TISSUE

2018 ICD-10-CM Codes

Code	Description	Notes	Recommended Placement
T14.90XA	Injury, unspecified, initial encounter	Parent code T14.90 (Injury, unspecified) is on the undefined diagnosis file	Undefined Diagnosis File
T14.90XD	Injury, unspecified, subsequent encounter		Undefined Diagnosis File
T14.90XS	Injury, unspecified, sequela		Undefined Diagnosis File
T14.91XA	Suicide attempt, initial encounter	T14.91 (Suicide attempt) is currently on the Diagnostic Workup File	Diagnostic Workup File (DWF)
T14.91XD	Suicide attempt, subsequent encounter	BHAP review	Diagnostic Workup File (DWF)
T14.91XS	Suicide attempt, sequela	BHAP review	Informational Diagnosis File
V86.05XA	Driver of 3- or 4- wheeled all-terrain vehicle (ATV) injured in traffic accident, initial encounter	All similar cdoes are informational	Informational Diagnosis File
V86.05XD	Driver of 3- or 4- wheeled all-terrain vehicle (ATV) injured in traffic accident, subsequent encounter		Informational Diagnosis File
V86.05XS	Driver of 3- or 4- wheeled all-terrain vehicle (ATV) injured in traffic accident, sequela		Informational Diagnosis File
V86.06XA	Driver of dirt bike or motor/cross bike injured in traffic accident, initial encounter		Informational Diagnosis File
V86.06XD	Driver of dirt bike or motor/cross bike injured in traffic accident, subsequent encounter		Informational Diagnosis File
V86.06XS	Driver of dirt bike or motor/cross bike injured in traffic accident, sequela		Informational Diagnosis File
V86.15XA	Passenger of 3- or 4- wheeled all-terrain vehicle (ATV) injured in traffic accident, initial encounter		Informational Diagnosis File
V86.15XD	Passenger of 3- or 4- wheeled all-terrain vehicle (ATV) injured in traffic accident, subsequent encounter		Informational Diagnosis File

2018 ICD-10-CM Codes

Code	Description	Notes	Recommended Placement
V86.15XS	Passenger of 3- or 4- wheeled all-terrain vehicle (ATV) injured in traffic accident, sequela		Informational Diagnosis File
V86.16XA	Passenger of dirt bike or motor/cross bike injured in traffic accident, initial encounter		Informational Diagnosis File
V86.16XD	Passenger of dirt bike or motor/cross bike injured in traffic accident, subsequent encounter		Informational Diagnosis File
V86.16XS	Passenger of dirt bike or motor/cross bike injured in traffic accident, sequela		Informational Diagnosis File
V86.25XA	Person on outside of 3- or 4- wheeled all-terrain vehicle (ATV) injured in traffic accident, initial encounter		Informational Diagnosis File
V86.25XD	Person on outside of 3- or 4- wheeled all-terrain vehicle (ATV) injured in traffic accident, subsequent encounter		Informational Diagnosis File
V86.25XS	Person on outside of 3- or 4- wheeled all-terrain vehicle (ATV) injured in traffic accident, sequela		Informational Diagnosis File
V86.26XA	Person on outside of dirt bike or motor/cross bike injured in traffic accident, initial encounter		Informational Diagnosis File
V86.26XD	Person on outside of dirt bike or motor/cross bike injured in traffic accident, subsequent encounter		Informational Diagnosis File
V86.26XS	Person on outside of dirt bike or motor/cross bike injured in traffic accident, sequela		Informational Diagnosis File
V86.35XA	Unspecified occupant of 3- or 4- wheeled all-terrain vehicle (ATV) injured in traffic accident, initial encounter		Informational Diagnosis File

2018 ICD-10-CM Codes

Code	Description	Notes	Recommended Placement
V86.35XD	Unspecified occupant of 3- or 4- wheeled all-terrain vehicle (ATV) injured in traffic accident, subsequent encounter		Informational Diagnosis File
V86.35XS	Unspecified occupant of 3- or 4- wheeled all-terrain vehicle (ATV) injured in traffic accident, sequela		Informational Diagnosis File
V86.36XA	Unspecified occupant of dirt bike or motor/cross bike injured in traffic accident, initial encounter		Informational Diagnosis File
V86.36XD	Unspecified occupant of dirt bike or motor/cross bike injured in traffic accident, subsequent encounter		Informational Diagnosis File
V86.36XS	Unspecified occupant of dirt bike or motor/cross bike injured in traffic accident, sequela		Informational Diagnosis File
V86.45XA	Person injured while boarding or alighting from a 3- or 4- wheeled all-terrain vehicle (ATV), initial encounter		Informational Diagnosis File
V86.45XD	Person injured while boarding or alighting from a 3- or 4- wheeled all-terrain vehicle (ATV), subsequent encounter		Informational Diagnosis File
V86.45XS	Person injured while boarding or alighting from a 3- or 4- wheeled all-terrain vehicle (ATV), sequela		Informational Diagnosis File
V86.46XA	Person injured while boarding or alighting from a dirt bike or motor/cross bike, initial encounter		Informational Diagnosis File
V86.46XD	Person injured while boarding or alighting from a dirt bike or motor/cross bike, subsequent encounter		Informational Diagnosis File
V86.46XS	Person injured while boarding or alighting from a dirt bike or motor/cross bike, sequela		Informational Diagnosis File

Code	Description	Notes	Recommended Placement
V86.55XA	Driver of 3- or 4- wheeled all-terrain vehicle (ATV) injured in nontraffic accident, initial encounter		Informational Diagnosis File
V86.55XD	Driver of 3- or 4- wheeled all-terrain vehicle (ATV) injured in nontraffic accident, subsequent encounter		Informational Diagnosis File
V86.55XS	Driver of 3- or 4- wheeled all-terrain vehicle (ATV) injured in nontraffic accident, sequela		Informational Diagnosis File
V86.56XA	Driver of dirt bike or motor/cross bike injured in nontraffic accident, initial encounter		Informational Diagnosis File
V86.56XD	Driver of dirt bike or motor/cross bike injured in nontraffic accident, subsequent encounter		Informational Diagnosis File
V86.56XS	Driver of dirt bike or motor/cross bike injured in nontraffic accident, sequela		Informational Diagnosis File
V86.65XA	Passenger of 3- or 4- wheeled all-terrain vehicle (ATV) injured in nontraffic accident, initial encounter		Informational Diagnosis File
V86.65XD	Passenger of 3- or 4- wheeled all-terrain vehicle (ATV) injured in nontraffic accident, subsequent encounter		Informational Diagnosis File
V86.65XS	Passenger of 3- or 4- wheeled all-terrain vehicle (ATV) injured in nontraffic accident, sequela		Informational Diagnosis File
V86.66XA	Passenger of dirt bike or motor/cross bike injured in nontraffic accident, initial encounter		Informational Diagnosis File
V86.66XD	Passenger of dirt bike or motor/cross bike injured in nontraffic accident, subsequent encounter		Informational Diagnosis File

2018 ICD-10-CM Codes

Code	Description	Notes	Recommended Placement
V86.66XS	Passenger of dirt bike or motor/cross bike injured in nontraffic accident, sequela		Informational Diagnosis File
V86.75XA	Person on outside of 3- or 4- wheeled all-terrain vehicle (ATV) injured in nontraffic accident, initial encounter		Informational Diagnosis File
V86.75XD	Person on outside of 3- or 4- wheeled all-terrain vehicle (ATV) injured in nontraffic accident, subsequent encounter		Informational Diagnosis File
V86.75XS	Person on outside of 3- or 4- wheeled all-terrain vehicle (ATV) injured in nontraffic accident, sequela		Informational Diagnosis File
V86.76XA	Person on outside of dirt bike or motor/cross bike injured in nontraffic accident, initial encounter		Informational Diagnosis File
V86.76XD	Person on outside of dirt bike or motor/cross bike injured in nontraffic accident, subsequent encounter		Informational Diagnosis File
V86.76XS	Person on outside of dirt bike or motor/cross bike injured in nontraffic accident, sequela		Informational Diagnosis File
V86.95XA	Unspecified occupant of 3- or 4- wheeled all-terrain vehicle (ATV) injured in nontraffic accident, initial encounter		Informational Diagnosis File
V86.95XD	Unspecified occupant of 3- or 4- wheeled all-terrain vehicle (ATV) injured in nontraffic accident, subsequent encounter		Informational Diagnosis File
V86.95XS	Unspecified occupant of 3- or 4- wheeled all-terrain vehicle (ATV) injured in nontraffic accident, sequela		Informational Diagnosis File
V86.96XA	Unspecified occupant of dirt bike or motor/cross bike injured in nontraffic accident, initial encounter		Informational Diagnosis File

2018 ICD-10-CM Codes

Code	Description	Notes	Recommended Placement
V86.96XD	Unspecified occupant of dirt bike or motor/cross bike injured in nontraffic accident, subsequent encounter		Informational Diagnosis File
V86.96XS	Unspecified occupant of dirt bike or motor/cross bike injured in nontraffic accident, sequela		Informational Diagnosis File
Z36.0	Encounter for antenatal screening for chromosomal anomalies	Parent code Z36 (Encounter for antenatal screening of mother) is on line 1	1 PREGNANCY
Z36.1	Encounter for antenatal screening for raised alphafetoprotein level		1 PREGNANCY
Z36.2	Encounter for other antenatal screening follow-up		1 PREGNANCY
Z36.3	Encounter for antenatal screening for malformations		1 PREGNANCY
Z36.4	Encounter for antenatal screening for fetal growth retardation		1 PREGNANCY
Z36.5	Encounter for antenatal screening for isoimmunization		1 PREGNANCY
Z36.81	Encounter for antenatal screening for hydrops fetalis		1 PREGNANCY
Z36.82	Encounter for antenatal screening for nuchal translucency		1 PREGNANCY
Z36.83	Encounter for fetal screening for congenital cardiac abnormalities		1 PREGNANCY
Z36.84	Encounter for antenatal screening for fetal lung maturity		1 PREGNANCY
Z36.85	Encounter for antenatal screening for Streptococcus B		1 PREGNANCY
Z36.86	Encounter for antenatal screening for cervical length		1 PREGNANCY
Z36.87	Encounter for antenatal screening for uncertain dates		1 PREGNANCY

2018 ICD-10-CM Codes

Code	Description	Notes	Recommended Placement
Z36.88	Encounter for antenatal screening for fetal macrosomia		1 PREGNANCY
Z36.89	Encounter for other specified antenatal screening		1 PREGNANCY
Z36.8A	Encounter for antenatal screening for other genetic defects		1 PREGNANCY
Z36.9	Encounter for antenatal screening, unspecified		1 PREGNANCY
Z40.03	Encounter for prophylactic removal of fallopian tube(s)	See issues document	195 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
Z71.82	Exercise counseling	See issues document	325 OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95TH PERCENTILE) AND OVERWEIGHT IN ADULTS (BMI >25) WITH CARDIOVASCULAR RISK FACTORS 589 OBESITY (ADULT BMI ≥ 30, CHILDHOOD BMI ≥ 95TH PERCENTILE) AND OVERWEIGHT IN ADULTS (BMI >25) WITH CARDIOVASCULAR RISK FACTORS 625 PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS
Z71.83	Encounter for nonprocreative genetic counseling		Diagnostic Workup File (DWF)
Z91.841	Risk for dental caries, low	CDT D0601-D0603 (caries risk assessment and documentation) is on line 57	57 PREVENTIVE DENTAL SERVICES
Z91.842	Risk for dental caries, moderate	Bruce Austin DMD, agrees with placement	57 PREVENTIVE DENTAL SERVICES
Z91.843	Risk for dental caries, high		57 PREVENTIVE DENTAL SERVICES
Z91.849	Unspecified risk for dental caries		57 PREVENTIVE DENTAL SERVICES

Section 8.0

New Discussion Items

Nasal Endoscopy for Acute Recurrent Sinusitis

Questions:

1) Should nasal endoscopy sinus surgery or any other sinus surgery be paired with treatment of acute recurrent rhinosinusitis?
2) Should open sinus surgery continue to be paired with acute sinusitis?
3) Should the current sinus guideline be clarified regarding what is meant by "several courses" of antibiotics and "a trial" of nasal steroids?
4) Should the sinus surgery guideline be further updated for clarity?

Question sources:

1) HSD
2) HERC staff
3) Tracy Muday, MD, medical director
4) OHA hearings division

Issue: HSD has requested pairing of sinus endoscopy procedures with acute recurrent sinusitis diagnoses. The AAO-HNS (2015) defines recurrent acute sinusitis (RARS) as four or more episodes per year of acute bacterial rhinosinusitis without signs or symptoms of rhinosinusitis between episodes; each episode must meet criteria for diagnosis of acute sinusitis. In contrast, chronic rhinosinusitis (CRS) is defined as twelve weeks or longer of 2 or more signs and symptoms with documented inflammation based on imaging or direct visualization. Endoscopic sinus surgery involves using an instrument to remove tissue from the sinuses with the goal of better drainage and aeration.

ICD-9 did not have codes for recurrent acute rhinosinusitis (RARS); codes only existed for acute rhinosinusitis and chronic rhinosinusitis. The prioritization of RARS was reviewed in 2012 as part of the ICD-10 ENT review, with the ENT reviewers not suggesting any change to the GEM mapping placement of RARS on the acute sinusitis line.

Procedures for pairing with acute sinusitis was last reviewed in April 2012, as part of the ICD-10 ENT review. At the 2012 review, the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) 2007 guideline found no recommendation for sinus endoscopy for acute sinusitis, and found that sinus endoscopy was given a Grade D (expert opinion) option for treatment/evaluation of recurrent acute rhinosinusitis. Based on this guideline, endoscopy sinus procedures were removed from the acute sinusitis line (now line 369). One CPT code (31256 Nasal/sinus endoscopy, surgical, with maxillary antrostomy) was mistakenly not removed from this line. In the 2015 update of the AAO-HNS sinusitis guideline, endoscopy continues to be not mentioned as a treatment for acute sinusitis. There remain a series of direct (not endoscopic) sinus surgeries on the acute sinusitis line. It is unclear from the ICD-10 ENT review whether the direct sinus surgeries were also intended for removal from this line; these procedures are rarely done now that endoscopic surgery has become mainstream due to the less invasive nature of endoscopic surgery.

From the April 2012 VBBS minutes:

> The group agreed that there was no evidence for adding nasal endoscopy to the acute sinusitis line and agreed with the suggestion that the 4 CPT codes for these types of procedures which currently appear on this line be removed. There was then discussion about whether nasal endoscopy should be covered for chronic sinusitis. Dr. Paul Flint, the ENT expert who came to discuss the ENT ICD-10 changes, was asked about this question. His response was that endoscopic surgery was effective for the treatment of chronic sinusitis. He reported that studies comparing

> medical management of chronic sinusitis with surgical therapy found that surgical patients had better outcomes. He agreed with the suggestion to not add these endoscopy codes to the acute sinusitis line.

The Prioritized List contains a guideline which defines the criteria that a patient must meet to have covered sinus surgery. One criteria is "4 or more episodes of acute rhinosinusitis in one year," which would qualify as recurrent acute sinusitis under the AAO-HNS definition. This guideline was written in 2004 due to concerns for overuse of sinus surgery. This guideline was reviewed as part of the ICD-10 ENT review; there are no notes for any suggested changes to the guideline as part of that review.

Chronic sinusitis was reviewed with the ENT ICD-10 review, and the effectiveness of surgery was scored at 50%.

Dr. Tracy Muday, an OHP medical director, has asked for clarification of requirements in the current sinus surgery guideline.

> We have struggled with the definition of "several courses of antibiotics" and "trial on inhaled and/or oral steroids." We define "several" as 3. My other ENT says this is not fair and that I'm changing the guidelines without telling them. They think one fill of inhaled or oral steroids is adequate. I have asked for at least two fills, and that the fluticasone be at least 2 sprays daily for adults. Again, "going beyond the guidelines."

The OHA hearings representative requested clarification of the sinus surgery guideline at the request of a hearings judge. The way the current Guideline Note 35 reads, there is a potential for misinterpretation of the qualifying requirements for surgery. A CCO was interpreting that a patient must meet A or B and C, D, E, F, G. The intent needs to be clarified.

Nasal Endoscopy for Acute Recurrent Sinusitis

Current Prioritized List status:
Diagnostic nasal/sinus endoscopy (CPT 31231-31235): diagnostic procedures list
Line 369 ACUTE SINUSITIS: contains ICD-10 codes for acute sinusitis (ICD-10 J01.x0) and for recurrent acute sinusitis (ICD-10 J01.x1). Contains various procedures codes for open sinus surgery
Line 469 CHRONIC SINUSITIS: contains ICD-10 codes for chronic sinusitis (ICD-10 J32). Contains various procedure codes for sinus surgery (endoscopic and open)

The following guideline applies to the acute and chronic sinusitis lines:
GUIDELINE NOTE 35, SINUS SURGERY
Lines 369,469
Sinus surgery (other than adenoidectomy) is indicated in the following circumstances:

A) 4 or more episodes of acute rhinosinusitis in one year

OR

B) Failure of medical therapy of chronic sinusitis including all of the following:
- Several courses of antibiotics AND
- Trial of inhaled and/or oral steroids AND
- Allergy assessment and treatment when indicated
  AND
- One or more of the following:
- Findings of obstruction of active infection on CT scan
- Symptomatic mucocele
- Negative CT scan but significant disease found on nasal endoscopy

OR

C) Nasal polyposis causing or contributing to sinusitis

OR

D) Complications of sinusitis including subperiosteal or orbital abscess, Pott's puffy tumor, brain abscess or meningitis

OR

E) Invasive or allergic fungal sinusitis

OR

F) Tumor of nasal cavity or sinuses

OR

G) CSF rhinorrhea

Adenoidectomy (CPT 42830, 42835) is included on Line 469 only for treatment of children with chronic sinusitis who fail appropriate medical therapy.

Nasal Endoscopy for Acute Recurrent Sinusitis

Evidence:

Orlandi 2016: International Consensus Statement on Allergy and Rhinology: Rhinosinusitis (study not included due to length. Available online

1) No mention of endoscopy for treatment or evaluation of acute sinusitis
2) Recurrent acute sinusitis:
    a. N=3 cohort studies (N=19, 14, 21 patients) for patient outcomes after endoscopy sinus surgery (ESS)
        i. Significant improvement in rhinosinusitis symptom inventory, antihistamine use, number of workdays missed, and number of acute infectious episodes. No significant change in antibiotic utilization
        ii. Harms may occur; significant costs associated with surgery
        iii. Aggregate Grade of Evidence: C (Level 3b: 3 studies)
        iv. Value Judgments: Properly selected patients with RARS may benefit both symptomatically and medically from ESS. This option should be assessed and utilized cautiously, however, because data remains limited.
        v. Policy Level: Option.

Costa 2015, retrospective cohort study of medical vs surgical therapy for RARS

1) A total of 220 RARS patients treated between 2006 and 2014 were retrospectively divided into 3 cohorts: medical only (MED); surgical only (SURG); or medical crossing over into surgical (CROSS).
    a. Surgical intervention: standard maxillary antrostomy and partial ethmoidectomy was performed for patients with negative computed tomography (CT) scans, and for patients with more extensive disease, additional sinuses were opened according to the distribution of disease.
    b. Medical therapy: oral antibiotics as well as nasal and/or oral corticosteroids for management of acute episodes of rhinosinusitis; they also received saline irrigations and allergy treatment when appropriate.
    c. Patients opting for medical therapy were given the option to elect endoscopic surgical treatment at any point during their care.
1) The SURG cohort showed greater reduction of SNOT-22 scores compared to the MED cohort at 3, 6, and 12 months follow-up ($p < 0.0001$).
2) In the CROSS vs SURG comparison, the CROSS cohort showed a comparable magnitude of reduction of SNOT-22 scores after surgery compared to the SURG cohort (p range from 0.1 to 0.5).
3) ***Conclusion:*** RARS patients can benefit from both medical and surgical treatment strategies, but surgical treatment results in greater symptomatic improvement compared to medical treatment.

Expert guidelines:

American Academy of Otolaryngology--Head and Neck Surgery (2015) practice guideline:

-Diagnosis of CHRONIC RHINOSINUSITIS (CRS) OR recurrent ACUTE RHINOSINUSITIS (ARS): Clinicians should distinguish CRS and recurrent ARS from isolated episodes of acute bacterial rhinosinusitis (ABRS) and other causes of sinonasal symptoms. *Recommendation based on cohort and observational studies with a preponderance of benefit over harm.*

-OBJECTIVE CONFIRMATION OF A DIAGNOSIS OF CHRONIC RHINOSINUSITIS (CRS): The clinician should confirm a clinical diagnosis of CRS with objective documentation of sinonasal inflammation, which may

be accomplished using anterior rhinoscopy, nasal endoscopy, or computed tomography. *Strong recommendation based on crosssectional studies with a preponderance of benefit over harm.*

Expert input:

Dr. Tim Smith, OHSU ENT

If the clinician is able to make the diagnosis of recurrent acute rhinosinusitis (it is a challenging diagnosis to make), and if the patient is managing inflammation of the nose with topical steroid therapy and saline irrigation therapy, and if they are still experiencing repeated bouts of acute bacterial rhinosinusitis, the literature is very clear that a limited form of endoscopic sinus surgery that would likely entail bilateral maxillary antrostomy and bilateral anterior ethmoidectomy, would be highly effective in reducing the number of infections, in improving quality of life, and in reducing exposure to repeated antibiotics and oral steroids (which have significant cost related to the long time Horizon of this disease--cataract formation, osteoporosis, resistant organisms, etc.). I have found that there is almost nothing more confusing to patients and clinicians when they are able to reach a diagnosis but their health insurance will not cover the treatment of that diagnosis.

Dr. Smith in later communications noted that acute sinusitis may require either endoscopic or open procedures when it is a complicated acute sinusitis. Since there are no codes for complicated acute sinusitis, it may be difficult to distinguish from acute, uncomplicated sinusitis.

After reviewing the staff evidence review, Dr. Smith noted that there are several other studies showing effectiveness of ESS for RARS from a couple of different institutions including ours. There are no RCTs available.

HERC staff summary:

Sinus/nasal endoscopy is not recommended by expert groups for evaluation or treatment of acute sinusitis. Sinus/nasal endoscopy is an option for treatment of recurrent acute rhinosinusitis based on expert opinion and case series/cohort studies when a patient has failed medical therapy. The evidence base for the effectiveness of surgery for RARS is limited.

It is confusing attempting to discern the history and intent of coverage for RARS based on minutes and review notes. It appears that the ENT reviewers intended to not cover surgery for acute sinusitis; it appears that the reviewers approved the prioritization of RARS with acute sinusitis; it appears that the ENT reviewers felt surgery was appropriate for 4 or more episodes of acute sinusitis (i.e. RARS) due to lack of change in the sinus surgery guideline. These three statements are mutually incompatible: either the guideline needs to be modified to remove the clause regarding 4 or more episodes of acute sinusitis as an indication or RARS needs to be paired with sinus surgery procedure codes. Our current expert, Dr. Tim Smith, is of the opinion that RARS should be paired with sinus surgery procedure codes.

Nasal Endoscopy for Acute Recurrent Sinusitis

HERC staff recommendations:

I. Biennial Review:

1) Review prioritization and treatments for acute sinusitis, RARS and chronic sinusitis as part of the 2020 Biennial Review

II. General Recommendations:

Surgery for acute sinusitis:

1) Remove remaining sinus endoscopy CPT codes from the acute sinusitis line per ICD-10 ENT review intent
    a. Remove CPT 31256 (Nasal/sinus endoscopy, surgical, with maxillary antrostomy) from line 369 ACUTE SINUSITIS
2) Remove direct sinus surgery CPT codes from the acute sinusitis line as it appears the intent of the ICD-10 ENT reviewers was to remove sinus surgery from that line and current expert guidelines do not mention surgery of any type as a treatment option for acute sinusitis
    a. Remove the following CPT codes from line 369 ACUTE SINUSITIS
        i. 31020 Sinusotomy, maxillary (antrotomy); intranasal
        ii. 31030 Sinusotomy, maxillary (antrotomy); radical (Caldwell-Luc) without removal of antrochoanal polyps
        iii. 31032 Sinusotomy, maxillary (antrotomy); radical (Caldwell-Luc) with removal of antrochoanal polyps
        iv. 31040 Pterygomaxillary fossa surgery, any approach
        v. 31050 Sinusotomy, sphenoid, with or without biopsy;
        vi. 31051 Sinusotomy, sphenoid, with or without biopsy; with mucosal stripping or removal of polyp(s)
        vii. 31070-31087 Sinusotomy frontal
        viii. 61782 Stereotactic computer-assisted (navigational) procedure; cranial, extradural (List separately in addition to code for primary procedure)
3) Change the treatment description for line 369 to MEDICAL ~~AND SURGICAL~~ TREATMENT
4) Remove line 369 from GN35

Clarification of requirements in guideline note 35—these changes are included in both options below

1) Clarify “several courses” of antibiotics as “at least 3 courses”
2) Clarify “a trial” of nasal and/or oral steroids as “at least 2 prescriptions for”
3) Further edits done to improve clarity of intent

III. Options for acute recurrent sinusitis

Option 1

1) Allow pairing of surgery for RARS. This is based on expert opinion and a very limited evidence base. It conforms with the intent of the HSC/HERC from 2004, although it is unclear if this was actually the intent of the ICD-10 ENT reviewers. It also appears to conform with clinical practice, as RARS is very difficult to differentiate from chronic sinusitis
    a. Remove recurrent acute rhinosinusitis diagnosis codes from line 369 ACUTE SINUSITIS and add to line 469 CHRONIC SINUSITIS
        i. J01.01 Acute recurrent maxillary sinusitis
        ii. J01.11 Acute recurrent frontal sinusitis
        iii. J01.21 Acute recurrent ethmoidal sinusitis
        iv. J01.31 Acute recurrent sphenoidal sinusitis

v. J01.41 Acute recurrent pansinusitis
vi. J01.81 Other acute recurrent sinusitis
vii. J01.91 Acute recurrent sinusitis, unspecified

2) Change line title of line 469 to ACUTE RECURRENT SINUSITIS; CHRONIC SINUSITIS
3) Modify GN35 as shown below
   a. Further defines when RARS qualifies for surgery

GUIDELINE NOTE 35, SINUS SURGERY

Lines ~~369,~~469

Sinus surgery (other than adenoidectomy) is indicated ~~in the following circumstances~~ when at least one of the following circumstances occur (A-G):

A) 4 or more episodes of acute bacterial rhinosinusitis in one year without signs or symptoms of rhinosinusitis between episodes and have failed optimal medical management defined at nasal steroid therapy, nasal saline therapy, and, if indicated, allergy treatment and are compliant with oral antibiotics and/or oral corticosteroids for management of acute episodes of rhinosinusitis

OR

B) Failure of medical therapy of chronic sinusitis including all of the following (1-3):

1) Several courses of antibiotics (3 or more) AND
2) Trial of inhaled and/or oral steroids (2 or more prescriptions for adequate doses of one or both) AND
3) Allergy assessment and treatment when indicated

AND

One or more of the following (a-c):

a) Findings of obstruction of active infection on CT scan OR
b) Symptomatic mucocele OR
c) Negative CT scan but significant disease found on nasal endoscopy

OR

C) Nasal polyposis causing or contributing to sinusitis

OR

D) Complications of sinusitis including subperiosteal or orbital abscess, Pott's puffy tumor, brain abscess or meningitis

OR

E) Invasive or allergic fungal sinusitis

OR

F) Tumor of nasal cavity or sinuses

OR

G) CSF rhinorrhea

Adenoidectomy (CPT 42830, 42835) is included on Line 469 only for treatment of children with chronic sinusitis who fail appropriate medical therapy.

Option 2:

1) Do not allow pairing of surgery with RARS. This conforms with the intent of the ICD-10 ENT reviewers to prioritize RARS with acute sinusitis but not with their intent regarding the guideline; there is limited evidence of effectiveness of surgery for RARS
   a. Keep ICD-10 J01._1 on line 369 ACUTE SINUSITIS

2) Modify GN 35 as shown below

GUIDELINE NOTE 35, SINUS SURGERY

Lines ~~369,~~469

Sinus surgery (other than adenoidectomy) is indicated ~~in the following circumstances~~ when at least one of the following circumstances occur (A-F):

~~A) 4 or more episodes of acute rhinosinusitis in one year~~

~~OR~~

~~B)~~ Failure of medical therapy of chronic sinusitis including all of the following(1-3):

1) Several courses of antibiotics (3 or more) AND

2) Trial of inhaled and/or oral steroids (2 or more prescriptions for adequate doses of one or both) AND

3) Allergy assessment and treatment when indicated

AND

One or more of the following (a-c):

a) Findings of obstruction of active infection on CT scan OR

b) Symptomatic mucocele OR

c) Negative CT scan but significant disease found on nasal endoscopy

A) OR

B) Nasal polyposis causing or contributing to sinusitis

OR

C) Complications of sinusitis including subperiosteal or orbital abscess, Pott's puffy tumor, brain abscess or meningitis

OR

D) Invasive or allergic fungal sinusitis

OR

E) Tumor of nasal cavity or sinuses

OR

F) CSF rhinorrhea

Adenoidectomy (CPT 42830, 42835) is included on Line 469 only for treatment of children with chronic sinusitis who fail appropriate medical therapy.

Medical therapy vs surgery for recurrent acute rhinosinusitis

Milena L. Costa, MD[1,2], Alkis J. Psaltis, MBBS (Hons), FRACS, PhD[3], Jayakar V. Nayak, MD, PhD[1] and Peter H. Hwang, MD[1]

Background: **Treatment indications for recurrent acute rhinosinusitis (RARS) remain poorly defined. We studied outcomes of medical vs surgical treatment of RARS, anatomic variants associated with RARS, and factors predicting crossover from medical to surgical treatment.**

Methods: **A total of 220 RARS patients treated between 2006 and 2014 were retrospectively divided into 3 cohorts: medical only (MED); surgical only (SURG); or medical crossing over into surgical (CROSS). Twenty-two item Sino-Nasal Outcome Test (SNOT-22) scores, modified Lund-Kennedy endoscopy scores, and prevalence of anatomic variants by computed tomography (CT) were compared. A total of 220 CT scans obtained for non-sinus indications served as controls. A logistic regression model was used for analysis.**

Results: **The mean baseline SNOT-22 scores for all cohorts were similar (MED = 48, SURG = 49, CROSS = 45, $p < 0.0001$). The SURG cohort showed greater reduction of SNOT-22 scores compared to the MED cohort at 3, 6, and 12 months follow-up ($p < 0.0001$). The crossover cohort converted to surgery after escalation of SNOT-22 score by a mean of 15 points ($p < 0.03$), and showed significant reduction postoperatively ($p < 0.0001$). Haller cell (odds ratio [OR] 3.9; $p < 0.0001$), concha bullosa (OR 3.7; $p < 0.003$), and accessory ostium (OR 2.2; $p < 0.01$) were more common in the entire RARS group vs controls; however, there were no inter-cohort differences in prevalence.**

Conclusion: **RARS patients can benefit from both medical and surgical treatment strategies, but surgical treatment results in greater symptomatic improvement compared to medical treatment. Patients cross over from medical to surgical treatment when SNOT-22 scores escalate by a mean of 15 points. Haller cell, concha bullosa, and accessory ostium are associated with RARS but are equally common in medical, surgical, and crossover cohorts.** © 2015 ARS-AAOA, LLC.

Key Words:
recurrent acute rhinosinusitis; chronic rhinosinusitis; medical therapy; endoscopic sinus surgery; SNOT-22

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Recurrent acute rhinosinusitis (RARS) is estimated to affect 1 in every 3000 western adults.[1] RARS is characterized by self limited, distinct episodes of rhinosinusitis, lasting less than 4 weeks in duration, separated by asymptomatic periods. Although no consensus exists as to the precise number of episodes required for a diagnosis of RARS, recent guidelines suggest 4 or more attacks per year to be clinically significant.[2] Despite its prevalence, RARS remains poorly studied. Only recently has its diagnosis been incorporated into clinical guidelines concerning the management of adult sinusitis[2] and to date there is a paucity of data relating to the optimal management of RARS. Recent systematic reviews of medical therapy for RARS have shown no evidence for the use of oral antibiotics and limited evidence for intranasal corticosteroids.[3,4] Studies of surgical treatment have showed significant improvement in the quality of life of patients undergoing surgery for RARS.[5,6] However, no studies so far have compared the outcomes between medical and surgical treatment strategies.

This study reports our institution's experience with RARS. We discuss our outcomes of medical vs surgical treatment and identify radiographic anatomic variants potentially associated with RARS. In addition we highlight factors that may predict which patients will cross over from medical to surgical therapy.

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Clinical Practice Guideline (Update): Adult Sinusitis Executive Summary

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract

The American Academy of Otolaryngology—Head and Neck Surgery Foundation has published a supplement to this issue featuring the updated "Clinical Practice Guideline: Adult Sinusitis" as a supplement to *Otolaryngology–Head and Neck Surgery*. To assist in implementing the guideline recommendations, this article summarizes the rationale, purpose, and key action statements. The 14 developed recommendations address diagnostic accuracy for adult rhinosinusitis, the appropriate use of ancillary tests to confirm diagnosis and guide management (including radiography, nasal endoscopy, computed tomography, and testing for allergy and immune function), and the judicious use of systemic and topical therapy. Emphasis was also placed on identifying multiple chronic conditions that would modify management of rhinosinusitis, including asthma, cystic fibrosis, immunocompromised state, and ciliary dyskinesia. An updated guideline is needed as a result of new clinical trials, new systematic reviews, and the lack of consumer participation in the initial guideline development group.

Keywords

sinusitis, rhinosinusitis

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Differences from Prior Guideline

This clinical practice guideline is as an update, and replacement, for an earlier guideline published in 2007 by the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF).[1] An update was planned for 5 years after the initial publication date and was further necessitated by new primary studies and systematic reviews that might suggest a need for modifying clinically important recommendations.[2] Changes in content and methodology from the prior guideline include the following:

- Addition of a consumer advocate to the guideline development group
- New evidence from 5 clinical practice guidelines, 42 systematic reviews, and 70 randomized controlled trials (RCTs)
- Emphasis on patient education and counseling with new explanatory tables
- Expanded action statement profiles to explicitly state quality improvement opportunities, confidence in the evidence, intentional vagueness, and differences of opinion
- Enhanced external review process to include public comment and journal peer review
- New algorithm to clarify decision making and action statement relationships
- Extension of watchful waiting (without antibiotic therapy) as an initial management strategy to all patients with uncomplicated acute bacterial rhinosinusitis (ABRS) regardless of severity, not just patients with "mild" illness (prior guideline)
- Change in recommendation from first-line antibiotic therapy for ABRS amoxicillin, with or without clavulanate, from amoxicillin alone (prior guideline)
- Addition of asthma as a chronic condition that modifies management of chronic rhinosinusitis (CRS)
- Three new key action statements on managing CRS that focus on polyps as a modifying factor, a recommendation in favor of topical intranasal therapy (saline irrigations, corticosteroids), and a recommendation against using topical or systemic antifungal agents

Table 1. Acute Rhinosinusitis Definitions.

Term	Definition
Acute rhinosinusitis	Up to 4 wk of *purulent nasal drainage* (anterior, posterior, or both) accompanied by *nasal obstruction, facial pain/pressure/fullness*,[a] or both: • *Purulent nasal discharge* is cloudy or colored, in contrast to the clear secretions that typically accompany viral upper respiratory infection, and it may be reported by the patient or observed on physical examination. • *Nasal obstruction* may be reported by the patient as nasal obstruction, congestion, blockage, or stuffiness, or it may be diagnosed by physical examination. • *Facial pain/pressure/fullness* may involve the anterior face or periorbital region, or it may manifest with headache that is localized or diffuse.
Viral rhinosinusitis	Acute rhinosinusitis that is caused by, or is presumed to be caused by, viral infection. A clinician should diagnose viral rhinosinusitis when • symptoms or signs of acute rhinosinusitis are present <10 d and the symptoms are not worsening.
Acute bacterial rhinosinusitis	Acute rhinosinusitis that is caused by, or is presumed to be caused by, bacterial infection. A clinician should diagnose acute bacterial rhinosinusitis when a. symptoms or signs of acute rhinosinusitis fail to improve within 10 d or more beyond the onset of upper respiratory symptoms *or* b. symptoms or signs of acute rhinosinusitis worsen within 10 d after an initial improvement (double worsening).

[a]Facial pain/pressure/fullness in the absence of purulent nasal discharge is insufficient to establish a diagnosis of acute rhinosinusitis.

Introduction

Sinusitis affects about 1 in 8 adults in the United States, resulting in more than 30 million annual diagnoses.[3,4] The direct cost of managing acute and chronic sinusitis exceeds $11 billion per year,[4,5] with additional expense from lost productivity, reduced job effectiveness, and impaired quality of life.[6-8] More than 1 in 5 antibiotics prescribed in adults are for sinusitis, making it the fifth-most common diagnosis responsible for antibiotic therapy.[5] Despite the high prevalence and economic impact of sinusitis, considerable practice variations exist across and within the multiple disciplines involved in managing the condition.[9,10]

The target patient for this guideline is aged 18 years or older with a clinical diagnosis of uncomplicated rhinosinusitis:

> *Rhinosinusitis* is defined as symptomatic inflammation of the paranasal sinuses and nasal cavity. The term *rhinosinusitis* is preferred because sinusitis is almost always accompanied by inflammation of the contiguous nasal mucosa.[11-13] Therefore, *rhinosinusitis* is used in the remainder of the guideline.
>
> *Uncomplicated rhinosinusitis* is defined as rhinosinusitis without clinically evident extension of inflammation outside the paranasal sinuses and nasal cavity at the time of diagnosis (eg, no neurologic, ophthalmologic, or soft tissue involvement).

Rhinosinusitis may be classified by duration as *acute* rhinosinusitis (ARS) if less than 4 weeks' duration or as *chronic* rhinosinusitis (CRS) if lasting more than 12 weeks, with or without acute exacerbations. ARS may be classified further by presumed etiology, based on symptoms and time course (Key Action Statement 1), into acute *bacterial* rhinosinusitis (ABRS) or *viral* rhinosinusitis (VRS) (**Table 1**). Distinguishing presumed bacterial versus viral infection is important because antibiotic therapy is inappropriate for the latter. When patients have 4 or more annual episodes of rhinosinusitis, *without* persistent symptoms in between, the condition is termed *recurrent* ARS.

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Table 2. Summary of Evidence-Based Statements.

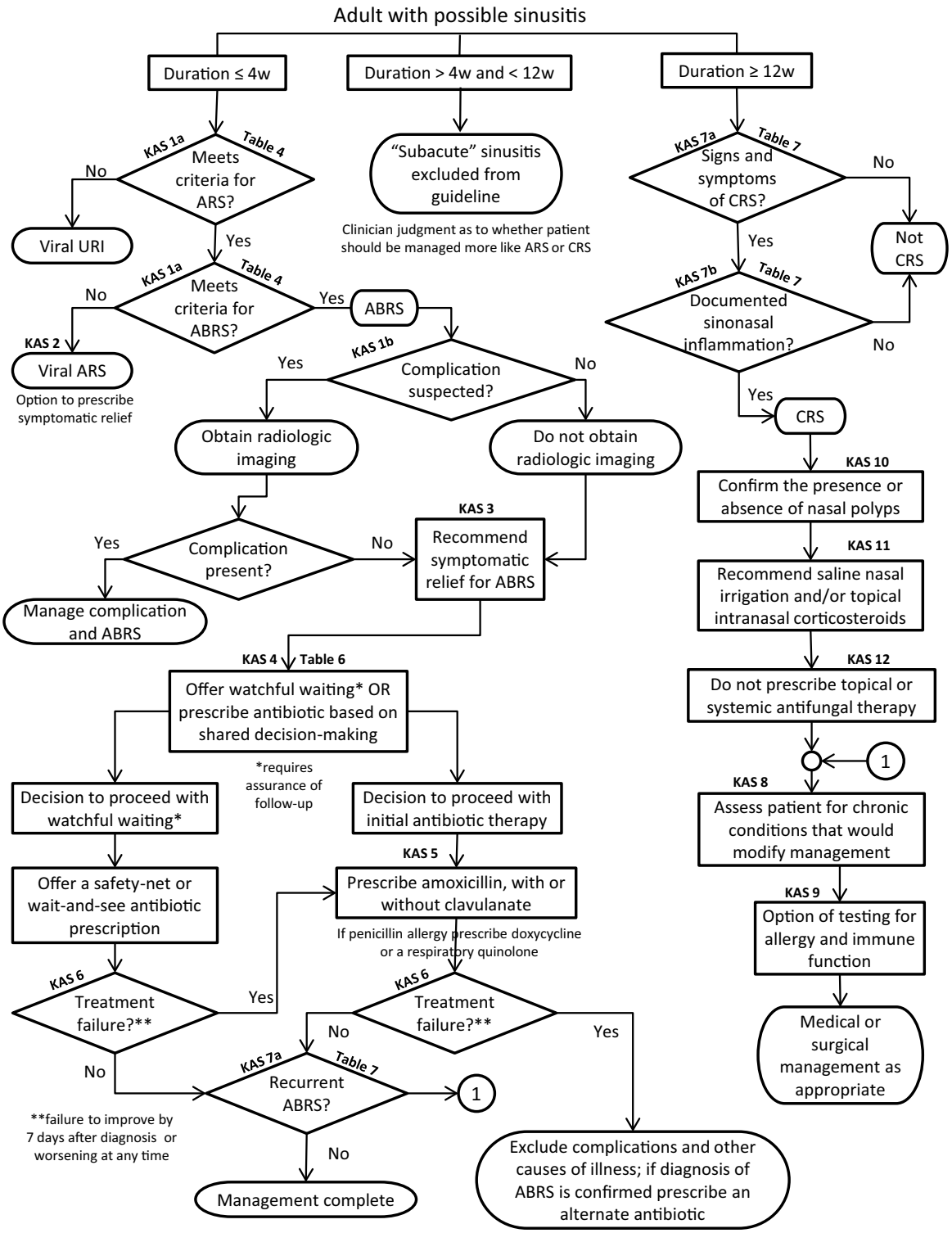
Statement	Action	Strength
1a. Differential diagnosis	Clinicians should distinguish presumed ABRS from ARS caused by viral upper respiratory infections and noninfectious conditions. A clinician should diagnose ABRS when (a) symptoms or signs of ARS (purulent nasal drainage accompanied by nasal obstruction, facial pain/pressure/fullness, or both) persist without evidence of improvement for at least 10 days beyond the onset of upper respiratory symptoms or (b) symptoms or signs of ARS worsen within 10 days after an initial improvement (double worsening).	Strong recommendation
1b. Radiographic imaging and ARS	Clinicians should not obtain radiographic imaging for patients who meet diagnostic criteria for ARS, unless a complication or alternative diagnosis is suspected.	Recommendation (against imaging)
2. Symptomatic relief of VRS	Clinicians may recommend analgesics, topical intranasal steroids, and/or nasal saline irrigation for symptomatic relief of VRS.	Option
3. Symptomatic relief of ABRS	Clinicians may recommend analgesics, topical intranasal steroids, and/or nasal saline irrigation for symptomatic relief of ABRS	Option
4. Initial management of ABRS	Clinicians should either offer watchful waiting (without antibiotics) or prescribe initial antibiotic therapy for adults with uncomplicated ABRS. Watchful waiting should be offered only when there is assurance of follow-up such that antibiotic therapy is started if the patient's condition fails to improve by 7 d after ABRS diagnosis or if it worsens at any time.	Recommendation
5. Choice of antibiotic for ABRS	If a decision is made to treat ABRS with an antibiotic agent, the clinician should prescribe amoxicillin with or without clavulanate as first-line therapy for 5 to 10 d for most adults.	Recommendation
6. Treatment failure for ABRS	If the patient worsens or fails to improve with the initial management option by 7 d after diagnosis or worsens during the initial management, the clinician should reassess the patient to confirm ABRS, exclude other causes of illness, and detect complications. If ABRS is confirmed in the patient initially managed with observation, the clinician should begin antibiotic therapy. If the patient was initially managed with an antibiotic, the clinician should change the antibiotic.	Recommendation
7a. Diagnosis of CRS or recurrent ARS	Clinicians should distinguish CRS and recurrent ARS from isolated episodes of ABRS and other causes of sinonasal symptoms.	Recommendation
7b. Objective confirmation of a diagnosis of CRS	The clinician should confirm a clinical diagnosis of CRS with objective documentation of sinonasal inflammation, which may be accomplished using anterior rhinoscopy, nasal endoscopy, or computed tomography.	Strong recommendation
8. Modifying factors	Clinicians should assess the patient with CRS or recurrent ARS for multiple chronic conditions that would modify management, such as asthma, cystic fibrosis, immunocompromised state, and ciliary dyskinesia.	Recommendation
9. Testing for allergy and immune function	The clinician may obtain testing for allergy and immune function in evaluating a patient with CRS or recurrent ARS.	Option
10. CRS with polyps	The clinician should confirm the presence or absence of nasal polyps in a patient with CRS.	Recommendation
11. Topical intranasal therapy for CRS	Clinicians should recommend saline nasal irrigation, topical intranasal corticosteroids, or both for symptom relief of CRS.	Recommendation
12. Antifungal therapy for CRS	Clinicians should not prescribe topical or systemic antifungal therapy for patients with CRS.	Recommendation (against therapy)

Abbreviations: ABRS, acute bacterial rhinosinusitis; ARS, acute rhinosinusitis; CRS, chronic rhinosinusitis; VRS, viral rhinosinusitis.

Nearly all authorities agree that CRS begins after 12 weeks' duration, but opinions about the duration of ARS vary, with some defining illness up to 12 weeks as ARS.[14] We agree with other guideline groups[15,16] that define ARS as up to 4 weeks' duration but recognize that this boundary is based more on consensus than research evidence. Moreover, very limited data are available on rhinosinusitis lasting 4 to 12 weeks, sometimes called *subacute* rhinosinusitis. We do not distinguish rhinosinusitis in this time frame as an explicit entity in the guideline, and decisions about whether such patients should be managed more like ARS or CRS must therefore be individualized.

Purpose

The purpose of this multidisciplinary guideline is to identify quality improvement opportunities in managing adult rhinosinusitis and to create explicit and actionable recommendations (**Table 2**, **Figure 1**) to implement these opportunities in



ARS, acute RS; AB, acute bacterial RS; CRS, chronic RS; KAS, key action statement; RS, rhinosinusitis; URI, upper respiratory infection

Figure 1. Adult with possible sinusitis. Table numbers correspond to tables in the full-text version of the guideline.[18]
ARS, acute RS; AB, acute bacterial RS; CRS, chronic RS; KAS, key action statement; RS, rhinosinusitis; URI, upper respiratory infection.

clinical practice. Specifically, the goals are to improve diagnostic accuracy for adult rhinosinusitis, promote judicious use of systemic and topical therapy, and promote appropriate use of ancillary tests to confirm diagnosis and guide management, including radiography, nasal endoscopy, computed tomography, and testing for allergy and immune function. Emphasis

Table 3. Patient Information Sheet on Diagnosis of Acute Sinusitis.

Question	Answer
What are the sinuses?	Sinuses are hollow spaces in the bones around the nose that connect to the nose through small, narrow channels. The sinuses stay healthy when the channels are open, which allows (a) air from the nose to enter the sinuses and (b) mucus made in the sinuses to drain into the nose.
What is sinusitis?	Sinusitis, also rhinosinusitis, affects about 1 in 8 adults annually and generally occurs when viruses or bacteria infect the sinuses (often during a cold) and begin to multiply. Part of the body's reaction to the infection causes the sinus lining to swell, blocking the channels that drain the sinuses. This causes mucus and pus to fill up the nose and sinus cavities.
How can I tell if I have acute sinusitis?	You have acute sinusitis when there has been up to 4 wk of cloudy or colored (not clear) drainage from the nose, plus 1 or both of the following: (a) a stuffy, congested, or blocked nose; (b) pain/pressure/fullness in the face, head, or around the eyes.
How can I tell if my sinusitis is caused by viruses or bacteria?	Acute *viral* sinusitis is likely if you have been sick less than 10 d and are not getting worse. Acute *bacterial* sinusitis is likely when you do not improve at all within 10 d of getting sick or when you get worse within 10 d after beginning to get better.
Why is it important to tell if my sinusitis is caused by bacteria?	Because sinusitis is treated differently according to cause, acute viral sinusitis does *not* benefit from antibiotics, but some patients with acute bacterial sinusitis may get better faster with an antibiotic.

was also placed on identifying multiple chronic conditions that would modify management of rhinosinusitis, including asthma, cystic fibrosis, immunocompromised state, and ciliary dyskinesia.

The guideline is intended for all clinicians who are likely to diagnose and manage adults with rhinosinusitis, and it applies to any setting in which an adult with rhinosinusitis would be identified, monitored, or managed. This guideline, however, does not apply to patients under age 18 years or to patients of any age with complicated rhinosinusitis.

The guideline will not consider management of the following clinical presentations, although differential diagnosis for these conditions and bacterial rhinosinusitis will be discussed: allergic rhinitis, eosinophilic nonallergic rhinitis, vasomotor rhinitis, invasive fungal rhinosinusitis, allergic fungal rhinosinusitis, vascular headaches, and migraines. Similarly, the guideline will not consider management of rhinosinusitis in patients with the following modifying factors, but it will discuss the importance of assessing patients with recurrent ARS or CRS for their presence: cystic fibrosis, immotile cilia disorders, ciliary dyskinesia, immune deficiency, prior history of sinus surgery, and anatomic abnormalities (eg, deviated nasal septum).

Surgical management of CRS is not discussed in this guideline, because of insufficient evidence (eg, RCTs) for evidence-based recommendations.

Methods

This guideline was developed following the methodology for updating guidelines detailed in the AAO-HNSF's guideline development manual.[17] Members of the panel represented the disciplines of otolaryngology–head and neck surgery, pediatrics, infectious disease, family medicine, dermatology, and a consumer advocate. For additional details on the methodology, please refer to the complete text of the guideline.[18] The 8 guideline recommendations are summarized in **Table 2**, with the corresponding action statements and profiles reproduced below. Supporting text and complete citations can be found in the guideline proper.[18]

Key Action Statements

STATEMENT 1A. DIFFERENTIAL DIAGNOSIS OF ACUTE RHINOSINUSITIS (ARS): Clinicians should distinguish presumed acute bacterial rhinosinusitis (ABRS) from ARS caused by viral upper respiratory infections and noninfectious conditions. A clinician should diagnose ABRS when (a) symptoms or signs of ARS (purulent nasal drainage accompanied by nasal obstruction, facial pain/pressure/fullness, or both) persist without evidence of improvement for at least 10 days beyond the onset of upper respiratory symptoms or (b) symptoms or signs of ARS worsen within 10 days after an initial improvement (double worsening). *Strong recommendation based on diagnostic studies with minor limitations and a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: Avoid inappropriate use of antibiotics for presumed viral infections (**Table 3**)
- Aggregate evidence quality: Grade B, systematic reviews, diagnostic studies with minor limitations regarding signs and symptoms associated with ABRS
- Level of confidence in evidence: Medium
- Benefit: Decrease inappropriate use of antibiotics for nonbacterial illness; distinguish noninfectious conditions from rhinosinusitis
- Harms, risks, costs: Risk of misclassifying ABRS as viral or vice versa
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Importance of avoiding inappropriate antibiotic treatment of viral or nonbacterial ill-

ness; emphasis on clinical signs and symptoms for initial diagnosis; importance of avoiding unnecessary diagnostic tests
- Intentional vagueness: None
- Role of patient preferences: None
- Exceptions: None
- Policy level: Strong recommendation
- Differences of opinion: None regarding the persistent and double-worsening presentations of ABRS; minor regarding whether to include a severe pattern of ABRS presentation (1 group member was in favor; 9 against)

STATEMENT 1B. RADIOGRAPHIC IMAGING AND ACUTE RHINOSINUSITIS (ARS): Clinicians should not obtain radiographic imaging for patients who meet diagnostic criteria for ARS, unless a complication or alternative diagnosis is suspected. *Recommendation (against imaging)* based on diagnostic studies with minor limitations and a preponderance of benefit over harm for not obtaining imaging.

Action Statement Profile

- Quality improvement opportunity: Avoid costly diagnostic tests that do not improve diagnostic accuracy yet expose the patient to unnecessary radiation
- Aggregate evidence quality: Grade B, diagnostic studies with minor limitations
- Level of confidence in evidence: High
- Benefit: Avoid unnecessary radiation exposure; avoid delays in diagnosis from obtaining and interpreting imaging studies; incur financial savings by not performing routine radiologic imaging; avoid incidental findings that may cause undue patient concern or result in additional imaging studies
- Risks, harms, costs: Delayed diagnosis of serious underlying condition
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Importance of avoiding unnecessary radiation and cost in diagnosing ARS
- Intentional vagueness: None
- Role of patient preferences: None
- Exceptions: Suspicion of complicated ARS or alternative diagnosis based on severe headache, proptosis, cranial nerve palsies, facial swelling, or other clinical findings
- Policy level: Recommendation (against)
- Differences of opinion: None

STATEMENT 2. SYMPTOMATIC RELIEF OF VIRAL RHINOSINUSITIS (VRS): Clinicians may recommend analgesics, topical intranasal steroids, and/or nasal saline irrigation for symptomatic relief of VRS. *Option based on RCTs with limitations and cohort studies with an unclear balance of benefit and harm that varies by patient.*

Action Statement Profile

- Quality improvement opportunity: To encourage consideration of supportive therapies that may improve quality of life for individuals suffering from VRS and furthermore support the avoidance of unnecessary antibiotics in viral disease
- Aggregate evidence quality: Grades B and C, RCTs with limitations and cohort studies
- Level of confidence in evidence: Medium
- Benefit: Reduction of symptoms; avoidance of unnecessary antibiotics
- Risks, harms, costs: Adverse effects of decongestants, antihistamines, topical steroid sprays; cost of medications
- Benefits-harm assessment: Balance of benefit and harm
- Value judgments: A desire to call attention to VRS as a subset of the "common cold" yet distinct from ABRS, which may benefit from explicit diagnosis and discussion of management options for symptomatic relief
- Intentional vagueness: The specific "symptomatic relief" is at the discretion of the clinician and patient but should not include antibiotics
- Role of patient preferences: Large role in selection and use of therapies for symptomatic relief based on shared decision making
- Exceptions: None
- Policy level: Option
- Differences of opinion: Minor regarding the need to explicitly discuss VRS in a distinct key action statement

STATEMENT 3. SYMPTOMATIC RELIEF OF ACUTE BACTERIAL RHINOSINUSITIS (ABRS): Clinicians may recommend analgesics, topical intranasal steroids, and/or nasal saline irrigation for symptomatic relief of ABRS. *Option based on RCTs with heterogeneous populations, diagnostic criteria, and outcome measures with a balance of benefit and harm.*

Action Statement Profile

- Quality improvement opportunity: Promote interventions that may relieve ABRS symptoms (analgesics, saline irrigation, topical intranasal steroids) and discourage interventions with questionable or unproven efficacy (antihistamines, systemic steroids, guaifenesin)
- Aggregate evidence quality: Grade A, systematic review of RCTs for topical nasal steroids; grade B, RCTs with heterogeneous populations, diagnostic criteria, and outcomes measures for saline irrigation and systemic steroids; grade D, first principles, for analgesics, decongestants, antihistamines (in nonatopic patients) and guaifenesin
- Level of confidence in evidence: Medium
- Benefit: Relief of facial pain with analgesics, modest increase in symptom relief from topical nasal steroids (number needed to treat, 14), and possible

Table 4. Patient Information Sheet on Treating Acute Bacterial Rhinosinusitis.

Question	Answer
How long will it take before I feel better?	Most patients with ABRS feel better within 7 d, and by 15 d about 90% are cured or improved.
Is there anything I can do for symptomatic relief?	There are several ways to relieve sinusitis symptoms that should be discussed with your doctor to decide which are best for you: 1. *Acetaminophen* or *ibuprofen* can relieve pain and fever. 2. *Saline irrigations*, or washing out the nose with salt water, can relieve symptoms and remove mucus that is hard to blow out. 3. *Nasal steroid sprays* can reduce symptoms after 15 d of use, but the benefit is small (about 14 people must use them to get 1 person better), and side effects include headache, nasal itching, and nose bleeds. 4. *Decongestants* may help you breathe easier and can be taken as a nasal spray (for no more than 3 d in a row, to avoid worsening congestion) or by mouth.
Is there anything I should not do?	*Antihistamines* and *oral steroid medicines* should not be used routinely, because they have side effects and do not relieve symptoms.
If I have ABRS, do I have to take an antibiotic?	No, both *watchful waiting* and *antibiotic therapy* are proven ways to treat ABRS. Most people get better naturally, and antibiotics only slightly increase symptom relief (about 10 to 15 people must use antibiotics to get 1 more person better after 7 to 15 d).
Is there any downside to using antibiotic?	Antibiotics have side effects that include rash, upset stomach, nausea, vomiting, allergic reactions, and they cause resistant germs.
What is "watchful waiting" for ABRS?	Watchful waiting means delaying antibiotic treatment of ABRS for up to 7 d after diagnosis to see if you get better on your own.
How is watchful waiting done?	Your doctor can give you an antibiotic prescription, but you should fill the prescription and take the antibiotic only if you do not get better after 7 d or if you get worse at any time. If you do use the antibiotic, contact your doctor's office and let the staff know.
If I use an antibiotic, for how many days should I take it?	Antibiotics are usually given for 10 d to treat ABRS, but shorter courses may be equally effective. Ask your doctor about a 5- to 7-d course of antibiotics since side effects are less common.

Abbreviation: ABRS, acute bacterial rhinosinusitis.

symptom relief from saline irrigations; avoidance of adverse events from ineffective therapies
- Risks, harms, costs: Side effects of medications, which include local and systemic adverse reactions; cost of medications
- Benefits-harm assessment: Balance of benefit and harm
- Value judgments: Provide symptomatic relief while minimizing adverse events and costs
- Intentional vagueness: We use the broad term *symptomatic relief* to acknowledge that there are several interventions available for this purpose and to encourage a conversation between clinicians and patients about which specific intervention(s) may be best for their specific ABRS symptoms
- Role of patient preferences: Large role for shared decision making regarding use of analgesics, topical nasal steroids, and saline irrigation
- Exceptions: None
- Policy level: Option
- Differences of opinion: None

STATEMENT 4. INITIAL MANAGEMENT OF ACUTE BACTERIAL RHINOSINUSITIS (ABRS): Clinicians should either offer watchful waiting (without antibiotics) or prescribe initial antibiotic therapy for adults with uncomplicated ABRS. Watchful waiting should be offered only when there is assurance of follow-up such that antibiotic therapy is started if the patient's condition fails to improve by 7 days after ABRS diagnosis or if it worsens at any time. *Recommendation based on systematic reviews of double-blind RCTs with some heterogeneity in diagnostic criteria and illness severity, as well as a relative balance of benefit and risk.*

Action Statement Profile

- Quality improvement opportunity: Make explicit to clinicians and patients that not prescribing antibiotics for clinically diagnosed ABRS is an appropriate initial management strategy because many patients will improve spontaneously and antibiotics could be started later if follow-up was ensured (**Table 4**)
- Level of confidence in evidence: Medium
- Aggregate evidence quality: Grade A, multiple systematic reviews of RCTs with some heterogeneity in diagnostic criteria and illness severity
- Benefit: Promote more informed, shared decision making regarding whether or not to prescribe initial antibiotics for ABRS, given the favorable natural history in placebo groups, the small to modest benefits of antibiotic therapy, and the higher rates of adverse events when antibiotics are prescribed; more selective initial use of antibiotics will reduce adverse events and the risk of bacterial resistance

- Risks, harms, costs: Antibiotics could be withheld from patients who would have derived benefit from their use; antibiotics could be prescribed to patients who would have improved equally on their own
- Benefits-harm assessment: Preponderance of benefit over harm (regarding the decision for initial management)
- Value judgments: Perception by the guideline update group (GUG) that watchful waiting, without antibiotics, is an underused strategy for initial management of uncomplicated ABRS, despite existing guidelines and systematic reviews that support this approach
- Intentional vagueness: No restrictions have been stated for illness severity (eg, mild, moderate, or severe), which was done in the prior guideline, because insufficient evidence to determine that severity would affect outcomes of antibiotic therapy, including the potential for complications
- Role of patient preferences: Large role for shared decision making
- Exceptions: Complicated sinusitis, immune deficiency, or coexisting bacterial illness; the clinician should also consider the patient's age, general health, cardiopulmonary status, and comorbid conditions when assessing suitability for watchful waiting
- Policy level: Recommendation
- Differences of opinion: No difference of opinion regarding the choice to initially observe or prescribe antibiotics (1 abstention); minor difference of opinion (1 against, 9 in favor) regarding the decision to remove severity (eg, mild illness) as a criterion for watchful waiting

STATEMENT 5. CHOICE OF ANTIBIOTIC FOR ACUTE BACTERIAL RHINOSINUSITIS (ABRS): If a decision is made to treat ABRS with an antibiotic agent, the clinician should prescribe amoxicillin with or without clavulanate as first-line therapy for 5 to 10 days for most adults. *Recommendation based on RCTs with heterogeneity and noninferiority design with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: Discourage initial prescribing of antibiotics other than amoxicillin, with or without clavulanate, that may have lower efficacy or have comparable efficacy but more adverse events
- Aggregate evidence quality: Grade A, systematic reviews of RCTs with heterogeneity and noninferiority design
- Level of confidence in evidence: Moderate regarding choice of antibiotic but lower regarding the optimal duration of antibiotic therapy because of limited supporting evidence and statistical power
- Benefit: Clinical outcomes that are comparable to broader-spectrum antibiotics for initial therapy; potential reduced bacterial resistance by using a narrow-spectrum antibiotic as first-line therapy; cost-effectiveness of amoxicillin versus other antibiotic choices
- Risks, harms, costs: Potential increased gastrointestinal adverse effects with amoxicillin-clavulanate compared to other antibiotics; adverse effects from penicillin allergy
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Promote safe and cost-effective initial therapy
- Intentional vagueness: Whether to prescribe amoxicillin or amoxicillin-clavulanate is at the discretion of the clinician, as is the duration of therapy because systematic review has not shown consistent benefits for 10 days of therapy compared with shorter courses; a longer course of therapy may be appropriate for more severe illness or when symptoms persist despite a shorter course
- Role of patient preferences: Moderate role for shared decision making; large role in determining duration of antibiotic therapy since adverse events are reduced with shorter duration of therapy
- Exceptions: Patients with penicillin allergy for whom amoxicillin is contraindicated
- *Policy level:* Recommendation
- *Differences of opinion:* None

STATEMENT 6. TREATMENT FAILURE FOR ACUTE BACTERIAL RHINOSINUSITIS (ABRS): If the patient fails to improve with the initial management option by 7 days after diagnosis or worsens during the initial management, the clinician should reassess the patient to confirm ABRS, exclude other causes of illness, and detect complications. If ABRS is confirmed in the patient initially managed with observation, the clinician should begin antibiotic therapy. If the patient was initially managed with an antibiotic, the clinician should change the antibiotic. *Recommendation based on RCTs with limitations supporting a cut point of 7 days for lack of improvement and expert opinion and first principles for changing therapy with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: Define realistic expectations regarding clinical response to initial management and to articulate clearly when reassessment of the patient is warranted
- Aggregate evidence quality: Grade B, RCTs with limitations supporting a cut point of 7 days for lack of improvement; Grade D, expert opinion and first principles for changing therapy, including the use of rescue antibiotic in RCTs
- Level of confidence in evidence: High
- Benefit: Prevent complications, detect misdiagnosis, institute effective therapy

Table 5. Definitions of Chronic Rhinosinusitis and Recurrent Acute Rhinosinusitis.

Term	Definition
Chronic rhinosinusitis	Twelve weeks or longer of 2 or more of the following signs and symptoms: • mucopurulent drainage (anterior, posterior, or both) • nasal obstruction (congestion), • facial pain/pressure/fullness, or • decreased sense of smell. AND inflammation is documented by one or more of the following findings: • purulent (not clear) mucus or edema in the middle meatus or anterior ethmoid region, • polyps in nasal cavity or the middle meatus, and/or • radiographic imaging showing inflammation of the paranasal sinuses.
Recurrent acute rhinosinusitis	Four or more episodes per year of acute bacterial rhinosinusitis without signs or symptoms of rhinosinusitis between episodes: • Each episode of acute bacterial rhinosinusitis should meet diagnostic criteria in Table 1.

- Risks, harms, costs: Delay of up to 7 days in changing therapy if patient fails to improve; medication cost
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Avoid excessive classification as treatment failures because of a premature time point for assessing outcomes; emphasize importance of worsening illness in definition of treatment failure
- Intentional vagueness: How to define "worsening" is left to the judgment of the clinician and patient, but there was group consensus that fluctuations in signs and symptoms within the first 48 to 72 hours of initial therapy were not uncommon and not necessarily indicative of failure
- Role of patient preferences: None (unless the patient declines reassessment)
- Exceptions: Include but are not limited to severe illness, complicated sinusitis, immune deficiency, prior sinus surgery, or coexisting bacterial illness; the clinician should also consider the patient's age, general health, cardiopulmonary status, and comorbid conditions in determining an appropriate cut point for assessing treatment failure; changing antibiotic therapy before failure would be appropriate in the face of adverse treatment effects
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 7A. DIAGNOSIS OF CHRONIC RHINOSINUSITIS (CRS) OR RECURRENT ACUTE RHINOSINUSITIS (ARS): Clinicians should distinguish CRS and recurrent ARS from isolated episodes of acute bacterial rhinosinusitis (ABRS) and other causes of sinonasal symptoms. *Recommendation based on cohort and observational studies with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: Raise awareness of the distinct clinical entities of CRS and recurrent ARS (**Table 5**) so that appropriate management strategies may be implemented
- Aggregate evidence quality: Grade C, cohort and observational studies
- Level of confidence in evidence: High
- Benefit: Distinguish conditions that might benefit from additional management strategies versus isolated cases of ABRS
- Risks, harms, costs: Potential misclassification of illness because of overlapping symptomatology with other illnesses; no cost
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Importance of accurate diagnosis
- Intentional vagueness: None
- Role of patient preferences: Not applicable
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 7B. OBJECTIVE CONFIRMATION OF A DIAGNOSIS OF CHRONIC RHINOSINUSITIS (CRS): The clinician should confirm a clinical diagnosis of CRS with objective documentation of sinonasal inflammation, which may be accomplished using anterior rhinoscopy, nasal endoscopy, or computed tomography. *Strong recommendation based on cross-sectional studies with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: Reduce overdiagnosis of CRS based on self-reported symptoms
- Aggregate evidence quality: Grade B, cross-sectional studies
- Level of confidence in evidence: High
- Benefit: Improved diagnostic certainty for CRS and fewer false-positive diagnoses, which allows patients with CRS to be managed more promptly and those without CRS to seek additional evaluation of their sinusitis-like symptoms and institute effective therapy

- Risks, harms, costs: None associated with improved diagnostic certainty, but diagnostic modalities have their own risk and direct cost profiles
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Strong consensus by the GUG that the need for objective documentation of sinonasal inflammation is likely underappreciated and underperformed, despite its critical role in substantiating a diagnosis of CRS
- Intentional vagueness: Which of the 3 listed diagnostic modalities to use is not stated
- Role of patient preferences: Large role for shared decision making with clinicians regarding choice of the confirmatory diagnostic modality
- Exceptions: None
- Policy level: Strong recommendation
- Differences of opinion: None

STATEMENT 8. MODIFYING FACTORS: Clinicians should assess the patient with chronic rhinosinusitis (CRS) or recurrent acute rhinosinusitis (ARS) for multiple chronic conditions that would modify management, such as asthma, cystic fibrosis, immunocompromised state, and ciliary dyskinesia. *Recommendation based on 1 systematic review and multiple observational studies with a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: Identify comorbid conditions that are known to accompany CRS and recurrent ARS, the knowledge of which would improve management of the sinusitis and, conversely, management of sinusitis may improve the associated chronic condition (asthma)
- Aggregate evidence quality: Grade B, 1 systematic review and multiple observational studies
- Level of confidence in evidence: Medium
- Benefit: Identify modifying factors that would alter management of CRS or recurrent ARS; identify conditions that require therapy independent of rhinosinusitis
- Risks, harms, costs: Identifying and treating incidental findings or subclinical conditions that might not require independent therapy; morbidity related to specific tests; variable costs based on testing ordered
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Consensus that identifying and managing modifying factors will improve outcomes
- Intentional vagueness: The method of assessing for these conditions is at the discretion of the clinician and may include history, physical examination, or diagnostic tests
- Role of patient preferences: Small
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 9. TESTING FOR ALLERGY AND IMMUNE FUNCTION: The clinician may obtain testing for allergy and immune function in evaluating a patient with chronic rhinosinusitis (CRS) or recurrent acute rhinosinusitis (ARS). *Option based on observational studies with an unclear balance of benefit versus harm.*

Action Statement Profile

- Quality improvement opportunity: Improve patient quality of life by identifying and managing allergies that often coexist with CRS and recurrent ARS and have overlapping symptoms that may make diagnosis difficult using strictly clinical criteria without testing
- Aggregate evidence quality: Grade C, systematic review of observational studies
- Level of confidence in evidence: Medium
- Benefit: Identify allergies or immunodeficient states that are potential modifying factors for CRS or recurrent ARS and improve management strategies
- Risks, harms, costs: Procedural discomfort; instituting therapy based on test results with limited evidence of efficacy for CRS or recurrent ARS; very rare chance of anaphylactic reactions during allergy testing; procedural and laboratory cost
- Benefits-harm assessment: Balance of benefit and harm
- Value judgments: Need to balance detecting allergy in a population with high prevalence versus limited evidence showing benefits of allergy management on rhinosinusitis outcomes
- Intentional vagueness: The methods and scope of testing for allergy and immune function are at the discretion of the clinician
- Role of patient preferences: Large for shared decision making
- Exceptions: None
- Policy level: Option
- Differences of opinion: None

STATEMENT 10. CHRONIC RHINOSINUSITIS (CRS) WITH POLYPS: The clinician should confirm the presence or absence of nasal polyps in a patient with CRS. *Recommendation based on observational studies with preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: Improve awareness of the prevalence of polyps in patients with CRS and their role as a modifying factor for further diagnostic assessment and treatment
- Aggregate evidence quality: High, Grade A, systematic review of multiple RCT
- Level of confidence in evidence: Medium
- Benefit: Prioritize referral for specialty evaluation, identify patients likely to benefit most from topical

(intranasal) or systemic corticosteroid therapy, identify patients for additional diagnostic tests to assess for conditions other than CRS that are associated with nasal polyposis and may require different management strategies
- Risks, harms, and costs: None related to identifying patients; specific costs and risks based on the choice of diagnostic procedure
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: Underappreciation of the importance of polyps as a modifying factor for CRS; perception of diagnostic uncertainty in the ability to detect or exclude the presence of polyps
- Intentional vagueness: The method of confirming the diagnosis is left to the discretion of the clinician, provided that a high degree of diagnostic certainty is achieved
- Role of patient preferences: None
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 11. TOPICAL INTRANASAL THERAPY FOR CHRONIC RHINOSINUSITIS (CRS): Clinicians should recommend saline nasal irrigation, topical intranasal corticosteroids, or both for symptom relief of CRS. *Recommendation based on a preponderance of benefit over harm.*

Action Statement Profile

- Quality improvement opportunity: Address underutilization; promote awareness of efficacy; reduce confusion over delivery method, frequency, and duration; educate patients on optimal administration
- Aggregate evidence quality: Grade A, systematic reviews of RCTs
- Level of confidence in evidence: High
- Benefit: Symptomatic relief, promoting awareness of effective over-the-counter interventions, discouraging improper and ineffective usage, and avoiding adverse events from systemic therapies
- Risks, harms, costs: Intranasal discomfort, burning, stinging; epistaxis; direct costs of saline or steroid
- Benefits-harm assessment: Preponderance of benefit over harm
- Value judgments: None
- Intentional vagueness: The choice of saline, steroid, or both is a shared decision; it is not clear how long the treatment should last, as the natural history is unknown
- Role of patient preferences: Large role for deciding which products to use and their duration
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

STATEMENT 12. ANTIFUNGAL THERAPY FOR CHRONIC RHINOSINUSITIS (CRS). Clinicians should not prescribe topical or systemic antifungal therapy for patients with CRS. *Recommendation (against therapy) based on systematic review of RCTs with a preponderance of benefit over harm (for not treating).*

Action Statement Profile

- Quality improvement opportunity: Discourage use of antifungal therapy for CRS based on lack of efficacy and presence of significant cost and adverse effects
- Aggregate evidence quality: Grade A, systematic reviews of RCTs
- Level of confidence in evidence: High
- Benefit: Avoid cost of ineffective medications, avoid unnecessary adverse events, direct management away from ineffective therapy to beneficial therapy (opportunity cost), avoid selection of resistant fungi and alterations of sinonasal flora
- Risks, harms, costs: None (for avoiding ineffective therapy)
- Benefits-harm assessment: Preponderance of benefit over harm (for not treating)
- Value judgments: Antifungal therapy is frequently used, with regional variations, for treating CRS despite good evidence of no efficacy
- Intentional vagueness: None
- Role of patient preferences: None
- Exceptions: Patients with allergic fungal sinusitis or invasive fungal sinusitis
- Policy level: Recommendation
- Differences of opinion: None

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Disclaimer

The clinical practice guideline is provided for information and educational purposes only. It is not intended as a sole source of guidance in managing adults with rhinosinusitis. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to diagnosing and managing this program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is

recommended under specific conditions but are not absolute. Guidelines are not mandates; these do not and should not purport to be a legal standard of care. The responsible physician, in light of all circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The AAO-HNSF emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care, or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.

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References

1. Rosenfeld RM, Andes D, Bhattacharyya N, et al. Clinical practice guideline: adult sinusitis. *Otolaryngol Head Neck Surg*. 2007;137(3):S1-S31.
2. Instititute of Medicine, Committee on Standards for Developing Trustworthy Guidelines. *Clinical Practice Guidelines We Can Trust*. Washington, DC: National Academies Press; 2011.
3. Lethbridge-Cejku M, Rose D, Vickerie J. Summary health statistics for US adults: National Health Interview Survey, 2004. *Vital Health Stat*. 2006;10(228):19-22.
4. Blackwell DL, Lucas JW, Clarke TC. Summary health statistics for US adults: national health interview survey, 2012. *Vital Health Stat*. 2014;10(260):1-171.
5. Sinus and Allergy Health Partnership. Antimicrobial treatment guidelines for acute bacterial rhinosinusitis. *Otolaryngol Head Neck Surg*. 2004;130(suppl):1-45.
6. Rudmik L, Smith TL, Schlosser RJ, et al. Productivity costs in patients with refractory chronic rhinosinusitis. *Laryngoscope*. 2014;124(9):2007-2012.
7. Stankiewicz J, Tami T, Truitt T, et al. Impact of chronic rhinosinusitis on work productivity through one-year follow-up after balloon dilation of the ethmoid infundibulum. *Int Forum Allergy Rhinol*. 2011;1:38-45.
8. Gliklich RE, Metson R. The health impact of chronic sinusitis in patients seeking otolaryngologic care. *Otolaryngol Head Neck Surg*. 1995;113(1):104-109.
9. Kaszuba SM, Stewart MG. Medical management and diagnosis of chronic rhinosinusitis: a survey of treatment patterns by United States otolaryngologists. *Am J Rhinol*. 2006;20(2):186-190.
10. Winstead W. Rhinosinusitis. *Prim Care*. 2003;30(1):137-154.
11. Snow V, Mottur-Pilson C, Hickner JM, et al. Principles of appropriate antibiotic use for acute sinusitis in adults. *Ann Intern Med*. 2001;134(6):495-497.
12. Bhattacharyya N. Chronic rhinosinusitis: is the nose really involved? *Am J Rhinol*. 2001;15(3):169-173.
13. Meltzer EO, Hamilos DL, Hadley JA, et al. Rhinosinusitis: Establishing definitions for clinical research and patient care. *Otolaryngol Head Neck Surg*. 2004;131(6):S1-S62.
14. Scadding GK, Durham SR, Mirakian R. BSACI guidelines for the management of rhinosinusitis and nasal polyposis. *Clin Exp Allergy*. 2007;38:260-275.
15. Chow AW, Benninger MS, Brook I, et al. IDSA clinical practice guideline for acute bacterial rhinosinusitis in children and adults. *Clinl Infect Dis*. 2012;54(8):e72-e112.
16. Desrosiers M, Evans GA, Keith PK, et al. Canadian clinical practice guidelines for acute and chronic rhinosinusitis. *Allergy Asthma Clin Immunol*. 2011;7(1):2.
17. Rosenfeld RM, Shiffman RN, Robertson P, et al. Clinical Practice Guideline Development Manual, Third Edition: a quality-driven approach for translating evidence into action. *Otolaryngol Head Neck Surg*. 2013;148(1):S1-S55.
18. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline: adult sinusitis. *Otolaryngol Head Neck Surg*. 2015;152(2S):S1-S39.

Intrathecal Pump Guideline

Question: Should a guideline be adopted to limit the use of intrathecal pumps for delivery of non-opioid medications?

Question source: HERC staff, HSD

Issue: Intrathecal pumps are devices inserted into the spine to allow administration of medications. Typically, such pumps are used for infusion of baclofen for spasticity, narcotics for malignant and non-malignant pain, and chemotherapy. The insertion and maintenance of these devices appear on a variety of lines on the Prioritized List.

Coverage for placement of intrathecal pumps was removed for back pain and soft tissue pain indications in January, 2009. At that meeting, the HOSC/HSC determined that coverage of maintenance and removal of previously implanted pumps was to be continued. GN72 was adopted to clarify that pump maintenance was only covered for pumps placed before the insertion coverage change (i.e. before 2009). This guideline was removed in January, 2016, as HSD was having issues in managing maintenance of pumps for OHP patients who came onto OHP coverage with a pump placed during previous non-OHP insurance coverage.

The CPT codes for the insertion, removal and maintenance of intrathecal pumps appear on a number of lines, including cancer lines and dysfunction lines. Intrathecal pumps are used for chemotherapy or for antispasmotic medication therapy on these lines, and this has been determined to be an appropriate use of these pumps in the past.

The CPT codes in question (62367-62370) can be paired with ICD-10 code Z45.49 (Encounter for adjustment and management of other implanted nervous system device) which is found on 3 lines on the Prioritized List. These CPT codes can also pair with diagnosis codes, such as cerebral palsy.

HSD has requested re-review of the placement of maintenance codes for these pumps, due to the high volume of requests for maintenance of pumps placed for pain diagnoses, generally back pain.

From the January, 2016 VBBS minutes:

> Gibson was concerned that adding the maintenance codes for these pumps to the complications line would allow use of an intervention that the Commission has previously determined was not effective. Hodges agreed, noting that OHP does not generally pay for complications directly related to uncovered procedures. Hodges felt that OHP should pay for pump removal for back pain indications, but not maintenance. Wentz noted that it was relatively common to have patients have pumps placed for back pain prior to coming on an OHP plan, and they need maintenance. It was noted that maintenance of these pumps could be covered as an exception if it was placed for a non-pairing condition if the patient was doing well. It was also noted that intrathecal pumps are not benign, but rather have some rather serious complications including CNS infections. The decision was to remove the pump maintenance codes from the back condition lines and delete the guideline note that applied to these lines. The subcommittee voted to not place the maintenance CPT codes or the maintenance ICD-10 Z code on the complications line. This leaves coverage for maintenance only for indications on the dysfunction or cancer lines. A patient may appeal for continued coverage through the exception process. This change will be implemented with the other changes to the treatment of conditions of the back and spine once their delay is lifted.

Intrathecal Pump Guideline

HSC/HERC history:
Discussed in 2002: intrathecal baclofen pumps added to the posture & movement line for the treatment of spasticity. At the following meeting a guideline was approved but never actually appeared on the Prioritized List.

The Commission received a request from Shriner's Hospital (OHSU) to consider pairing the CPT code for spinal infusion pump for Baclofen therapy to treat severe spasticity on the dysfunction line 335, Neurological Dysfunction in Posture and Movement Caused by Chronic Conditions. Detailed testimony from medical consultants and a review of the literature revealed that intrathecal Baclofen was potentially cost-saving (and very likely cost-neutral) for the OHP, but that a strict guideline should be added to this line.

Diagnosis: NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
Treatment: MEDICAL AND SURGICAL TREATMENT (EG. DURABLE MEDICAL EQUIPMENT AND ORTHOPEDIC PROCEDURES)
Line: 336

1. Inclusion criteria for intrathecal baclofen therapy (IBT) associated with CPT codes 62360-62362:
   a. Spasticity due to spinal cord injury, multiple sclerosis, cerebral palsy, brain injury (1year post trauma) due to stroke, or anoxia.
   b. Spasticity interferes with function (e.g. sleeping, dressing, and/or positioning).
   c. Spasticity is severe with an Ashworth score of 3.
   d. Patient is 4 years of age and has sufficient body mass to support a pump.
   e. Patient/family/caregivers and providers agree on treatment goals and are motivated to achieve treatment goals.

2. Exclusion criteria for IBT:
   a. Infection is present at time of screening or implant.
   b. Patient has history of allergy/hypersensitivity to oral baclofen.

3. General Clinical Considerations for IBT:
   a. Prior soft tissue lengthening procedures, tendon release, and selective posterior rhizotomy are not contraindications to IBT therapy.
   b. Patients with spasticity of spinal origin should be refractory to oral baclofen or experience intolerable CNS side effects at effective doses. However, oral anti-spasticity medication is not a prerequisite for patients with spasticity of cerebral origin.
   c. IBT therapy should be considered when patients experience spasticity-related pain.

4. Test Screening Flow Chart for IBT:

a. Day 1 Bolus: 50mcg → If response →Implant
b. If no response→ Day 2 Bolus 75mcg →If response→Implant
c. If no response→ Day 3 Bolus 100mcg →If response→Implant
d. If no response Patient ineligible for implant

Treatment for coordination disorder (ICD-9 code 315.4) is included in this line for children age 3 and under and, for children over the age of 3, treatment is for diagnostic purposes only and is limited to a maximum of 120 days.

Utilization data:
In the past 6 months, 200 claims for insertion, removal, revision, or maintenance of these pumps were received with diagnoses related to back pain (radiculopathy, spinal stenosis, etc.), complex regional pain syndrome, or other chronic pain diagnoses. 104 claims were received with diagnoses related to spasticity (cerebral palsy, intracerebral injury, multiple sclerosis, paraplegia, quadriplegia, etc.). 22 claims were made with completely inappropriate diagnoses (GERD, osteoarthritis of the knee, interstitial cystitis, bipolar disorder, etc.). No claims were received with cancer related diagnoses.

The majority of the claims submitted for back conditions appeared to be for maintenance of already placed pumps.

Intrathecal Pump Guideline

Current Prioritized List status:

CPT code	Code Description	Line(s)
62320-62323	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid	75 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
62350	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; without laminectomy	75 97 CHILDHOOD LEUKEMIAS 130 BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD 239 ACUTE LYMPHOCYTIC LEUKEMIAS (ADULT) AND MULTIPLE MYELOMA 242 ACUTE PROMYELOCYTIC LEUKEMIA 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 299 CANCER OF BRAIN AND NERVOUS SYSTEM 402 ACUTE MYELOID LEUKEMIA 403 MYELOID DISORDERS 495 SPASTIC DIPLEGIA
62351	With laminectomy	75,97,130,239,242,290,299,402,403,495
62355	Removal of previously implanted intrathecal or epidural catheter	75,97,130,239,242,290,299,402,403,495
62360	Implantation or replacement of device for intrathecal or epidural drug infusion; subcutaneous reservoir	75,97,130,239,242,290,299,402,403,495
62361	nonprogrammable pump	75,97,130,239,242,290,299,402,403,495
62362	programmable pump, including preparation of pump, with or without programming	75,97,130,239,242,290,299,402,403,495
62365	Removal of subcutaneous reservoir or pump, previously implanted for intrathecal or epidural infusion	97,130,239,242,290,299,402,403,495
62367	Electronic analysis of programmable, implanted pump for intrathecal or epidural drug infusion (includes evaluation of reservoir status, alarm status, drug prescription status); without reprogramming or refill	75,97,130,239,242,290,299,402,403,495
62368	with reprogramming	75,97,130,239,242,290,299,402,403,495
62369	with reprogramming and refill	75,97,130,239,242,290,299,402,403,495
62370	with reprogramming and refill (requiring skill of a physician or other qualified health care professional)	75,97,130,239,242,290,299,402,403,495

Evidence

Opioid delivery for chronic non-cancer pain

1) **Noble 2016**, Cochrane review of opioid use for chronic non-cancer pain
    a. N=26 studies (4893 participants)
        i. 25 case series or uncontrolled trials
        ii. 1 RCT comparing 2 opioids
    b. Intrathecal opioid delivery: N=10 studies with 231 participants
        i. Participants who discontinued due to adverse effects: : 8.9% [95% CI: 4.0% to 26.1%]), compared to 22.9% [95% confidence interval (CI): 15.3% to 32.8%] for oral opioids
        ii. Participants who discontinued due to insufficient pain relief: 7.6% [95%CI: 3.7% to 14.8%] vs 10.3% [95% CI: 7.6% to 13.9%] for oral opioids
    c. All three modes of administration (oral, transdermal and intrathecal) were associated with clinically significant reductions in pain, but the amount of pain relief varied among studies.
    d. Findings regarding quality of life and functional status were inconclusive due to an insufficient quantity of evidence for oral administration studies and inconclusive statistical findings for transdermal and intrathecal administration studies.
    e. **Authors' conclusions** Many patients discontinue long-term opioid therapy (especially oral opioids) due to adverse events or insufficient pain relief; however, weak evidence suggests that patients who are able to continue opioids long-term experience clinically significant pain relief. Whether quality of life or functioning improves is inconclusive. Many minor adverse events (like nausea and headache) occurred, but serious adverse events, including iatrogenic opioid addiction, were rare.

Treatment of cancer related pain

1) Cochrane review has been withdrawn
2) **Upadhyay 2012**, review of intrathecal drug delivery for cancer pain management
    a. Lack of clear cut indications or universally accepted guideline and lack of multicentric randomized clinical trials limit its utilization. Studies on cost effectiveness in terminal patients, adverse effects, and complication of such therapy are also lacking.
    b. The goals of IT therapy are to preserve patient quality of life, functional activity, and independence, regardless of the prognosis.
    c. There is still weak evidence to support its use as replacement of comprehensive medical management.
    d. Because of its cost factor, invasive nature of the device with inheritance risks of potential side effects and limited clinical experience, its use should be reserved for certain selected patients who required large doses of systemic opioid and side effects limits further dose increment
3) **Kurita 2010**, European Palliative Care Research Collaborative systematic review of spinal opioids for cancer pain
    a. N=44 articles (nine randomized controlled trials (RCTs), two non-randomized cohort studies, 28 uncontrolled prospective studies, and five case series).

i. All trials included only cancer patients who had failed systemic treatment, either because of inadequate analgesia or because of intolerable side effects

b. Relief of pain and/or side effects were reported in 42 articles; however, there were few studies of high quality design (RCTs) and these studies had methodological limitations that reduced their quality of evidence to very low.

c. Reported complications: Epidural hematoma, post dural puncture headache, external leakage of cerebrospinal fluid, hearing loss and Meniere-like syndrome, pain on injection, catheter tip dislodgement, catheter occlusion and accidental catheter withdrawal are well-known mechanical complications. Furthermore, infections such as local (catheter entry site) infection, catheter track infection, epidural abscess, meningitis and systemic infections have also been described in the literature.

a. Conclusion: There are few RCTs and these are of very low quality. As a result, they provide weak recommendation for using spinal opioids in adult cancer patients. Further studies are clearly needed.

Anti-spasmodic medication administration

1) **Hasnat 2015**, Cochrane review of intrathecal pumps for baclofen delivery in children with CP
   a. N=6 studies, all found to have high or unclear risk of bias
      i. 5 RCTs, 1 trial
      ii. 4 of the 5 RCTs assessed short term delivery of intrathecal baclofen (lumbar puncture, etc.)
      iii. 1 of the 5 RCTs assessed effectiveness of implantable intrathecal baclofen pumps over 6 months.
   b. The four short-term studies demonstrated that intrathecal baclofen therapy reduces spasticity in children with cerebral palsy. However, two of these studies utilized inappropriate techniques for statistical analysis of results. The single longer-term study demonstrated minimal reduction in spasticity with the use of intrathecal baclofen therapy.
   c. One of the short-term studies and the longer term study showed improvement in comfort and ease of care. The longer term study found a small improvement in gross motor function and also in some domains of health-related quality of life.
   d. **Authors' conclusions:** There is some limited short-term evidence that intrathecal baclofen is an effective therapy for reducing spasticity in children with cerebral palsy. The effect of intrathecal baclofen on long-term spasticity outcomes is less certain. The validity of the evidence for the effectiveness of intrathecal baclofen in treating spasticity in children with cerebral palsy from the studies in the review is constrained by the small sample sizes of the studies and methodological issues in some studies. There is some evidence that intrathecal baclofen improves ease of care and the comfort and quality of life of the individuals receiving it, but again small sample sizes and methodological issues in the studies mean that these results should be interpreted with caution.
2) **Taricco 2009,** Cochrane review of pharmacological interventions for spasticity following spinal cord injury
   a. N=9 studies
      i. 8 cross-over and 1 parallel-group trial

b. Two studies (14 patients) showed a significant effect of intrathecal baclofen in reducing spasticity (Ashworth Score and ADL performances), compared to placebo, without any adverse effects.

c. Other studies of oral anti-spasmodics, including tizanidine, gabapentin, clonidine, diazepam, amytal and baclofen) did not provide evidence of clinical significant effectiveness other than tizanidine improving Ashworth Score but not in ADL performances. The tizanidine group reported significant rates of adverse effects (drowsiness, xerostomia).

d. Authors' conclusions: There is insufficient evidence to assist clinicians in a rational approach to antispastic treatment for SCI. Further research is urgently needed to improve the scientific basis of patient care.

Complications

1) **Bottros 2014**, review of intrathecal medication administration (https://www.dovepress.com/current-perspectives-on-intrathecal-drug-delivery-peer-reviewed-fulltext-article-JPR)
    a. Complications include
        i. Medication errors leading to hemodynamic instability, respiratory depression, and potentially death
        ii. Mechanical complications including intrathecal catheter displacement causing cerebrospinal fluid leakage and potential local hygroma, intrathecal catheter kinking, catheter pump disconnection leading to leakage of administered agent, loss of pump propellant leading to altered rate of drug delivery, and gear shaft wear/motor stall causing drug underinfusion
        iii. a retrospective evaluation showed that among IDDS-related complications, the most common complication was associated with a patient's adverse reaction to a drug. Serious complications include anaphylaxis, respiratory depression or arrest, and/or meningitis from a contaminated solution. More specifically, intrathecal opioids may cause centrally mediated respiratory depression, nausea, vomiting, sedation, pruritus, constipation, urinary retention, cognitive impairment, and headache
        iv. Intrathecal baclofen has been shown to potentially cause nausea, vomiting, dizziness, urinary retention, constipation, headache, fatigue, hypotonia, and paresthesias. Life-threatening withdrawal can occur in patients in whom baclofen is abruptly discontinued
        v. Coffey et al found that patients with noncancer pain treated with intrathecal opioid therapy had an increased mortality (0.088% at 3 days after implantation, 0.39% at 1 month, and 3.89% at 1 year) compared with similar patients who were using other therapies. While the exact mechanism was not fully elucidated, they hypothesized that respiratory depression due to intrathecal drug overdose or mixed intrathecal and systemic drug interactions could be a possibility

vi. Surgical complications include bleeding, infection, cerebrospinal fluid leakage, seroma formation, neurological injury, shredded catheters, and malpositioned subcutaneous pockets
vii. The incidence of superficial or deep infection after placement of IDDS ranges from 2% to 5% based on case series with results from more than 100 patients. The risk of deep infections including epidural abscess and meningitis ranges from 0% to 0.5% in the same series.
viii. Patient-specific complications include possible hormonal fluctuations with opioid therapy. For instance, follicle-stimulating hormone, luteinizing hormone, testosterone, and growth hormone levels may decrease, inducing symptoms such as fatigue, reduced libido, and sexual dysfunction

Other policies

1) **NICE 2016**
    a. Intrathecal chemotherapy is in the treatment guideline for non-Hodgkin lymphoma
2) **NICE 2012 (https://www.nice.org.uk/guidance/cg145)**
    a. Consider treatment with continuous pump-administered intrathecal baclofen in children and young people with spasticity if, despite the use of non-invasive treatments, spasticity or dystonia are causing difficulties with any of the following:
        i. pain or muscle spasms
        ii. posture or function
        iii. self-care (or ease of care by parents or carers)
    b. Be aware that children and young people who benefit from continuous pump administered intrathecal baclofen typically have:
        i. moderate or severe motor function problems (GMFCS level III, IV or V)
        ii. bilateral spasticity affecting upper and lower limbs.
    c. Be aware of the following contraindications to treatment with continuous pump-administered intrathecal baclofen:
        i. the child or young person is too small to accommodate an infusion pump
        ii. local or systemic intercurrent infection.
    d. Be aware of the following potential contraindications to treatment with continuous pump-administered intrathecal baclofen:
        i. co-existing medical conditions (for example, uncontrolled epilepsy or coagulation disorders)
        ii. a previous spinal fusion procedure
        iii. malnutrition, which increases the risk of post-surgical complications (for example, infection or delayed healing)
        iv. respiratory disorders with a risk of respiratory failure.
    e. If continuous pump-administered intrathecal baclofen is indicated in a child or young person with spasticity in whom a spinal fusion procedure is likely to be necessary for scoliosis, implant the infusion pump before performing the spinal fusion.
    f. When considering continuous pump-administered intrathecal baclofen, balance the benefits of reducing spasticity against the risk of doing so because spasticity sometimes supports function (for example, by compensating for muscle weakness). Discuss these possible adverse effects with the child or young person and their parents or carers.

g. Before making the final decision to implant the intrathecal baclofen pump, perform an intrathecal baclofen test to assess the therapeutic effect and to check for adverse effects.
h. When deciding whether the response to intrathecal baclofen is satisfactory, assess the following where relevant to the treatment goals:
    i. reduction in spasticity
    ii. reduction in dystonia
    iii. reduction in pain or muscle spasms
    iv. improved posture, including head control
    v. improved function
    vi. improved self-care (or ease of care by parents or carers).

3) Aetna 2017 (http://www.aetna.com/cpb/medical/data/100_199/0161.html)

a. *Anti-spasmodic drugs*
    i. Aetna considers an implantable infusion pump medically necessary when used to intrathecally administer anti-spasmodic drugs (e.g., baclofen) to treat chronic intractable spasticity in persons who have proven unresponsive to less invasive medical therapy as determined by the following criteria:
        1. Member has failed a six-week trial of non-invasive methods of spasticity control, such as oral anti-spasmodic drugs, either because these methods fail to adequately control the spasticity or produce intolerable side effects; *and*
        2. Member has a favorable response to a trial intrathecal dosage of the anti-spasmodic drug prior to pump implantation.
    ii. Intrathecal baclofen (Lioresal) is considered medically necessary for the treatment of intractable spasticity caused by spinal cord disease, spinal cord injury, or multiple sclerosis and for stiff person syndrome. Baclofen is considered medically necessary for persons who require spasticity to sustain upright posture, balance in locomotion, or increased function.
    iii. Documentation in the member's medical record should indicate that the member's spasticity was unresponsive to other treatment methods and that the oral form of baclofen was ineffective in controlling spasticity or that the member could not tolerate the oral form of the drug. A trial of oral baclofen is not a required prerequisite to intrathecal baclofen therapy in children ages 12 years old or less due to the increased risk of adverse effects from oral baclofen in this group.
    iv. The medical record should document that the member showed a favorable response to the trial dosage of the baclofen before subsequent dosages are considered medically necessary. An implanted pump for continuous fusion is considered not medically necessary for members who do not respond to a 100 mcg intrathecal bolus.
    v. Intrathecal baclofen is considered experimental and investigational as a treatment for neuromyotonia (Isaac's syndrome), hydrocephalus, and rheumatoid arthritis.
b. *Drugs for treatment of chronic intractable pain*
    i. A preliminary trial of intraspinal (epidural or intrathecal) administration of opioid drugs (e.g., morphine), ziconotide (Prialt), and/or clonidine is considered medically necessary for persons with of severe chronic intractable pain of

malignant or non-malignant origin that is unresponsive to less invasive medical therapy *and*:

1. The member's history must indicate that he or she has not responded adequately to non-invasive methods of pain control, such as systemic opioids (including attempts to eliminate physical and behavioral abnormalities which may cause an exaggerated reaction to pain).
2. An implantable infusion pump is considered medically necessary when used to administer opioid drugs (e.g., morphine), ziconotide (Prialt), and/or clonidine intrathecally or epidurally for treatment of severe chronic intractable pain of malignant or non-malignant origin in persons who meet criteria above and where the following criteria are met:
    a. a preliminary trial of intraspinal opioid drug administration with a temporary intrathecal/epidural catheter has substantiated adequately acceptable pain relief with a 50 percent reduction in pain, the degree of side effects (including effects on the activities of daily living), and acceptance; and
    b. For nonmalignant pain only,a psychological evaluation has been obtained and indicates that the individual is a favorable candidate for permanent intrathecal pump implantation
3. Implantable infusion pumps for intrathecal or epidural infusion of opioids, ziconotide, and clonidine are considered experimental and investigational as a treatment for gastroparesis and for all other indications because their effectiveness for indications other than the one listed above has not been established. (Note: Currently, morphine and ziconotide are the only FDA-approved analgesics for long-term intrathecal infusion [Turk et al, 2011]).

c. *Contraindications to implantable infusion pumps*
    i. Implantable infusion pumps are considered not medically necessary for persons with the following contraindications to implantable infusion pumps:
        1. Members who have an active infection that may increase the risk of the implantable infusion pump; *or*
        2. Members whose body size is insufficient to support the weight and bulk of the device; *or*
        3. Members with known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.); *or*
        4. Members with other implanted programmable devices where the crosstalk between devices may inadvertently change the prescription

d. *Experimental and investigational uses of implanted infusion pumps*
    i. Implanted infusion pumps are considered experimental and investigational for all other indications, including *any* of the following:
        1. Implantable infusion pumps for intrahepatic administration of chemotherapy for indications other than noted above, including treatment of hepatic metastases from cancers other than colorectal cancer; *or*
        2. Implantable pumps for the infusion of heparin for recurrent thromboembolic disease; *or*
        3. Implantable pumps for the infusion of insulin to treat diabetes; *or*

4. Implantable pumps for the infusion of baclofen for chronic neuropathic pain (e.g., complex regional pain syndrome/reflex sympathetic dystrophy).

HERC staff summary: Based on trusted sources, intrathecal pumps appear to be efficacious for treatment of spasticity. Intrathecal pumps are reportedly used for administration of chemotherapy in non-Hodgkin's Lymphoma. Cancer related pain appears to be a questionable indication, with limited evidence supporting its use. However, most expert guidelines generally support the use of intrathecal opioid administration in cancer patients who cannot tolerate or get inadequate analgesia from systemic opioid therapy and who have life-limiting active disease. Use for non-cancer chronic pain has poor evidence of efficacy. There are significant complications associated with intrathecal pumps, including CNS infections, respiratory depression and death. There was a significantly increased mortality seen in patients using intrathecal opioid pumps compared to patients receiving oral opioids for chronic non-cancer pain.

HERC staff recommendations**:**

1) Remove the following CPT codes from line 290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT. Only allow maintenance and removal of such pumps on this line.
    a. 62350 Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; without laminectomy
    b. 62351 …with laminectomy
    c. 62360 Implantation or replacement of device for intrathecal or epidural drug infusion; subcutaneous reservoir
    d. 62361 …nonprogrammable pump
    e. 62362 …programmable pump, including preparation of pump, with or without programming
2) Add ICD-10 Z45.49 (Encounter for adjustment and management of other implanted nervous system device) to lines 75,97,130,239,242,290, 299,402,403,495
3) Add CPT 62350-62351, 62360-62362 to line 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS to allow use for spasticity conditions
4) Add CPT 62320-62323 (Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid) to line 495 SPASTIC DIPLEGIA to allow trials of medications are required in the new guideline
5) Adopt a new guideline as shown below regarding intrathecal or epidural medication infusion

GUIDELINE NOTE 169, TREATMENTS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

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

CONDITION	**CPT/HCPCS Code**	**TREATMENT**	**Rational**
Chronic non-malignant pain or any indication other than spasticity, pain due to active life-limiting malignancy, or treatment of active CNS malignancy	62350-62351, 62360-62362	Intrathecal or epidural drug infusion device insertion or replacement or revision	Significantly greater harms that other effective treatments

GUIDELINE NOTE XXX INTRATHECAL OR EPIDURAL DRUG INFUSION
Lines 75,97,130,239,242,290,297,299,402,403,495

Implantation, revision and replacement of devices for intrathecal or epidural drug infusion systems is only included on these lines when the patient meets the criteria for at least one of the categories below:

1) Placed for administration of baclofen for spasticity if
    a. The patient has had an adequate trial of non-invasive methods of spasticity control and not had adequate control of spasticity or had intolerable side effects with these methods, AND

   b. The spasticity is causing difficulties with at least one of the following:
      i. posture or function
      ii. balance in locomotion
      iii. self-care (or ease of care by parents or caregivers), AND
   c. The patient has a favorable response to a trial intrathecal dosage of the anti-spasmodic drug prior to pump implantation
2) Palliation for severe, intractable pain due to life-limiting active cancer which
   a. has not been responsive to non-invasive systemic pain control strategies or had intolerable side effects from such strategies , AND
   b. when a preliminary trial of intraspinal opioid drug administration with a temporary intrathecal/epidural catheter has substantiated adequately acceptable pain relief with a 50 percent reduction in pain, acceptable degree of side effects (including effects on the activities of daily living), and patient acceptance
3) Used for treatment of active CNS malignancy as part of a standard evidence-based protocol

Intrathecal or epidural drug infusion pump insertion, revision, and replacement are included on line 660 for use with chronic non-malignant pain and all other indications not listed above. See Guideline Note 169, TREATMENTS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS. Removal of pumps placed for such indications is included on line 290.

Maintenance (i.e. reprogramming, medication refill) of epidural or intrathecal medication infusion pumps is only included on these lines for patients who

1) have no significant complications with the current medication regimen, AND
2) who are receiving significant improvement in posture, function, or ability to perform ADLs, OR
3) who are undergoing treatment for active CNS malignancy as part of a standard evidence-based protocol.

Maintenance of these infusion systems may be paired with ICD-10 Z45.49 (Encounter for adjustment and management of other implanted nervous system device).

[Intervention Review]

Long-term opioid management for chronic noncancer pain

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ABSTRACT

Background

Opioid therapy for chronic noncancer pain (CNCP) is controversial due to concerns regarding long-term effectiveness and safety, particularly the risk of tolerance, dependence, or abuse.

Objectives

To assess safety, efficacy, and effectiveness of opioids taken long-term for CNCP.

Search methods

We searched 10 bibliographic databases up to May 2009.

Selection criteria

We searched for studies that: collected efficacy data on participants after at least 6 months of treatment; were full-text articles; did not include redundant data; were prospective; enrolled at least 10 participants; reported data of participants who had CNCP. Randomized controlled trials (RCTs) and pre-post case-series studies were included.

Data collection and analysis

Two review authors independently extracted safety and effectiveness data and settled discrepancies by consensus. We used random-effects meta-analysis' to summarize data where appropriate, used the I^2 statistic to quantify heterogeneity, and, where appropriate, explored heterogeneity using meta-regression. Several sensitivity analyses were performed to test the robustness of the results.

Main results

We reviewed 26 studies with 27 treatment groups that enrolled a total of 4893 participants. Twenty five of the studies were case series or uncontrolled long-term trial continuations, the other was an RCT comparing two opioids. Opioids were administered orally (number of study treatments groups [abbreviated as "k"] = 12, n = 3040), transdermally (k = 5, n = 1628), or intrathecally (k = 10, n = 231). Many participants discontinued due to adverse effects (oral: 22.9% [95% confidence interval (CI): 15.3% to 32.8%]; transdermal:

12.1% [95% CI: 4.9% to 27.0%]; intrathecal: 8.9% [95% CI: 4.0% to 26.1%]); or insufficient pain relief (oral: 10.3% [95% CI: 7.6% to 13.9%]; intrathecal: 7.6% [95% CI: 3.7% to 14.8%]; transdermal: 5.8% [95% CI: 4.2% to 7.9%]). Signs of opioid addiction were reported in 0.27% of participants in the studies that reported that outcome. All three modes of administration were associated with clinically significant reductions in pain, but the amount of pain relief varied among studies. Findings regarding quality of life and functional status were inconclusive due to an insufficient quantity of evidence for oral administration studies and inconclusive statistical findings for transdermal and intrathecal administration studies.

Authors' conclusions

Many patients discontinue long-term opioid therapy (especially oral opioids) due to adverse events or insufficient pain relief; however, weak evidence suggests that patients who are able to continue opioids long-term experience clinically significant pain relief. Whether quality of life or functioning improves is inconclusive. Many minor adverse events (like nausea and headache) occurred, but serious adverse events, including iatrogenic opioid addiction, were rare.

PLAIN LANGUAGE SUMMARY

Opioids for long-term treatment of noncancer pain

The findings of this systematic review suggest that proper management of a type of strong painkiller (opioids) in well-selected patients with no history of substance addiction or abuse can lead to long-term pain relief for some patients with a very small (though not zero) risk of developing addiction, abuse, or other serious side effects. However, the evidence supporting these conclusions is weak, and longer-term studies are needed to identify the patients who are most likely to benefit from treatment.

BACKGROUND

This systematic review differs in several ways from a previous systematic review on this topic that our group performed (Noble 2008). Because reviews in *The Cochrane Library* have fewer restrictions on the size of the review than a traditional peer-reviewed article, we were able to include the outcomes health-related quality of life and functional status in this review. The evidence base changed, with the inclusion of newly published studies (Collado 2008; Pascual 2007; Rauck 2008; Shaladi 2007; Thorne 2008) and non-English-language studies (Bettoni 2006; Klapetek 1971; Pimenta 1998), one study that we have reclassified as prospective (Kumar 2001), and one study that was not identified in our earlier searches (Thimineur 2004). In addition, two studies that were included in our previous review were excluded in this review, because we recently found that they were actually retrospective studies through personal communications with the study authors (Kanoff 1994; Tutak 1996). However, the differences in the studies that met general inclusion criteria did not impact the conclusions of the review in any important way. In addition, we updated our methodology to reflect more current methods by reducing the minimum number of studies needed to perform a meta-regression from 10 to five, implementing an updated quality-assessment approach using a revised instrument, not excluding studies with particularly low scores, and using each of the instrument items as a covariate to investigate heterogeneity where appropriate.

Chronic noncancer pain

The International Association for the Study of Pain (IASP) defines chronic pain as "pain which persists past the normal time of healing," which is considered to be pain lasting for three months or longer (IASP 1986). Chronic pain is a common problem worldwide. A World Health Organization survey of primary care patients seeking care at 15 centers in 14 countries across Asia, Africa, Europe, South America, and North America found that 22% of primary care patients reported pain lasting longer than 6 months (Gureje 1998). A systematic review of four international studies conducted in developed countries found prevalence rates of any type and severity level of chronic pain ranging from 10.5% to 55.2% of the population (Harstall 2003). The Pain in Europe survey of 46,000 individuals showed that one in five people suffer from chronic pain (Breivik 2006). In this survey, chronic pain sufferers reported 7 years of chronic pain on average, with some reporting pain lasting more than 20 years (Breivik 2006). An estimated 9% of Americans (Clark 2002) and 19% of Europeans (Breivik 2006) have moderate to severe chronic noncancer pain

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Intrathecal Drug Delivery System (IDDS) for Cancer Pain Management: A Review and Updates

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Abstract

Cancer pain remains undertreated and a significant number of patients with cancer pain die from severe untreated pain. With increasing survival rate in cancer, the prevalence of cancer pain is also increasing in number. Though majority of patients with cancer pain can be effectively treated with conventional medical management, still a significant portion of patients required some form of interventional pain management techniques. Among the interventional techniques, intrathecal drug delivery is increasingly used in cancer pain management. Our objective of this article is to review literatures and clinical studies on intrathecal drug delivery system (IDDS) in cancer pain management and to provide updates on its use, precautions, contraindications, side effects and its management, socioeconomic consideration, and management of IDDS in difficult or uncommon situations.

Keywords

cancer pain, intrathecal analgesia, intrathecal drug delivery system, interventional pain management, conventional medical management

Introduction

Despite the growing knowledge of pain pathways, receptors, neurotransmitters, neuromodulation, and availability of newer drugs and increasing awareness and education, cancer pain remains undertreated. A significant number of patients with cancer pain die from severe untreated pain despite effective multidisciplinary techniques that should treat these patients effectively.[1–3] The prevalence of cancer pain has been reported to be 30% to 40% in early stage which increases to 70% to 90% in advanced stage[4] and chronic pain after cure of cancer might be as high as 33%.[5] Per data from American Cancer Society, 5-year survival in patients with cancer has increased from 50% in 1975 to 1977 to 68% in 1999 to 2006.[6] These figures indicate that with increased cancer survival rate there will be a proportionate increase in the prevalence of cancer pain, which implies that more number of patients with cancer will require one or other modalities of pain management. Despite these fearful data, majority of patients (85%-90%) with cancer pain can be effectively treated using conventional analgesics by following the guideline of World Health Organization (WHO).[7,8] a minor but significant number of patients (10%-15%) require some form of advanced or interventional pain management modalities for effective control of their pain.[3,9] In a prospective study by Zech et al of 2118 patients with cancer pain managed by the WHO guidelines, 8% required nerve blocks, 3% neurolytic blocks, and 3% spinal analgesia (epidural/intrathecal [IT]) as interventional analgesic techniques.[7] The true incidence of patients requiring interventional analgesic techniques remains unknown because of varying inclusion criteria and practices in different centers. Implantable IT drug delivery system (IDDS) has been used in various chronic painful conditions for more than 30 years. Intrathecal drugs (opioid with or without adjuvant might be an effective option in selected group of patients with cancer pain refractory to conventional medical management.[10] The aim of this article is to review literatures and past studies and reports and to discuss its uses, side effects, and complications and their management.

Concept of IT Polyanalgesia

The concept of IT polyanalgesia following IT injection of morphine was started in 1979 by Wang et al who conducted a double-blind study and injected IT morphine in 8 cancer

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Review

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Spinal opioids in adult patients with cancer pain: A systematic review: A European Palliative Care Research Collaborative (EPCRC) Opioid Guidelines Project

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On behalf of the European Palliative Care Research Collaborative (EPCRC)

Abstract

Background: A systematic review, undertaken according to an initiative to revise European Association for Palliative Care guidelines on the use of opioids for cancer pain, which aimed to analyse analgesic efficacy and side effects of spinal opioids in adult cancer patients previously treated with systemic opioids.

Methods: Search strategy elaborated with MeSH terms and words related to cancer, palliative care, pain, spinal route and opioids. PubMed, Embase and Cochrane assessed in Nov 2009. Studies were analysed and classified according to quality of evidence and strength of recommendation.

Results: Out of 2939 abstracts, 44 articles were selected (nine randomized controlled trials (RCTs), two non-randomized cohort studies, 28 uncontrolled prospective studies, and five case series). Relief of pain and/or side effects were reported in 42 articles; however, there were few studies of high quality design (RCTs) and these studies had methodological limitations that reduced their quality of evidence to very low.

Conclusion: There are few RCTs and these are of very low quality. As a result, they provide weak recommendation for using spinal opioids in adult cancer patients. Further studies are clearly needed.

Keywords

Neoplasm, pain, opioids, epidural injections, spinal injections, palliative care

Introduction

Since the 1970s, when endogenous opioids and opioid receptors were first isolated in the central nervous system, attempts have been made to optimize opioid therapy by delivering opioids centrally rather than systemically. Although the vast majority of cancer patients obtain satisfactory pain relief from individualized systemic treatment,[1] there remain the few whose pain is refractory to systemic treatments.[2] These patients may obtain relief from neuraxial opioid therapy. For chronic use, spinal therapies (epidural or intrathecal catheters) are the most widely used of the neuraxial opioid therapies, and in many pain management and palliative care facilities spinal therapy is considered and used as an alternative treatment when systemic opioid treatment fails. A few systematic reviews of the literature have formerly assessed efficacy and side effects of spinal therapies, and a substantial number of, in particular, uncontrolled trials of

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[Intervention Review]

Intrathecal baclofen for treating spasticity in children with cerebral palsy

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ABSTRACT

Background

Cerebral palsy is a disorder of movement and posture arising from a non-progressive lesion in the developing brain. Spasticity, a disorder of increased muscle tone, is the most common motor difficulty and is associated with activity limitation to varying degrees in mobility and self care.

Oral baclofen, a gamma-aminobutyric acid (GABA) agonist, has been used in oral form to treat spasticity for some time, but it has a variable effect on spasticity and the dose is limited by the unwanted effect of excessive sedation. Intrathecal baclofen produces higher local concentrations in cerebrospinal fluid at a fraction of the equivalent oral dose and avoids this excessive sedation.

Objectives

To determine whether intrathecal baclofen is an effective treatment for spasticity in children with cerebral palsy.

Search methods

We searched the CENTRAL, MEDLINE, EMBASE and CINAHL databases, handsearched recent conference proceedings, and communicated with researchers in the field and pharmaceutical and drug delivery system companies.

Selection criteria

We included studies which compared the effect of intrathecal baclofen treatment on spasticity, gross motor function or other areas of function with controls.

Data collection and analysis

Two authors selected studies, two authors extracted data and two authors assessed the methodological quality of included studies.

Main results

Six studies met the inclusion criteria. The data obtained were unsuitable for the conduct of a meta-analysis; we have completed a qualitative summary.

All studies were found to have high or unclear risk of bias in some aspects of their methodology.

Five of the six studies reported data collected in the randomised controlled phase of the study. A sixth study did not report sufficient results to determine the effect of intrathecal baclofen versus placebo. Of these five studies, four were conducted using lumbar puncture or other short-term means of delivering intrathecal baclofen. One study assessed the effectiveness of implantable intrathecal baclofen pumps over six months.

The four short-term studies demonstrated that intrathecal baclofen therapy reduces spasticity in children with cerebral palsy. However, two of these studies utilised inappropriate techniques for statistical analysis of results. The single longer-term study demonstrated minimal reduction in spasticity with the use of intrathecal baclofen therapy.

One of the short-term studies and the longer term study showed improvement in comfort and ease of care. The longer term study found a small improvement in gross motor function and also in some domains of health-related quality of life.

Some caution is required in interpreting the findings of the all the studies in the review due to methodological issues. In particular, there was a high risk of bias in the methodology of the longer term study due to the lack of placebo use in the control group and the absence of blinding to the intervention after randomisation for both participants and investigators.

Authors' conclusions

There is some limited short-term evidence that intrathecal baclofen is an effective therapy for reducing spasticity in children with cerebral palsy. The effect of intrathecal baclofen on long-term spasticity outcomes is less certain.

The validity of the evidence for the effectiveness of intrathecal baclofen in treating spasticity in children with cerebral palsy from the studies in the review is constrained by the small sample sizes of the studies and methodological issues in some studies.

Spasticity is a impairment in the domain of body structure and function. Consideration must also be given to the broader context in determining whether intrathecal baclofen therapy is effective. The aim of therapy may be, for example, to improve gross motor function, to increase participation at a social role level, to improve comfort, to improve the ease of care by others or to improve the overall quality of life of the individual. Intrathecal baclofen may improve gross motor function in children with cerebral palsy, but more reliable evidence is needed to determine this.There is some evidence that intrathecal baclofen improves ease of care and the comfort and quality of life of the individuals receiving it, but again small sample sizes and methodological issues in the studies mean that these results should be interpreted with caution.

Further evidence of the effectiveness of intrathecal baclofen for treating spasticity, increasing gross motor function and improving comfort, ease of care and quality of life is needed from other investigators in order to validate these results.

The short duration of the controlled studies included in this review did not allow for the exploration of questions regarding whether the subsequent need for orthopaedic surgery in children receiving intrathecal baclofen therapy is altered, or the safety and the economic implications of intrathecal baclofen treatment when long-term therapy is administered via an implanted device. Controlled studies are not the most appropriate study design to address these questions, cohort studies may be more appropriate.

PLAIN LANGUAGE SUMMARY

Intrathecal baclofen for treating spasticity in children with cerebral palsy

Spasticity, which is an increase in muscle tone, is the most common difficulty with movement seen in children with cerebral palsy. Baclofen is a medication which acts on receptors in the brain and spinal cord to reduce abnormal muscle tone. It has been used as an oral medication for many years. The disadvantages of oral administration are that only a small amount of the medication crosses the blood-brain barrier before it can exert an effect, and that the dose is limited by the unwanted effect of excessive sedation. The administration of baclofen into the fluid surrounding the spinal cord overcomes these problems. This treatment is called intrathecal baclofen therapy and it is administered via a pump placed under the skin connected to a catheter which enters the membranes covering the spinal cord to deliver the baclofen directly into the fluid surrounding the spinal cord and brain.

This review concludes that there is a small amount of evidence from studies performed to date that intrathecal baclofen is an effective treatment for reducing spasticity in children with cerebral palsy in the short-term. The effect of intrathecal baclofen on spasticity in children with cerebral palsy over the long term is less clear.

Two short-term studies (by the same investigators) demonstrate a reduction in spasticity, but a single, longer term study shows minimal evidence for reduced spasticity with the use of intrathecal baclofen. Two further short-term studies showed reduction in spasticity with

[Intervention Review]

Pharmacological interventions for spasticity following spinal cord injury

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ABSTRACT

Background

Spasticity is a major health problem for patients with a spinal cord injury (SCI). It limits their mobility and affects their independence in activities of daily living (ADL) and work. Spasticity may also cause pain, loss of range of motion, contractures, sleep disorders and impair ambulation in patients with an incomplete lesion. The effectiveness of available drugs is still uncertain and they may cause adverse effects. Assessing what works in this area is complicated by the lack of valid and reliable measurement tools. The aim of this systematic review is to critically appraise and summarise existing information on the effectiveness of available treatments, and to identify areas where further research is needed.

Objectives

To assess the effectiveness and safety of baclofen, dantrolene, tizanidine and any other drugs for the treatment of long-term spasticity in SCI patients, as well as the effectiveness and safety of different routes of administration of baclofen.

Search strategy

We searched the Cochrane Injuries Group Specialised Register, CENTRAL, MEDLINE/PubMed, EMBASE, Zetoc, Web of Knowledge, CINAHL and Current Controlled Trials. We also checked the reference lists of relevant papers to identify any further studies. The searches were last conducted in July 2008.

Selection criteria

All parallel and cross-over randomised controlled trials (RCTs) including spinal cord injury patients complaining of 'severe spasticity'. Studies where less than 50% of patients had a spinal cord injury were excluded.

Data collection and analysis

Methodological quality of studies (allocation concealment, blinding, patient's characteristics, inclusion and exclusion criteria, interventions, outcomes, losses to follow up) was independently assessed by two investigators. The heterogeneity among studies did not allow quantitative combination of results.

Main results

Nine studies met the inclusion criteria. Study designs were: 8 cross-over and 1 parallel-group trial. Two studies (14 SCI patients), showed a significant effect of intrathecal baclofen in reducing spasticity (Ashworth Score and ADL performances), compared to placebo, without any adverse effects. The study comparing tizanidine to placebo (118 SCI patients) showed a significant effect of tizanidine in improving Ashworth Score but not in ADL performances. The tizanidine group reported significant rates of adverse effects (drowsiness, xerostomia). For the other drugs (gabapentin, clonidine, diazepam, amytal and oral baclofen) the results did not provide evidence for clinically significant effectiveness.

Authors' conclusions

There is insufficient evidence to assist clinicians in a rational approach to antispastic treatment for SCI. Further research is urgently needed to improve the scientific basis of patient care.

PLAIN LANGUAGE SUMMARY

Not enough evidence about the effects of drugs used to try and reduce spasticity in the limbs after spinal cord injury

A major problem after spinal cord injury is muscle resistance to having the arms or legs moved (spasticity). There can also be spasms. This can severely limit a person's mobility and independence, and can cause pain, muscle problems, and sleep difficulties. Treatments to try and reduce spasticity include exercise, and drugs to try and decrease the muscle tone. The review found there was not enough evidence from trials to assess the effects of the range of drugs used to try and relieve spasticity after spinal cord injury. The authors of the review call for more research and make recommendations as to how this research should be conducted.

BACKGROUND

Spasticity is a major health problem for patients with a spinal cord injury (SCI). In a study reporting the incidence of spasticity one year after SCI, 67% of patients had developed spasticity associated with involuntary uncontrolled movements (spasms), 37% received antispastic medication, and 11% failed to respond to the treatment (Maynard 1990).

In a database of self-reported secondary medical problems, 99 SCI patients reported spasticity as the main complication (53%), followed by pain (44%), and pressure ulcers (38%) (Walter 2002). The prevalence of secondary impairments in long standing SCI has been studied on 482 individuals via a mailed questionnaire. Spasticity was the second most reported complication (40%) after urinary tract infections. Spasticity was more frequent in patients with quadriplegia and in cases with incomplete lesion (Frankel B and C). Moreover, there was a significant association between the occurrence of secondary impairment and perceived health status and personal income (Noreau 2000).

Spasticity severely limits patients' mobility and positioning, and affects independence in activities of daily living (ADL) and work. Spasticity may also cause pain, loss of range of motion, contractures, sleep disorders and impaired ambulation in patients with an incomplete lesion. The usual approach to treating spasticity relies on trying to decrease muscle tone with physical exercises and medication (baclofen, dantrolene sodium, diazepam, clonidine) used as monotherapy or in combination.

More recently, new medications have been proposed (tizanidine, cannabinoid (Campbell 2001), 4-aminopyridine (Donovan 2000), botulinum toxin (Richardson 2000)), as well as older drugs (i.e. baclofen) via new administration routes such as an implanted intrathecal pump (Creedon 1997). The effectiveness of these drugs is still uncertain and they may cause adverse effects. Assessing what works in this area is further complicated by the lack of valid and reliable measurement tools able to capture the whole spectrum of impairment caused by the condition, rather than just assessing the severity of spasticity (Priebe 1996).

Why it is important to do this review

Physical Therapy for Interstitial Cystitis

Question: Should physical therapy (PT) be paired with interstitial cystitis?

Question source: HSD claims reconsideration

Issue: HSD has received several requests for physical therapy to treat interstitial cystitis. Interstitial cystitis is also known as bladder pain syndrome (BPS), a type of chronic pain that affects the bladder. Symptoms include feeling the need to urinate urgently, needing to urinate often, and pain with sex. IC/BPS is associated with depression and lower quality of life. Many of those affected also have irritable bowel syndrome and/or fibromyalgia. There is no cure for interstitial cystitis. Treatments that may improve symptoms include lifestyle changes, medications, or procedures. Lifestyle changes may include stopping smoking and reducing stress. Medications may include ibuprofen, pentosan polysulfate, or amitriptyline. Procedures may include bladder distention, nerve stimulation, or surgery. Pelvic floor exercises (Kegels) and long-term antibiotics are not recommended.

N30.1 (Interstitial cystitis (Chronic)) is on line 332 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION. Various procedures are included on this line, but not physical therapy.

The CPT codes specifically appearing on HSD claims are 97140 (Manual (physical) therapy techniques to 1 or more regions, each 15 minutes) and 97161-97164 (Physical therapy evaluation and re-evaluation), which appear on many lines on the Prioritized List.

Evidence:

1) **Pazin 2016**, systematic review of treatments for interstitial cystitis
    a. FitzGerald et al (2012) compared massage therapy with myofascial physiotherapy. Multi-center RCT, N=81 (42 PT vs 39 massage), 10 sixty minute sessions over 12 weeks. They reported that in the massage therapy group, bladder pain and voiding frequency decreased by 25.86 % and 10.48 % respectively, and that in the myofascial physiotherapy group, greater decreases of 37.70 % and 14.70 % respectively were observed.
    b. No other studies met inclusion criteria

Guidelines:

1) **Hanno 2014**, American Urological Association guideline on interstitial cystitis
    a. First line treatments include education, behavioral modifications, and stress management
    b. Second line treatments include:
        i. Appropriate manual physical therapy techniques (e.g., maneuvers that resolve pelvic, abdominal and/or hip muscular trigger points, lengthen muscle contractures, and release painful scars and other connective tissue

restrictions), if appropriately-trained clinicians are available, should be offered to patients who present with pelvic floor tenderness. Pelvic floor strengthening exercises (e.g., Kegel exercises) should be avoided. *Clinical Principle Standard (Evidence Strength- Grade A)*

1. Based on the Fitzgerald 2012 RCT findings only

ii. Noted: Very importantly, there is no evidence that physical therapy aimed at pelvic floor strengthening (such as Kegel exercises) can improve symptoms, and in fact this type of pelvic floor therapy may worsen the condition.

iii. Appropriate manual physical therapy techniques include maneuvers that resolve pelvic, abdominal and/or hip muscular trigger points, lengthen muscle contractures, and release painful scars and other connective tissue restrictions. Unfortunately, appropriate physical therapy expertise and experience is not available in all communities. In the absence of appropriate expertise, routine forms of pelvic physical therapy that are primarily aimed at strengthening of the pelvic floor are not recommended.

2) **Cox 2016**, Canadian Urologic Association guideline on interstitial cystitis/bladder pain syndrome (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5065402/pdf/cuaj-5-6-e136.pdf)

a. *Physiotherapy and massage (RECOMMENDED for patients with pelvic floor dysfunction, Grade A)*

i. Many IC/BPS patients have high-tone pelvic floor muscle dysfunction (PFD). Those patients who have tenderness on physical exam might benefit from various physical therapy techniques, including: physiotherapy (± biofeedback); myofascial tender points release; or intravaginal Thiele massage. Various techniques have been described that involve skillful, hands-on maneuvers directed toward relaxation, elongation, stretching, and massaging of tightened muscles. Physical therapists with expertise in pelvic floor muscle relaxation should be involved. Evidence supporting this management option in IC/BPS is more robust, with RCTs and prospective case series reporting moderate or marked improvement of symptoms in 50–62% of patients and an additional 21% of patients having complete resolution of symptoms in one study.

Other policies:

1) Major insurers cover pelvic physical therapy for interstitial cystitis

HERC staff summary: Based on expert guidelines, physical therapy is recommended for treatment of interstitial cystitis in those patients with tenderness as a primary symptom. This expert recommendation is based mainly on a single RCT. Appropriately trained physical therapists are required as inappropriate PT can be harmful. Many alternative, far more invasive therapies are available on the current line for pairing with interstitial cystitis.

Physical Therapy for Interstitial Cystitis

HERC staff recommendations:

1) Add pelvic physical therapy to line 332 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION (CPT codes below are included for pelvic PT on the urinary incontinence line and gender dysphoria lines).
    a. CPT 97140 Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), one or more regions, each 15 minutes
    b. CPT 97161-97164 Physical therapy evaluation or reevaluation
    c. Do not include exercise based PT (e.g. Kegels) as such therapy has been shown to be harmful. These CPT codes are on the urinary incontinence and gender dysphoria lines
        i. CPT 97110 Therapeutic procedure, one or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
        ii. CPT 97530 Therapeutic activities, direct (one on one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes
2) Adopt a new guideline note for line 332 as shown below
    a. Multiple other diagnoses are included on line 332 which are not appropriate for pairing with pelvic PT

GUIDELINE NOTE XXX PELVIC PHYSICAL THERAPY FOR INTERSTITIAL CYSTITIS

Line 332

Pelvic physical therapy (CPT 97140 and 97161-97164) is included on this line only for treatment of interstitial cystitis in patients who present with pelvic floor tenderness. Such pelvic PT is only included on this line when provided by professionals trained and experienced in pelvic floor therapy and as limited in Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES.

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REVIEW ARTICLE

Treatment of bladder pain syndrome and interstitial cystitis: a systematic review

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Abstract
Introduction and hypothesis Bladder pain syndrome/interstitial cystitis (BPS/IC) has various treatments; however, no standardized treatment has been established. The aim was to analyze different types of treatment of BPS/IC and their effectiveness.
Methods A literature review with a search strategy for articles related to BPS/IC published between 1990 and 2014 was conducted on MEDLINE, PUBMED, and SCOPUS. Only randomized controlled trials in women were included in the meta-analysis, while other experimental studies were used as bases for a systematic review of the topic. Clinical trial quality was defined according to the Jadad scale.
Results Of 356 articles, 13 were included in the analysis. The intervention methods were as follows: instillation of hyaluronic acid, botulinum toxin A, intravesical lidocaine, hyperbaric chamber, massage, physiotherapy, phosphate-buffered saline, piroxicam in combination with doxepin, and others. We did not find any treatment with at least two randomized controlled trials for meta-analysis. Among the assessment tools for symptoms of BPS/IC, the most frequently used were the visual analogue scale, voiding record, and the O'Leary–Sant questionnaire.
Conclusion Existing studies were not able to define the best approach for the treatment of BPS/IC. The lack of standardized treatment may be related to the diversity of interventions used; therefore, further studies with better methodological quality are needed.

Keywords Bladder pain syndrome · Interstitial cystitis · Drug treatment · Prospective and clinical trials

Introduction

Chronic pelvic pain (CPP) is characterized by severe, acyclic pain in the lower abdomen or pelvis that lasts for at least 6 months, which can interfere with daily activities and thus requires medical or surgical treatment [1, 2]. Its etiology is not clear and often results from a complex interaction among the gastrointestinal, urinary, neurological, gynecological, and musculoskeletal systems, being further influenced by psychological and sociocultural factors [3].

Some interaction with other organs is possible, such as the urinary tract, in which case bladder pain syndrome or interstitial cystitis (BPS/IC) can develop [4]. IC is more restricted to cases with cystoscopic and histological findings typical of the disease (Hunner's ulcers) [5]. The International Society for the Study of BPS (ESSIC) chose to use the name "bladder pain syndrome" for the clinical picture, with typical findings that are combined with voiding urgency or frequent voiding associated with CPP.

Bladder pain syndrome/interstitial cystitis is a condition that results in discomfort or recurrent abdominal and pelvic pains in the absence of urinary tract infections. The change in symptomatology includes discomfort, increased bladder pressure, sensitivity and intense pain in the bladder and pelvic areas, increased voiding frequency and urgency, or a combination of these symptoms. The pain often worsens during menstruation and may intensify during intercourse (National Institute of Diabetes and Digestive and Kidney Diseases

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Approved by the AUA Board of Directors September 2014

Authors' disclosure of potential conflicts of interest and author/staff contributions appear at the end of the article.

This document was amended in 2014 to reflect literature that was released since the original publication of this guideline.

Note to the Reader:

As of December 5, 2014, the Panel has updated this Guideline to indicate suggested dosing of triamcinolone, which reflects the expert opinion of the Panel.

DIAGNOSIS AND TREATMENT OF INTERSTITIAL CYSTITIS/BLADDER PAIN SYNDROME

Philip M. Hanno, David Allen Burks, J. Quentin Clemens, Roger R. Dmochowski, Deborah Erickson, Mary Pat FitzGerald, John B. Forrest, Barbara Gordon, Mikel Gray, Robert Dale Mayer, Robert Moldwin, Diane K. Newman, Leroy Nyberg Jr., Christopher K. Payne, Ursula Wesselmann, Martha M. Faraday

Purpose: The purpose of this Guideline is to provide a clinical framework for the diagnosis and treatment of interstitial cystitis/bladder pain syndrome (IC/BPS).

Methods: A systematic review of the literature using the MEDLINE® database (search dates 1/1/83-7/22/09) was conducted to identify peer-reviewed publications relevant to the diagnosis and treatment of IC/BPS. Insufficient evidence was retrieved regarding diagnosis; this portion of the guideline, therefore, is based on Clinical Principles and Expert Opinion. The review yielded an evidence base of 86 treatment articles after application of inclusion/exclusion criteria. The AUA update literature review process, in which an additional systematic review is conducted periodically to maintain guideline currency with newly-published relevant literature, was conducted in July 2013. This review identified an additional 31 articles relevant to treatment. These publications were used to create the majority of the treatment portion of the guideline. When sufficient evidence existed, the body of evidence for a particular treatment was assigned a strength rating of A (high), B (moderate), or C (low). Additional treatment information is provided as Clinical Principles and Expert Opinion when insufficient evidence existed. See text and algorithm for definitions and detailed diagnostic, management, and treatment frameworks.

GUIDELINE STATEMENTS

Diagnosis:

1. The basic assessment should include a careful history, physical examination, and laboratory examination to rule in symptoms that characterize IC/BPS and rule out other confusable disorders (see text for details). *Clinical Principle*

2. Baseline voiding symptoms and pain levels should be obtained in order to measure subsequent treatment effects. *Clinical Principle*

3. Cystoscopy and/or urodynamics should be considered as an aid to diagnosis only for complex presentations; these tests are not necessary for making the diagnosis in uncomplicated presentations. *Expert Opinion*

Treatment:

Overall Management:

4. Treatment strategies should proceed using more conservative therapies first, with less conservative therapies employed if symptom control is inadequate for acceptable quality of life; because of their irreversibility, surgical treatments (other than fulguration of Hunner's lesions) are appropriate only after other

Acute Peripheral Nerve Injuries

Question: How should the intent of the Plastic Surgery ICD-10 review group be clarified regarding coverage of repair of acute peripheral nerve injuries?

Question source: HERC staff; Tracy Muday, OHP medical director

Issue: in 2012, the Plastic Surgery ICD-10 review group proposed the addition of a new line to allow coverage of acute peripheral nerve injuries. At that time, peripheral nerve injuries were included in two lines (one medical, one surgical) which were both below the funding line. The intent of the review group was to allow coverage for repair of acute injuries (initially defined as <8 weeks, later extended to <6 months). The rationale for this change was "If you don't repair a nerve, you will have a residual defect. If upper extremity is desensate, will significantly impact functionality."

It was not noted, or possibly not recognized, during this review that many nerve injuries are also included, with appropriate repair CPT codes, on line 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT.

The diagnoses suggested for this new line were S74.00xA-S74.11x (Injury of sciatic nerve, Injury of femoral nerve). Also mentioned in the review materials were S44.00xA-S44.42xA / S54.00xA-S54.22xA / S64.00xA-S64.498A (Injury of ulnar nerve, Injury of median nerve, Injury of radial nerve, Injury of axillary nerve, Injury of musculocutaneous nerve) and S94.00xA-S94.22xA (Injury of lateral plantar nerve, Injury of medial plantar nerve, Injury of deep peroneal nerve). However this series of codes was never adopted for this line, although it appears to be the intent of the review group. The diagnoses were noted to come from the two peripheral enthesopathy lines (now 490 and 508), and were supposed to stay on these lines. These diagnoses do not currently appear on the enthesopathy lines and do not appear to have ever been on those lines. These diagnoses only currently appear on line 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT.

The new line has CPT codes from then line 531 PERIPHERAL ENTHESOPATHIES Treatment: SURGICAL TREATMENT, which contain the vast majority of nerve repair CPT codes.

The guideline proposed by the review group and accepted in modified form by HERC included references to two lines (now lines 512 PERIPHERAL NERVE DISORDERS Tx MEDICAL TREATMENT and 539 PERIPHERAL NERVE DISORDERS Tx SURGICAL TREATMENT). However, the diagnoses included on line 431 ACUTE PERIPHERAL MOTOR AND DIGITAL NERVE INJURY do not appear on either of these lines, and never did.

At some point, line 519 PHLEBITIS AND THROMBOPHLEBITIS, SUPERFICIAL was mistakenly added to GN 133. There is no mention in any minutes of this addition and it appears to be in error. Additionally, line 489 BELL'S PALSY, EXPOSURE KERATOCONJUNCTIVITIS also now appears in the guideline, although it does not contain appropriate diagnoses.

Acute Peripheral Nerve Injuries

From the ICD-10 Plastic Surgery review group recommendations:
Line XXX
Condition: ACUTE PERIPHERAL NERVE INJURY
Treatment: SURGICAL THERAPY

ICD10: S74.00xA-S74.11x
CPT codes: CPT codes from line 531

Create a new line with diagnoses from lines 516 PERIPHERAL ENTHESOPATHIES Treatment: MEDICAL THERAPY and line 531 PERIPHERAL ENTHESOPATHIES Treatment: SURGICAL TREATMENT. The new line would be a surgical only line. The diagnoses on this line would stay on the current lines (516 and 531). Rationale: in the acute setting, urgent treatment can prevent lifelong complications and/or disability.

PLACED SENSORY NERVES ON LOWER LINES (535, 557) WITH THE EXCEPTION OF DIGITAL NERVES, WHICH REMAIN ON ACUTE NERVE INJURY LINE

S44.00xA-S44.42xA
S54.00xA-S54.22xA
S64.00xA-S64.498A
Codes S94.00xA-S94.22xA

The following guideline would apply to the new line

GUIDELINE NOTE XXX ACUTE PERIPHERAL NERVE INJURY
Line XXX

Repair of acute peripheral nerve injuries are included on line XXX (now 431 ACUTE PERIPHERAL MOTOR AND DIGITAL NERVE INJURY). Non-surgical medical care of these injuries are covered on line 535 (now 512 PERIPHERAL NERVE DISORDERS Tx MEDICAL TREATMENT). Chronic nerve injuries are covered on line 557 (now 539 PERIPHERAL NERVE DISORDERS Tx SURGICAL TREATMENT).

Note: this guideline was revised during the VBBS/HERC meetings to include a definition of acute nerve injury (originally <8 weeks, revised later to <6 months).

Rescoring recommendations
Category 7
Impact on Healthy Life Years 4
Rationale: If you don't repair a nerve, you will have a residual defect. If upper extremity is desensate, will significantly impact functionality
Impact on Pain and Suffering 1
Population effects 0
Vulnerable 0
Tertiary Prevention 1
Effectiveness 3
Need for service 0.90
Net cost 2
Score 324
Line 450

Current Prioritized List status:
Line 431 contains the following diagnosis codes:
G57.2 (Lesion of femoral nerve) [also on 512,539]
S74.0 (Injury of sciatic nerve at hip and thigh level) [also on 212]
S74.1 (Injury of femoral nerve at hip and thigh level) [also on 212]

Line 212 contains the following diagnosis codes:
S44.00xA-S44.42xA
S54.00xA-S54.22xA
S64.00xA-S64.498A
S94.00xA-S94.22xA

The following CPT codes appear on line 212 and line 431 (as well as other lines):
64xxx series (suture of nerve, nerve grafts, nerve repair)

HERC staff recommendations:

1) Biennial Review 2020 (effective January 1, 2020):
    a. Delete line 431 ACUTE PERIPHERAL MOTOR AND DIGITAL NERVE INJURY
        i. All diagnoses are already on line 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT other than G57.2 (Lesion of femoral nerve); all appropriate CPT repair codes appear on line 212
        ii. Add ICD-10 G57.2 (Lesion of femoral nerve) to line 212
    b. Modify GN133 as shown below:
        i. The lines referenced are:
            1. 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT
            2. 431 ACUTE PERIPHERAL MOTOR AND DIGITAL NERVE INJURY
            3. 489 BELL'S PALSY, EXPOSURE KERATOCONJUNCTIVITIS
            4. 512 PERIPHERAL NERVE DISORDERS Tx MEDICAL TREATMENT
            5. 519 PHLEBITIS AND THROMBOPHLEBITIS, SUPERFICIAL
            6. 539 PERIPHERAL NERVE DISORDERS Tx SURGICAL TREATMENT

GUIDELINE NOTE 133, ACUTE PERIPHERAL MOTOR AND DIGITAL NERVE INJURY

Lines 212,~~431,489,~~512,~~519,~~539

Repair of acute (<6 months) peripheral nerve injuries are included on Line 212 ~~and 431~~. Non-surgical medical care of these injuries are included on Line 512 ~~489~~. Surgical repair of c~~C~~hronic nerve injuries are included on Line~~s 512, 519 and~~ 539.

2) Interim modification (effective October 1, 2017)
    a. Add peripheral nerve injury ICD-10 codes as proposed by the ICD-10 Plastic Surgery review group to lines 512 PERIPHERAL NERVE DISORDERS Tx MEDICAL TREATMENT and 539 PERIPHERAL NERVE DISORDERS Tx SURGICAL TREATMENT:
        i. S44.00xA-S44.42xA / S54.00xA-S54.22xA / S64.00xA-S64.498A (Injury of ulnar nerve, Injury of median nerve, Injury of radial nerve, Injury of axillary nerve, Injury of musculocutaneous nerve)
        ii. S94.00xA-S94.22xA (Injury of lateral plantar nerve, Injury of medial plantar nerve, Injury of deep peroneal nerve).
    b. Add additional peripheral nerve injury ICD-10 codes from line 431 to lines 512 PERIPHERAL NERVE DISORDERS Tx MEDICAL TREATMENT and 539 PERIPHERAL NERVE DISORDERS Tx SURGICAL TREATMENT
        i. S74.0 (Injury of sciatic nerve at hip and thigh level)
        ii. S74.1 (Injury of femoral nerve at hip and thigh level)
    c. Revise GN133 as shown below.
        i. The lines referenced are:
            1. 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT
            2. 431 ACUTE PERIPHERAL MOTOR AND DIGITAL NERVE INJURY

3. 512 PERIPHERAL NERVE DISORDERS Tx MEDICAL TREATMENT
4. 539 PERIPHERAL NERVE DISORDERS Tx SURGICAL TREATMENT

ii. The removed lines are

1. 519 PHLEBITIS AND THROMBOPHLEBITIS, SUPERFICIAL
2. 489 BELL'S PALSY, EXPOSURE KERATOCONJUNCTIVITIS

GUIDELINE NOTE 133, ACUTE PERIPHERAL MOTOR AND DIGITAL NERVE INJURY

Lines 212,431,~~489,~~512,~~519,~~539

Repair of acute (<6 months) peripheral nerve injuries are included on Line 212 and 431. Non-surgical medical care of these injuries are included on Line 512 ~~489~~. Surgical repair of c~~C~~hronic nerve injuries are included on Line~~s 512, 519 and~~ 539.

Testicular Prosthetics

Question: Should testicular prosthetics be covered for reconstruction after various testicular surgeries or be considered cosmetic?

Question source: Ellen Pinney, OHA ombudsperson

Issue: Testicular prosthetics are covered after testicular removal for torsion or surgery for undescended testicle. However, they are not covered after surgery for testicular cancer or for gender dysphoria. Ms. Pinney contacted the HERC on behalf of a patient with testicular cancer who had a request for a testicular prosthetic denied as being cosmetic.

Review of minutes finds that testicular prosthetic insertion as a separate procedure (CPT 54660 Insertion of testicular prosthesis (separate procedure)) was added to the testicular torsion and undescended testes lines with the creation of the original Prioritized List in 1994. The placement of a prosthetic done at the time of orchiectomy (CPT 54520 Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach) is covered for a wide variety of indications.

The addition of testicular prosthetics (CPT 54660) was originally approved for the gender dysphoria line in 2013 and was in place until October 2016, when it was removed as part of a discussion regarding non-coverage for penile prostheses. This removal from the gender dysphoria line appears to be an error, as this CPT code does not relate to penile prostheses in any way.

Most private insurers and other state Medicaid programs consider testicular prosthesis medically necessary for replacement of congenitally absent testes, or testes lost due to disease, injury, or surgery. Some require documentation of detrimental psycho-social sequelae with documentation from a psychiatric evaluation. Breast reconstruction after mastectomy is covered by federal mandate.

According to internet search information, for out-of-pocket payment the total cost of a testicular prosthesis placement surgery is approximately $3,000. Oregon Medicaid reimburses $254, not including the cost of anesthesia, facility fees, etc.

Testicular Prosthetics

CPT code	Code description	Current line(s)
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach	98 UNDESCENDED TESTICLE 116 CANCER OF TESTIS 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT 250 TORSION OF TESTIS 263 CANCER OF PENIS AND OTHER MALE GENITAL ORGANS 317 GENDER DYSPHORIA/TRANSEXUALISM 332 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION 334 CANCER OF PROSTATE GLAND 473 GONADAL DYSFUNCTION, MENOPAUSAL MANAGEMENT
54522	Orchiectomy, partial	98,116,250,263 586 BENIGN NEOPLASM OF MALE GENITAL ORGANS: TESTIS, PROSTATE, EPIDIDYMIS
54530	Orchiectomy, radical, for tumor; with abdominal exploration	116,263
54535	Orchiectomy, radical, for tumor; with abdominal exploration	116, 263
54660	Insertion of testicular prosthesis (separate procedure)	98, 250
54690	Laparoscopy, surgical; orchiectomy	98, 116, 429 ADRENOGENITAL DISORDERS, 473

<u>HERC staff recommendations</u>:

1) Add CPT 54660 (Insertion of testicular prosthesis (separate procedure)) to the following lines. This list should cover all cancer and traumatic loss of testicles and return coverage for gender dysphoria as previously intended by the HERC
    a. 116 CANCER OF TESTIS
    b. 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT
    c. 263 CANCER OF PENIS AND OTHER MALE GENITAL ORGANS
    d. 317 GENDER DYSPHORIA/TRANSEXUALISM
2) Add CPT 54660 to the following lines to match the placement of immediate placement of prosthesis after orchiectomy:
    a. 332 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
    b. 334 CANCER OF PROSTATE GLAND
    c. 473 GONADAL DYSFUNCTION, MENOPAUSAL MANAGEMENT

Capsulorrhaphy for Recurrent Shoulder Dislocation

Question: should capsulorrhaphy be a covered procedure for recurrent shoulder dislocation?

Question source: HSD claims reconsideration

Issue: Capsulorrhaphy is a surgical technique which uses thermal energy to treat several types of shoulder instability. The procedure uses heat to shrink and tighten the shoulder capsule, which is the connective tissue around the shoulder joint that helps to keep it stable. Thermal capsular shrinkage was developed as a less invasive way to treat a shoulder that is loose or frequently dislocates. Early short-term results with thermal capsulorrhaphy were encouraging, and the procedure rapidly gained in popularity. However, more recent results with patients over a longer follow-up period have shown a much higher failure rate than was first seen. Also, more complications have been reported (American Academy of Orthopedic Surgeons, http://orthoinfo.aaos.org/topic.cfm?topic=a00034).

HSD has received multiple requests for coverage of capsulorrhaphy for recurrent shoulder dislocation. Currently, capsulorhapthy is only on line 423 DISORDERS OF SHOULDER, INCLUDING SPRAINS/STRAINS GRADE 4 THROUGH 6. Recurrent should dislocation is on line 364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS. Currently on line 364 is CPT 29806 Arthroscopy, shoulder, surgical; capsulorrhaphy.

A review of the literature did not find other indications for capsulorrhaphy other than for recurrent shoulder dislocation.

CPT code	Code Description
23462	Capsulorrhaphy, anterior, any type; with coracoid process transfer
23465	Capsulorrhaphy, glenohumeral joint, posterior, with or without bone block
23466	Capsulorrhaphy, glenohumeral joint, any type multi-directional instability

Evidence

1) **Longo 2015**, systematic review of repair of shoulder instability
    a. N=24 articles comparing patients with open or arthroscopic repair or with conservative treatment of multidirectional instability (MDI)
        i. N=861 shoulders in 790 patients
        ii. Median follow up 4.2 years
    b. The redislocation event occurred in 17 of 226 (7.5%) shoulders with open capsular shift management, in 21 of 268 (7.8%) shoulders with arthroscopic plication management, in 12 of 49 (24.5%) shoulders undergoing arthroscopic thermal shrinkage, and in 11 of 55 (22%) shoulders undergoing arthroscopic laser-assisted capsulorrhaphy. Conclusions: Arthroscopic capsular plication and open capsular shift are the best surgical procedures for treatment of MDI after failure of rehabilitative management. Arthroscopic capsular plication shows results comparable to open capsular shift. Level of Evidence: Level IV, systematic review of Level I to IV studies.

Capsulorrhaphy for Recurrent Shoulder Dislocation

HERC staff summary:
Capsulorrhaphy has good short-term results but worse long-term outcomes than open surgical repair for recurrent should dislocation—there appears to be a 3 fold increase in redislocation with capsulorrhaphy or other thermal shrinkage techniques compared to open procedures. There are also multiple case reports in the literature of complications from this procedure.

HERC staff recommendations:

1) Do not add capsulorrhaphy to line 364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS
    a. More effective surgical procedures are available for treatment of recurrent shoulder dislocation
2) Remove CPT 29806 (Arthroscopy, shoulder, surgical; capsulorrhaphy) from line 364 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS
    a. Open surgical techniques have better long term outcomes and fewer complications
3) Remove CPT 23462-23466 (Capsulorrhaphy) from line 423 DISORDERS OF SHOULDER, INCLUDING SPRAINS/STRAINS GRADE 4 THROUGH 6
    a. Only used for shoulder dislocation treatment; these diagnoses are not present on line 423
4) Add CPT 23462-23466 (Capsulorrhaphy) and 29806 (Arthroscopy, shoulder, surgical; capsulorrhaphy) to line 500
5) Add an entry to GN168 as shown below

GUIDELINE NOTE 168, TREATMENTS WITH MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS FOR CERTAIN CONDITIONS

The following treatments are prioritized on Line 500 for the conditions listed here:

CONDITION	**CPT/HCPCS code**	**TREATMENT**	**Rationale**
Shoulder dislocation	29806, 23462-23466	Capsulorrhaphy	More effective treatments are available

Systematic Review

Multidirectional Instability of the Shoulder: A Systematic Review

Umile Giuseppe Longo, M.D., M.Sc., Ph.D., Giacomo Rizzello, M.D., Mattia Loppini, M.D., Joel Locher, M.D., Stefan Buchmann, M.D., Nicola Maffulli, M.D., M.S., Ph.D., and Vincenzo Denaro, M.D.

Purpose: To analyze outcomes of surgical and conservative treatment options for multidirectional instability (MDI). **Methods:** A systematic review of the literature according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines was performed. A comprehensive search of the PubMed, MEDLINE, CINAHL, Cochrane, EMBASE, and Google Scholar databases using various combinations of the keywords "shoulder," "multidirectional instability," "dislocation," "inferior instability," "capsulorrhaphy," "capsular plication," "capsular shift," "glenoid," "humeral head," "surgery," and "glenohumeral," over the years 1966 to 2014 was performed. **Results:** Twenty-four articles describing patients with open capsular shift, arthroscopic treatment, and conservative or combined management in the setting of atraumatic MDI of the shoulder were included. A total of 861 shoulders in 790 patients was included. The median age was 24.3 years, ranging from 9 to 56 years. The dominant side was involved in 269 (58%) of 468 shoulders, whereas the nondominant side was involved in 199 (42%) shoulders. Patients were assessed at a median follow-up period of 4.2 years (ranging from 9 months to 16 years). Fifty-two of 253 (21%) patients undergoing physiotherapy required surgical intervention for MDI management, whereas the overall occurrence of redislocation was seen in 61 of 608 (10%) shoulders undergoing surgical procedures. The redislocation event occurred in 17 of 226 (7.5%) shoulders with open capsular shift management, in 21 of 268 (7.8%) shoulders with arthroscopic plication management, in 12 of 49 (24.5%) shoulders undergoing arthroscopic thermal shrinkage, and in 11 of 55 (22%) shoulders undergoing arthroscopic laser-assisted capsulorrhaphy. **Conclusions:** Arthroscopic capsular plication and open capsular shift are the best surgical procedures for treatment of MDI after failure of rehabilitative management. Arthroscopic capsular plication shows results comparable to open capsular shift. **Level of Evidence:** Level IV, systematic review of Level I to IV studies.

See commentary on page 2444

Multidirectional instability (MDI) of the shoulder was initially described by Neer and Foster in 1980 as instability in 2 or more directions.[1] In the medical literature, a number of definitions exist for MDI, making classification of these patients difficult and leading to considerable variation of an MDI diagnosis. The precise incidence of MDI of the glenohumeral joint is unknown. In 2008 in Norway, 7% of operations for shoulder instability were caused by MDI.[2] Among sedentary individuals, the condition is more common in young women with poor muscular development. MDI often affects athletic or active individuals, even without generalized joint laxity, who participate in sports or work requiring repetitive overhead movements.[3] After the age of 40 years, the condition is less common because of the natural stiffening of tissues around the shoulder.

Since the initial description, research in basic science and clinic evidence have contributed to a better understanding of glenohumeral stability and MDI. Congenital hyperlaxity,[4] muscular disbalance, and bony and capsulolabral anatomy (labral hypoplasia, glenoid size)[5] may lead to recurrent dislocation

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Transcutaneous Neurostimulators

Question: Should transcutaneous electrical nerve stimulation [TENS], Scrambler therapy, and all similar transcutaneous neurostimulators be added to the new treatments with no clinically important benefit line?

Question source: HSD staff, HERC staff, Jay Richards, DO

Issue: During the initial creation of the Prioritized List in 1999, TENS was considered for the above the line spinal conditions lines and neurologic dysfunction lines but not added. TENS was last reviewed in February, 2010 and found to have no evidence of effectiveness.

From the HOSC February, 2010 minutes

TENS

Smits introduced a summary document reviewing the evidence for the effectiveness for TENS treatment for chronic and acute pain conditions. The HOSC found lack of evidence of effectiveness. Saha reported on a review of back pain treatments by Chou et al in the 2007 Annals of Internal Medicine, which found no benefit for TENS for acute or chronic back pain. The HOSC members agreed that this service should not be covered due to lack of effectiveness. Smits reported that there were additional CPT/HCPCS codes which were not included in the handout that needed to be added to the Never Covered List if TENS is not to be covered. Recommendations:

1) Delete 64550 (Application of surface (transcutaneous) neurostimulator) from Lines 522, 551 and 622. Recommend adding 64550 (Application of surface (transcutaneous) neurostimulator) to Never Covered List.
2) Delete 97032 from all 57 lines on Prioritized List. Recommend adding 97032 to Never Covered List
3) Recommend adding HCPCS codes A4556-A4558, A4595, A4630, E0720, E0730, E0731 to Never Covered List

Currently, all cutaneous neurostimulator CPT and HCPCS codes are on the Services Recommended for Non-Coverage table.

64550 Application of surface (transcutaneous) neurostimulator
97014 Application of a modality to 1 or more areas; electrical stimulation (unattended)
97032 Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
E0720 Transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation
E0730 Transcutaneous electrical nerve stimulation (tens) device, four or more leads, for multiple nerve stimulation
G0283 Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care

GUIDELINE NOTE 56, NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE includes the following sentence:

> Transcutaneous electrical nerve stimulation (TENS; CPT 64550, 97014 and 97032) is not included on the Prioritized List for any condition due to lack of evidence of effectiveness.

Federal rule no longer allows absolute exclusion for DME. Therefore the GN56 sentence is in conflict with federal rule.

In May, 2017, a similar technology, Alpha Stim, was reviewed and found to have no evidence of effectiveness. The following entry was added to GN 169:

GUIDELINE NOTE 169, TREATMENTS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

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

CONDITION	CPT/HCPCS Code	TREATMENT	Rational
Chronic pain, anxiety, depression, insomnia, all other indications	CPT 64550, 97014, 97032 HCPCS E0720, E0730	Cranial electrical stimulation	No clinically important benefit for chronic pain; insufficient evidence of effectiveness for all other indications

Scrambler Therapy

Recently, the HERC has been contacted about Scrambler therapy, which is a similar electrical stimulation device used to treat chronic pain. It is coded with CPT 0278T (Transcutaneous electrical modulation pain reprocessing (e.g, scrambler therapy), each treatment session (includes placement of electrodes)). Scrambler therapy is a noninvasive pain modifying technique that utilizes transcutaneous electrical stimulation of pain fibers with the intent of re-organizing maladaptive signaling pathways. It is used to treat various types of chronic pain.

From Jay Richards, DO:

> Currently Radiant Pain center in Portland and myself are the only providers in Oregon using this treatment.
>
> As a primary care provider in a rural area it has been a huge struggle to provide pain relief options for many of our OHP patients. The population that has been the hardest to treat are those suffering for neuropathic pain. A disproportionately large number of these patients are on chronic narcotics, despite evidence to show this class of medication isn't indicated. Many also do not get improvement from commonly used medication like gabapentin, the expensive Lyrica and other treatments like physical therapy, chiropractic's and acupuncture. Promoting exercise in this population is also challenging because the pain is aggravated with movement, which leads to increased sedentary lifestyle.
>
> In 2015, I came across a noninvasive, low risk treatment called Scrambler Therapy. It uses electrical impulses delivered through electrodes attached to different dermatomes in areas of normal skin, surrounding the area of neuropathy. The theory is this specialized signal scrambles the burning nerve pain signal delivered by the c-delta pain fibers, which is the hallmark of neuropathy. Over a series of 10 consecutive treatments the burning pain progressively reduces in intensity. After the patient has been without pain for 48 hours the pain is considered to be "in remission".
>
> I met with the device vendor and set up a small demo on a couple of my patients. All of them felt the device helped their pain the first day, but what sold me was one patient with severe diabetic neuropathy returned the following morning asking if he could continue the treatment. Seeing his benefit I decided to proceed with the purchase of the device and start an after-hours pain treatment clinic for community patients with neuropathy.
>
> Over the course of 2016 I have seen 26 patients. Of these, 12 were eligible for treatment due to having an appropriate condition and ability to pay a sliding fee, which ranged from pro-bono to $150 per treatment session. All patients had a comprehensive review of their pain and medications. Only those with symptoms of neuropathy and an elevated DN4 score, where able to proceed with treatment.

The average pain score for the 12 patients prior to the first treatment was 7/10. Of the 12 treated, 5 did not have sustained pain improvement beyond the full 10 treatment course, despite the average pain level during treatment being reduced to 2/10. Interestingly, and what I find to be the most rewarding, is 7 of the 12 patients who completed the full course of treatment achieved pain scores ranging from 0-2/10, which where sustained from 3 months to over a year after treatment.

Several patients were also able to reduce or eliminate their medications. Four patients stopped their narcotic and the fifth one is working to reduce her dependence on oxycodone. Also 2 prescriptions for Lyrica were stopped. All 7 with improved pain have increased their activity level and one is actively seeking a job after 8 years of unemployment due to his diabetic neuropathy.

Participating in this treatment and experiencing these patient's improvement has been very rewarding. My experience treating patients with Scrambler Therapy is this can be a viable option for patients with neuropathy, particularly diabetic and chemotherapy induced neuropathy. It is noninvasive and a very low risk procedure. It does not treat all pain and patients should be screened well before starting treatment. The treatment is also very provider dependent so success depends both on treating the correct type of pain and placing the electrodes in the correct locations.

I recognize higher power studies are needed to show better evidence-based practice. Hopefully, over the next couple years we will see randomized trials published from Mayo Clinic and Johns Hopkins, who are currently studying Scrambler Therapy.

<u>Evidence</u>

1) **Majithea 2016**, systematic review of Scrambler therapy
    a. Note: no studies identified which were not included in this systematic review
    b. N=20 studies
        i. 2 RCTs (N=14 patients in abstract only paper, N=30 patients in published trial), 1 open label RCT (N=52 patients), 11 prospective cohort studies (N=477 patients, 10 in abstract only paper), 5 "clinical practice experience" articles (N=417 patients), 1 retrospective cohort study (N=201 patients)
        ii. Studies of "varying clinical quality"
        iii. Studies generally small and short-term, and most lacked a comparator group and were not randomized.
    c. Results:
        i. RCTs: one study found no difference between treatment and placebo arms (Campbell 2013, N=14, abstract only), the other found significant improvement in reported pain in active treatment group compared to placebo treated group (Starkweather 2015, N=30)

1. The Starkweather study was small and short term and the authors concluded that further research was needed

ii. Other articles found significant reduction in pain scores

d. Conclusions: The positive findings from preliminary studies with Scrambler Therapy support that this device provides benefit for patients with refractory pain syndromes. Larger, randomized studies are required to further evaluate the efficacy of this approach.

Other policies:
Most major insurers do not cover Scrambler therapy

Clinical practice guidelines: none found recommending Scrambler therapy

HERC staff summary:
The evidence base regarding the benefits of transcutaneous electrical modulation pain reprocessing (i.e., scrambler therapy) as a treatment for pain from any etiology is extremely limited. Early, pilot studies with small numbers of patients treated for short periods of time are promising, but larger, well conducted, randomized trials are needed. There are no clinical practice guidelines that recommend scrambler therapy and major insurers are not covering this therapy. Based on the limited literature, scrambler therapy appears to be investigational.

HERC staff recommendations:

1) Add CPT 64550, 97014 and 97032 and HCPCS E0720, E0730, and G0283 (Transcutaneous electrical nerve stimulation [TENS]; electrical stimulation) to line 660 CONDITIONS FOR WHICH CERTAIN TREATMENTS HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
2) Add CPT 0278T (Transcutaneous electrical modulation pain reprocessing (e.g, scrambler therapy), each treatment session (includes placement of electrodes)) to line 660
3) Delete the following sentence from GUIDELINE NOTE 56, NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE
~~Transcutaneous electrical nerve stimulation (TENS; CPT 64550, 97014 and 97032) is not included on the Prioritized List for any condition due to lack of evidence of effectiveness.~~
4) Modify the entry to GN169 adopted in May, 2017 as shown below

GUIDELINE NOTE 169, 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, for the conditions listed here:

CONDITION	CPT/HCPCS Code	TREATMENT	Rational	Date of last Review
All conditions ~~Chronic pain, anxiety, depression, insomnia, all other indications~~	64550, 97014, 97032, 0278T E0720, E0730, and G0283	Transcutaneous electrical nerve stimulation [TENS]; Scrambler therapy; Cranial electrical stimulation; all similar transcutaneous electrical neurostimulation therapies	No clinically important benefit (CES) or insufficient evidence of effectiveness (all other) for chronic pain; insufficient evidence of effectiveness for all other indications	August, 2017

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REVIEW ARTICLE

Scrambler Therapy for the management of chronic pain

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Abstract
Purpose Chronic pain is a widespread and debilitating condition, encountered by physicians in a variety of practice settings. Although many pharmacologic and behavioral strategies exist for the management of this condition, treatment is often unsatisfactory. Scrambler Therapy is a novel, non-invasive pain modifying technique that utilizes transcutaneous electrical stimulation of pain fibers with the intent of re-organizing maladaptive signaling pathways. This review was conducted to further evaluate what is known regarding the mechanisms and mechanics of Scrambler Therapy and to investigate the preliminary data pertaining to the efficacy of this treatment modality.
Methods The PubMed/Medline, SCOPUS, EMBASE, and Google Scholar databases were searched for all articles published on Scrambler Therapy prior to November 2015. All case studies and clinical trials were evaluated and reported in a descriptive manner.
Results To date, 20 reports, of varying scientific quality, have been published regarding this device; all but one small study, published only as an abstract, provided results that appear positive.
Conclusion The positive findings from preliminary studies with Scrambler Therapy support that this device provides benefit for patients with refractory pain syndromes. Larger, randomized studies are required to further evaluate the efficacy of this approach.

Keywords Scrambler Therapy · Pain · Chronic pain · Chemotherapy-induced peripheral neuropathy

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Introduction

Chronic pain is estimated to affect 100 million people in the USA alone, resulting in up to $635 billion in medical expenses and lost productivity each year. [1] It predisposes to psychiatric comorbidity, and its massive impact is highlighted by the fact that it is the most common cause of long-term disability in the USA [2].

In simplest terms, pain can be defined as a bodily sensation experienced during genuine, or perceived, tissue injury [3]. In the acute setting, this sensation can serve as a protective role by alerting an individual to avoid potentially harmful stimuli and to protect the body during healing. When pain fails to communicate biologically useful or accurate information, it is maladaptive and thereby becomes a disease state in its own right. It is generally agreed that pain becomes "chronic" when it persists beyond the expected period of tissue injury and healing. The specific duration of symptoms required to

qualify for a diagnosis of chronic pain is debatable, but generally is considered to be in the range of 3 to 6 months [4].

The perception of noxious stimuli originates from nociceptors of the peripheral nervous system. Nociceptors recognize stimuli in the form of thermal, mechanical, or chemical inputs. The stimulation leads to activation of primary sensory nerve fibers that transmit this information to the central nervous system, via a complex network of interneurons housed predominantly in the dorsal root ganglia, posterior horn of the spinal cord, brain stem, and thalamus. Ultimately, signals reach the forebrain for interpretation of the sensory experience. There are multiple mechanisms that underlie the dysregulation of this system in chronic pain. In the setting of injury, for example, inflammatory changes in the biochemical milieu surrounding peripheral nerves can result in hypersensitization of nociceptors, such that pain signals are communicated in the absence of appropriate stimuli [5]. Neurons surrounding damaged tissue have even shown the ability to develop spontaneous discharges that communicate pain information in the absence of external input [6]. Similarly, spinal cord neurons in the central nervous system exposed to repetitive pain stimuli may undergo changes that result in transmission of action potentials with a reduced threshold of synaptic input [7].

Currently, several treatment modalities exist for the management of chronic pain, including physical therapy, pharmacologic therapy, behavioral medicine, neuromodulation, minimally-invasive interventions, and surgery. Unfortunately, the heterogeneous nature of chronic pain syndromes and the lack of a functional understanding of chronic pain contribute to the absence of a clearly identifiable, appropriate management strategy for many patients. Nonetheless, pharmacologic measures are commonly prescribed as a component of chronic pain management. With many medications available, such as non-steroidal anti-inflammatory agents, anticonvulsants, antidepressants, and opioids, it is exceedingly common for patients to use multiple agents to try to achieve reasonable pain control. [8].

Recognizing the limitations and hazards of polypharmacy, increasing emphasis has been placed on the non-pharmacologic options for management of persistent pain. A strategy combining psychological and physical medicine approaches can provide significant benefit for many patients [9]. Neuromodulatory techniques, particularly since the commercial availability of wearable transcutaneous electrical nerve stimulation (TENS) units in the mid-1970s, have gained popularity as an adjunct to both pharmacological and non-pharmacologic pain managements [10]. While promising in theory, the scientific data supporting such methods remain limited, without consistently-shown benefit, underscoring the need for novel therapeutic options [11, 12].

The aim of this paper is to review what is known about the mechanism of a relatively new neuromodulatory approach, Scrambler Therapy, and discuss the trials and clinical experience, published to date, regarding its use.

Methods

Reports regarding Scrambler Therapy were identified by a combination of database search, communication with investigators, and reviewing bibliographies of previously published manuscripts (Fig. 1). Several databases were utilized in the literature search, including PubMed/Medline, SCOPUS, EMBASE, and Google Scholar. Search terms including "Scrambler Therapy" and "Calmare" were used to identify all articles published prior to November 1, 2015. The search was refined with the use of Boolean terminology, specifically "Scrambler Therapy OR Calmare," which yielded the largest number of articles. Results of these studies were reviewed and reported with an analytic intent that was primarily descriptive.

Scrambler Therapy development and mechanisms

Giuseppe Marineo, a biophysicist who developed an interest in treating chronic pain, developed Scrambler Therapy and conducted basic and applied research related to its use. Marineo claims that chronic pain is the consequence of a phenomenon produced by the persistence in time of pain pathway activation, a typical condition of neuropathies. This process results in a loss of the linearity in the cause–effect relation that characterizes the physiological acute pain (which is

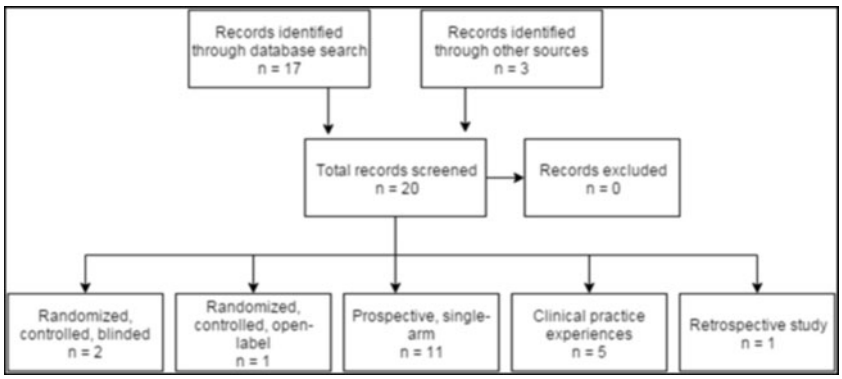

Fig 1 Flowchart depicting search methodology and records included in qualitative analysis

protective) and creates a new type of nonlinear behavior of the pain system, that tends to self-sustain an anomalous response to painful and non-painful stimuli. Marineo proposes that the entire chronic pain process can be controlled by intervening on the afferent information aspects of pain, the variable that characterizes and mainly regulates every activity of the nervous system and represents its natural cybernetic expression [13]. In short, Scrambler Therapy's active principle is information control that manipulates the modulation or remodulation of the pain system, and its physiological or pathological responses, in line with plastic properties of the nervous system. More specifically, a Scrambler Therapy unit is composed of five electrical stimulation channels that, through the surface receptors of C fibers, replace the endogenous pain information with a synthetic one of "non-pain" or "normal-self" that travels through the same pain pathways to the brain. Through plasticity within brain networks mediating the perception of pain, a series of treatments "retrain" the brain so that the area of concern is no longer considered painful. Marineo proposes that his functioning principle, like its neurophysiological target that uses receptors of C fibers, replaces the chronic pain information, rather than attempting to block its ascending path. An in-depth analysis on these differences is described in the International Patent PCT/IT2007/000647 and U.S. Patent No. 8,380,317.

Scrambler Therapy has also drawn comparisons to spinal cord stimulation, which is another interventional technique that has been utilized in the treatment of refractory chronic pain. Spinal cord stimulation has been proven to be efficacious in a diverse array of pain syndromes, including refractory angina, failed back syndrome, and complex regional pain syndrome (CRPS), with the ability to reduce pain intensity in some cases by over 50 % [14]. The drawback of this approach has largely been its invasiveness and cost.

What is the normal course of Scrambler Therapy?

Several authors of the present manuscript utilize Scrambler Therapy in clinical practice. Information in the following section is derived from their experience in treating hundreds of patients for a variety of pain syndromes. A patient treated with Scrambler Therapy has the area of pain identified and then has electrodes placed on normal tissue around the painful site. The electrodes are not placed at the site of actual pain, but, instead, placed at a nearby location of preserved sensation. The dermatomal location is to feed this "non-pain" confusing information into the regular nervous circuit using peripheral nerves, rather than accessing the spinal cord. The intensity of stimulation is adjusted according to patient comfort and, if the placement is correct, pain will usually be replaced by the Scrambler device sensation, which is often described as "pleasant, vibratory, and/or humming". Up to the full set of five sets of electrodes can be used to treat the area(s) of pain. The device is allowed to run for a total of 30–45 min once the electrodes have been optimally positioned and stimulation intensity correctly regulated. After a session's completion, patients may report a soothing sensation and note that the pain has been markedly reduced or has disappeared entirely.

The benefit from Scrambler Therapy, after the first treatment, generally lasts for a relatively short period of time. When treatment is reinitiated the next day, the same process happens, but the benefit generally lasts longer, e.g., for a few hours. In most cases, if the treatment has been given properly, with each treatment session, the non-pain (or meaningful relief) timeframe is extended. The duration of posttreatment relief classically lengthens with continued treatments until, ideally, the benefit is maintained throughout the entire day. Usually, Scrambler Therapy is given for a total of ten treatment sessions on consecutive weekdays, if feasible, although some patients need fewer and some patients need more treatments. Pain relief can be expected to persist for weeks to months after treatment is stopped. When patients relapse, booster sessions can be administered. It may only take one or two booster sessions to re-establish the benefit that previously occurred, and this benefit may last for a substantial period of time (oftentimes months or longer).

Scrambler Therapy is an operator-dependent methodology. Treatment success is highly dependent on the ability of the operator to eliminate pain during each single treatment without any significant patient discomfort. Failure to completely resolve pain in a treated area (or have a Visual Analog Score < =1) during each treatment session may lead to less satisfactory results. Experience has confirmed that more expert operators can eliminate pain during Scrambler Therapy when less experienced ones have failed. This may explain, in part, why data coming from different publications are relatively heterogeneous.

Scrambler Therapy clinical trials

To date, 20 trials/reports of Scrambler Therapy are available for review (Table 1) [13, 15–33]. Eighteen have been published as manuscripts [13, 17–33] and two only as abstracts [15, 16]. One is a retrospective study [33], five deal with clinical practice experiences [19, 21, 23, 26, 27], 11 are prospective single-arm clinical trials [13, 15, 17, 18, 22, 24, 25, 28, 30–32], one is a randomized open-label controlled trial [20], and two are randomized, blinded, placebo-controlled trials [16, 29].

The first trial was authored by the Scrambler Therapy developer, Marineo, in 2003 and reported the results of the treatment of 11 patients with cancer-associated, drug-resistant, visceral pain [13]. This manuscript noted that pain was quickly and markedly reduced in the studied patients, with 9 of 11 patients stopping the use of pharmacologic pain therapy altogether after the first five sessions, without any associated side

Table 1 Summary of Scrambler Therapy trials

	Reports, by first author	Year	Patients	Condition	Results	Trial type	Comments
1	Marineo [13]	2003	11	Drug-resistant visceral pain	Substantial pain reduction	Prospective trial	
2	Sabato [24]	2005	226	Multiple chronic pain syndromes	80 % of patients with greater than a 50 % pain reduction	Prospective trial	
3	Smith [30]	2010	18	Chemotherapy-induced neuropathy	Over 50 % reduction in pain	Prospective trial	16 evaluable
4	Abdi [15]	2011	10	Back pain	28 % reduction in pain	Prospective trial	Abstract only
5	Marineo [20]	2011	52	Post-herpetic neuralgia, spinal canal stenosis, and postsurgical neuropathic pain	Pain reduced more in Scrambler arm, than the control arm at 1 and 3 months ($P < 0.0001$)	Randomized, controlled trial	Open-label trial
6	Ricci [28]	2012	82	Various cancer and non-cancer pains	Mean pain scores dropped from 6.2/10 prior to treatment to 1.6 just after completing 10 treatment days to 2.9, 2 weeks after finishing treatment.	Prospective trial	73 evaluable patients
7	Ghatak [18]	2011	8	Chronic low back pain	Pain score drop from 8.12 to 6.93; Drop in Oswestry Disability Index from 49.88 to 18.44	Prospective trial	Open label
8	Sparadeo [27]	2012	173	Chronic pain >6 months	Marked pain reduction	Clinical practice experience	91 provided 3–6 months follow-up
9	Coyne [17]	2013	39	Cancer pain syndromes, including chemotherapy-induced neuropathy	Significant pain reduction with 10 treatment days that largely lasted for 3 months	Prospective trial	
10	Smith [25]	2013	10	Post-herpetic neuralgia	95 % pain reduction, that largely lasted for 3 months	Prospective trial data	Some patients were the same as in a previous trial [18]
11	Ko [19]	2013	3	Post-herpetic neuralgia	Marked pain reduction	Clinical practice experience	
12	Park [23]	2013	3	Cancer bone metastases	Marked pain reduction	Clinical practice experience	
13	Campbell [16]	2013	14	Chemotherapy-induced neuropathy	No differences between active and placebo arms	Prospective, double-blind, placebo-controlled trial	Abstract only
14	Pachman [22]	2014	37	Chemotherapy-induced neuropathy	Average pain decreased by 53 % at end of treatment and benefit largely remained for 10 weeks after completion.	Prospective trial	Decrease in tingling and numbness, too.
15	Sparadeo [26]	2014	91	Variety of pain syndromes	Substantial pain reduction	Clinical practice experience	Consecutive patients; Some patients were the same as in a previous trial [30]
16	Moon [21]	2014	147	Variety of pain syndromes		Clinical practice experience	
17	Starkweather [29]	2015	30	Low back pain	Significant improvements in active vs control group for: (1) worse pain and pain interference states; (2) pain sensitivity measures, and (3) differential mRNA expression of 17 pain genes	Prospective, double-blind, placebo-controlled trial	
18	Notaro [31]	2015	25	Bone and visceral metastases	All patients experienced at least a 50 % drop in pain scores, with average duration of response of 7.7 weeks; improved sleep performance	Prospective trial	
19	Compagnone [33]	2015	201	Variety of pain syndromes	Reduction from mean pain score of 7.41 at baseline to 1.6 following treatment	Retrospective cohort	
20	Lee [32]	2016	20	Various cancer-related pain syndromes	Mean pain score decreased from 7.4 to 3.7 by visit 3	Prospective, single-arm	

effects. Pain scores were reported to have decreased from approximately 8.5 out of 10, at study initiation, to approximately 0.5 out of 10, after 10 treatments. No adverse effects were reported.

A second trial was published in 2005, with Marineo as a co-author [24]. A total of 226 patients with neuropathic pain were treated, including patients with failed back surgery, brachial plexus neuropathy, and other chronic pain conditions. This trial, while also uncontrolled, was impressively large and reported that 80 % of subjects had at least a 50 % pain reduction and 10 % experienced a reduction of 25–49 %. Ten percent (10 %) had no appreciable response. No adverse effects were reported.

Additional groups became involved in the clinical evaluation of this therapy with the publication in 2010 of the first study that did not include Marineo as a co-author [30]. This was a pilot trial in 16 evaluable patients with chronic chemotherapy-induced peripheral neuropathy, conducted at Virginia Commonwealth University. The findings from this study were in line with the success seen with the previously reported trials. After ten treatments, the average reported pain score dropped nearly 60 %, with four patients achieving complete resolution of pain. Patients with recurrent pain were successfully retreated with 1–3 subsequent treatments.

The next trial, currently only available as an abstract, involved ten patients with failed back surgery treated by an anesthesiology-trained pain physician [15]. While it only noted a 28 % mean pain reduction, there were patients on this trial who had substantial relief after multiple other therapies had failed to provide benefit. The author of this abstract, a co-author on the present manuscript, notes that there are three reasons why his success rate might have been relatively low: (1) he had limited operator experience; (2) he included study subjects with multifactorial intractable pain despite intensive polypharmacy; and (3) treatment while adjuvant anticonvulsants were continued. Empiric observations have suggested less than optimal outcomes if these medications are not discontinued prior to treatment [21].

Marineo and colleagues published the first randomized, controlled trial in 2011, which involved 52 patients with chronic neuropathic pain related to postsurgical causes, postherpetic neuralgia, or spinal cord stenosis [20]. Scrambler Therapy was compared to a control arm that utilized standard pharmacologic guideline-based recommendations, including frequent phone calls to modify analgesics. The pain reduction, after finishing 10 days of treatment, was 28 % in the control group (pain scores dropped from 8.0 to 5.8 out of 10) compared to a 91 % reduction with the Scrambler group (pain scores dropped from 8.1 to 0.7; $p < 0.0001$). Pain scores in the control arm were 5.7 and 5.9 at 2 and 3 months, respectively, as opposed to 1.4 and 2.0 in the Scrambler group ($p < 0.0001$). Analgesic consumption, including opioids, antidepressants, and anticonvulsants, decreased by 72 % in the Scrambler group. Allodynia also was reduced in the Scrambler patients, from 77 % at baseline to 15 % at 3 months. Benefit was obtained relatively equally amongst patients of all of the three diagnostic categories.

The sixth trial involved 82 (73 evaluable) prospectively-treated patients, about half of whom had cancer-related pain [28]. Mean pain scores reduced from 6.2/10 before to 1.6/10 at the end of treatment and were 2.9/10 1 month after treatment was finished. Similar results were seen in patients with and without cancer. When patients were asked whether they would repeat this treatment, 97 % (71/73) responded affirmatively.

The seventh trial involved a cohort of eight patients treated with Scrambler Therapy for chronic low back pain [18]. Patients were treated for six consecutive days; pain scores were recorded prior to initiation of treatment and after each session. The mean pain score was 8.12/10 at baseline, dropping to 6.93/10 after the first treatment. The mean pain score dropped to 3.63/10 in day 6. The group also recorded the Oswestry Disability Index (ODI) and found that mean score dropped from 49.88/100 to 18.44/100 by the end of the study, signifying an average drop from severe to minimal disability.

The eighth investigation was a prospective trial that reported on a series of 39 patients with cancer pain syndromes, including 33 with chemotherapy-induced peripheral neuropathy [17]. Scrambler Therapy was associated with significant positive changes from baseline for a large number of outcomes, including degree of pain, interference with normal activities, and sensory neuropathy symptoms. The benefit persisted up to 3 months.

A small prospective trial published in 2013 involved 10 patients with post-herpetic neuralgia and included some data previously reported in another publication [25]. The work reported a 95 % reduction in pain scores at 1 month, with sustained benefit observed at 2 and 3 month follow-up times.

In 2014, a prospective pilot trial experience was published, involving the treatment of 37 patients with chemotherapy-induced peripheral neuropathy, noting about a 50 % reduction in pain, tingling, and numbness [22]. The increase in Scrambler benefit over the course of the trial suggested that, despite initial operator training in the administration of Scrambler Therapy, a learning curve was evident in this trial. The last 25 % of patients entered on this clinical trial did substantially better than did the first 25 % of patients, likely a reflection of improved technique afforded by greater experience.

The first attempt to compare Scrambler Therapy to a sham control was presented as an abstract at the 2013 Annual Meeting of the American Society of Clinical Oncology, involving 14 patients who were treated in a randomized, controlled, and double-blind manner [16]. Results from this study have not been published as a manuscript. While the authors did note that the sham treatment from this particular trial was believable, in that the patients could not more often detect

which of the two procedures was the true one, the authors did not observe any real improvements in neuropathy in the patients treated with the sham procedure versus Scrambler Therapy. This may well have been because this group had little experience with the technique prior to conducting their study. This finding fits with above-noted work that observed that there is a learning curve for the appropriate application of this therapy for treating chemotherapy neuropathy [22], which likely also applies to the treatment of other conditions. Additionally, the results of this trial support that there was not much of a placebo effect in this trial, as no benefit was noted in either trial arm. Paradoxically, this would support the argument that the positive results reported in other chemotherapy neuropathy Scrambler Therapy trials are not just ascribable to a placebo effect.

In 2015, a single-blind, sham-controlled, randomized clinical trial involving 30 patients with low back pain was reported from Virginia Commonwealth University [29]. These authors noted significant decreases in the Brief Pain Inventory (BPI) back pain scores and pain interference scores ($P \leqq 0.05$). They also noted improvements in pain sensitivity, as measured by participants' thresholds for pain in the initially painful area. Of note, the group randomized to Scrambler Therapy had substantial decreases in 10 serum messenger RNAs (mRNAs) associated with nerve pain such as nerve growth factor (NGF) and glial derived nerve factor (GDNF), compared to no decreases in the sham group, understanding that these mRNAs have not yet been established as correlates for pain.

More recently, two subsequent single-arm prospective trials have been published which support therapeutic benefit. A pilot study was reported from an Italian hospital, evaluating outcomes of Scrambler Therapy in 25 patients with pain related to bony and visceral metastases [31]. Each patient was scheduled for 10 daily sessions of treatment, and pain outcomes were measured by the use of a numeric pain scale. All patients were reported to have experienced at least a 50 % decrease in pain scores, with a mean pain score of 8.4 at baseline dropping to 2.9 after completion of the treatment course. The average duration of "pain control" (defined as >50 % reduction from baseline pain score) was 7.7 +/− 5.3 weeks. Sleep performance was also noted to improve significantly for the cohort. In Korea, Lee et al. performed an open-label, single-arm, exploratory study involving 20 patients with CIPN, metastatic bone pain, and postsurgical neuropathic pain [32]. Pain scores decreased significantly, as did consumption of rescue opioid medication.

Clinical Practice Experiences

Two case series, published in 2013, each included three patients with cancer pain or post-herpetic pain [19, 23]. Both of these reports came from different authors and both reported positive benefits in the patients who were treated.

Sparadeo et al. reported their clinical practice experience regarding 91 of their initial 173 patients, representing all of those for whom they had collected data. These patients had a variety of pain syndromes, including CRPS, spine pain, neuralgias (such as post-herpetic or post-chemotherapy), and multi-focal pain problems [27]. As part of their practice, with these 91 patients, they collected visual pain scores before and after each treatment for all of them and BPI questionnaires, in a subset of them, prior to treatment initiation and at 3- and 6-month follow-up times. The mean pain score prior to the first treatment was 7.2/10; it was 3.0/10 on the 10th day, prior to that day's treatment. Relatively similar results were seen for the different pain syndromes. BPI scores at 3 to 6 months of follow-up were reported to be improved by more than 50 %.

In a second manuscript, Sparadeo and D'Amato [26] analyzed the pre- and posttreatment data of 95 individuals (some of whom had been reported in the previous publication) entering their Scrambler Therapy program for treatment of chronic neuropathic pain, divided into two groups: CRPS and chronic spine-based pain. All patients were weaned from opioids and anticonvulsants being used for pain control. The data analysis revealed that 70 % of the entire sample was still reporting significant improvement 3 to 6 months following treatment. The two studied groups had similar levels of pain and degrees of lifestyle impact. Additionally, the 3–6-month successes were similar in the two treatment groups.

Another clinical practice experience report involved 147 patients treated at two United States military sites and one South Korean site. They noted that 38 % of patients had at least a 50 % pain reduction that lasted for more than a month [21].

Retrospective Study

Lastly, one retrospective report on Scrambler Therapy, involving 201 patients across multiple centers, was recently reported [33]. Patients were treated for a variety of chronic pain syndromes; the most common indications included post-herpetic neuralgia, chronic low back pain, and polyneuropathy/peripheral neuropathy. Patients were treated for a mean number of 10 sessions, with 39 patients experiencing complete resolution of pain symptoms sooner than this. The mean pain scores were 7.41 prior to treatment and 1.6 following treatment ($P < 0.0001$). Achieving a pain score of 0 during treatment was observed to associate with durability of pain control, prompting the authors to advocate for complete response as a target of therapy sessions.

Does Scrambler Therapy actually work?

Arguments against Scrambler Therapy certainly exist, with critics attributing much of the benefit to a placebo effect. Some of the positive endorsements in social media and on the Internet are only anecdotal. Additionally, the developer

of Scrambler Therapy participated in the initial clinical trials, and this could be perceived as a potential conflict of interest even though it is scientifically desirable and logical to expect the device inventor to report the first set of results. Additionally, some of the reports claim that there is a phenomenal benefit that lasts for a long time, which sounds too good to be true. Lastly, there are no large, placebo-controlled, double-blinded clinical trials to estimate the effectiveness of Scrambler Therapy.

On the other hand, while some reports [13, 20, 24, 25] involved the inventor of the Scrambler device, these positive findings have been independently replicated by diverse groups [15–19, 21–23, 26–30] in nearly all of the reported studies, involving over 900 patients in total. In some cases, the benefit achieved has been substantial, with some patients achieving complete pain resolution and substantially reduced dependence on pharmacologic therapy. There has been only one report of a negative experience [16]. This was from one small, placebo-controlled trial in patients with chemotherapy-induced peripheral neuropathy. This was published only as an abstract, did not show much of a reduction in either study arm (arguing against a placebo effect), and was produced by a group that did not have much experience using Scrambler Therapy. This raises concerns regarding the validity of this trial, as data have supported that there is an extended learning curve with the provision of Scrambler Therapy, particularly for chemotherapy-induced neuropathy [22]. At the same time, it must be noted that although this is the only negative trial published on Scrambler Therapy, the possibility of publication bias cannot be excluded. Negative experiences may not be put into publication form for various reasons, and so the currently available literature may be overestimating the positive experience with this technology.

The downsides of trying Scrambler Therapy

The downsides of trying Scrambler Therapy for chronic pain primarily relate to the time and expense associated with its administration, in addition to noting that many proposed treatments for chronic pain have not withstood the rigors of time and/or well conducted randomized trials. Additionally, the therapy is not yet widely available and some insurance companies will not pay for it due to lack of evidence or will reimburse it at very low rates. However, some insurance companies are covering this treatment as they have started to note the benefit of this therapy in allowing patients to return to work, with decreased use of medications and procedures. Scrambler Therapy relies on practitioner skill and familiarity with technique, which can influence outcomes, as has been noted in the literature. This might impede rapid integration into practice, especially in the absence of formalized training.

Additional Research

Additional work is needed to better understand the mechanism of Scrambler Therapy and to conduct larger randomized clinical trials investigating the efficacy of Scrambler Therapy in a number of chronic pain states. A large, multi-center, randomized, sham-controlled double-blinded trial, involving patients with a variety of chronic pain syndromes, would strengthen the conclusions from initial studies. The data compiled, to date, support the feasibility and value of such an undertaking. Multiple other research lines of investigation would be helpful for further defining the worth of Scrambler Therapy. Such work could better evaluate the types of patients who benefit, the best means for teaching operators, and the compatibility of this approach with other treatment approaches. For example, as indicated above, there are recommendations to titrate down and discontinue anticonvulsant medications prescribed for pain management prior to initiating Scrambler Therapy, based on the theory and empiric clinical experience that these agents may interfere with the therapeutic mechanisms involved. Whether this is truly necessary could be a focus of future research. To better define the mechanisms of action, studies of brain reactivity (functional MRI) and peripheral nerve function (changes in epidermal nerve fiber density or electrophysiological measures or quantitative sensory nerve testing) would be useful [34].

Compliance with Ethical Standards

Conflict of interest Potential conflict of interest: Competitive Technologies provided Scrambler devices and supplies to Mayo Clinic, Virginia Commonwealth University, and Johns Hopkins for conducting research.

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References

1. Simon L (2012) Relieving pain in America: A blueprint for transforming prevention, care, education, and research. J Pain Pall Care Phmaracotherapy 26:197–198
2. Stewart WF, Ricci JA, Chee E, Morganstein D, Lipton R (2003) Lost productive time and cost due to common pain conditions in the US workforce. JAMA 290:2443–2454. doi:10.1001/jama.290.18.2443
3. Merskey H, Bogduk N (1994) Classification of chronic pain, 2nd edn. IASP Press, Seattle
4. Merskey H, Harold E (1986) Classification of chronic pain: descriptions of chronic pain syndromes and definitions of pain terms. Pain 3:S1–226

5. Woolf CJ, Doubell TP (1994) The pathophysiology of chronic pain—increased sensitivity to low threshold A beta-fibre inputs. Curr Opin Neurobiol 4:525–534
6. Zimmermann M (2001) Pathobiology of neuropathic pain. Eur J Pharmacol 429:23–37
7. Ji RR, Kohno T, Moore KA, Woolf CJ (2003) Central sensitization and LTP: do pain and memory share similar mechanisms? Trends Neurosci 26:696–705. doi:10.1016/j.tins.2003.09.017
8. Freynhagen R, Bennett MI (2009) Diagnosis and management of neuropathic pain. BMJ 339:b3002. doi:10.1136/bmj.b3002
9. Allegrante JP (1996) The role of adjunctive therapy in the management of chronic nonmalignant pain. Am J Med 101:33S–39S
10. Maurer D (1974) Transcutaneous stimulator and stimulation method. Google Patents.
11. Cruccu G, Aziz TZ, Garcia-Larrea L, Hansson P, Jensen TS, Lefaucheur JP, Simpson BA, Taylor RS (2007) EFNS guidelines on neurostimulation therapy for neuropathic pain. Eur J Neurol 14: 952–970. doi:10.1111/j.1468-1331.2007.01916.x
12. Nnoaham KE, Kumbang J (2008) Transcutaneous electrical nerve stimulation (TENS) for chronic pain. Cochrane Database Syst Rev: CD003222. doi:10.1002/14651858.CD003222.pub2
13. Marineo G (2003) Untreatable pain resulting from abdominal cancer: new hope from biophysics? JOP 4:1–10
14. Deer TR, Mekhail N, Provenzano D, Pope J, Krames E, Leong M, Levy RM, Abejon D, Buchser E, Burton A, Buvanendran A, Candido K, Caraway D, Cousins M, DeJongste M, Diwan S, Eldabe S, Gatzinsky K, Foreman RD, Hayek S, Kim P, Kinfe T, Kloth D, Kumar K, Rizvi S, Lad SP, Liem L, Linderoth B, Mackey S, McDowell G, McRoberts P, Poree L, Prager J, Raso L, Rauck R, Russo M, Simpson B, Slavin K, Staats P, Stanton-Hicks M, Verrills P, Wellington J, Williams K, North R (2014) The appropriate use of neurostimulation of the spinal cord and peripheral nervous system for the treatment of chronic pain and ischemic diseases: the Neuromodulation Appropriateness Consensus Committee. Neuromodulation 17:515–550. doi:10.1111/ner.12208
15. Abdi S, Lakkimsetty VM, Barrera J, Candiotti K, Lubarsky D (2011) The Use of "Scrambler Therapy" for Failed Back Surgery Syndrome. Pain Physician 14:E465–E491
16. Campbell T, Nimunkar AJ, Retseck J, Eickhoff JC, Backonja M, Cleary JF, Kwekkeboom KL, Yen TY (2013) A randomized, double-blind study of "Scrambler" therapy versus sham for painful chemotherapy-induced peripheral neuropathy (CIPN). J Clin Oncol 31:suppl; abstr 9635.
17. Coyne PJ, Wan W, Dodson P, Swainey C, Smith TJ (2013) A Trial of Scrambler Therapy in the Treatment of Cancer Pain Syndromes and Chronic Chemotherapy-Induced Peripheral Neuropathy. J Pain Palliat Care Pharmacother 27:359–364. doi:10.3109/15360288.2013.847519
18. Ghatak RK, Nandi SN, Bhakta A, Mandal GC, Bandyopadhyay M, Kumar S (2011) Prospective study of application of biological communication (cybernatics) in management of chronic low back pain—a preliminary report. Nepal Med Coll J 13:257–260
19. Ko YK, Lee HY, Lee WY (2013) Clinical experiences on the effect of scrambler therapy for patients with postherpetic neuralgia. Korean J Pain 26:98–101. doi:10.3344/kjp.2013.26.1.98
20. Marineo G, Iorno V, Gandini C, Moschini V, Smith TJ (2011) Scrambler Therapy May Relieve Chronic Neuropathic Pain More Effectively Than Guideline-Based Drug Management: Results of a Pilot, Randomized, Controlled Trial. J Pain Symptom Manage 43: 87–95. doi:10.1016/j.jpainsymman.2011.03.015
21. Moon JY, Kurihara C, Beckles JP, Williams KE, Jamison DE, Cohen SP (2014) Predictive factors associated with success and failure for calmare (Scrambler) therapy: a multi-center analysis. Clin J Pain 31:750–756. doi:10.1097/AJP.0000000000000155
22. Pachman DR, Weisbrod BL, Seisler DK, Barton DL, Fee-Schroeder KC, Smith TJ, Lachance DH, Liu H, Shelerud RA, Cheville AL, Loprinzi CL (2014) Pilot evaluation of Scrambler therapy for the treatment of chemotherapy-induced peripheral neuropathy. Support Care Cancer 23:943–951. doi:10.1007/s00520-014-2424-8
23. Park HS, Sin WK, Kim HY, Moon JY, Park SY, Kim YC, Lee SC (2013) Scrambler therapy for patients with cancer pain - case series. Korean J Pain 26:65–71. doi:10.3344/kjp.2013.26.1.65
24. Sabato AF, Marineo G, Gatti A (2005) Scrambler therapy. Minerva Anestesiol 71:479–482
25. Smith TJ, Marineo G (2013) Treatment of postherpetic pain with scrambler therapy, a patient-specific neurocutaneous electrical stimulation device. Am J Hosp Palliat Care. doi:10.1177/1049909113494002
26. Sparadeo F, Kaufman C, D'Amato S (2014) Scrambler Therapy: Effective use of artificial neurons for the treatment of neuropathic pain. J Life Care Plan 14(4):19–30
27. Sparadeo FCK, D'Amato S (2012) Scrambler Therapy: An Innovative and Effective Treatment for Chronic Neuropathic Pain. J Life Care Plan 11(3):3–15
28. Ricci M, Pirotti S, Scarpi E, Burgio M, Maltoni M, Sansoni E, Amadori D (2011) Managing chronic pain: results from an open-label study using MC5-A Calmare(R) device. Support Care Cancer 20:405–412. doi:10.1007/s00520-011-1128-6
29. Starkweather AR, Coyne P, Lyon DE, Elswick RK Jr, An K, Sturgill J (2015) Decreased low back pain intensity and differential gene expression following calmare(R): results from a double-blinded randomized sham-controlled study. Res Nurs Health 38: 29–38. doi:10.1002/nur.21632
30. Smith TJ, Coyne PJ, Parker GL, Dodson P, Ramakrishnan V (2010) Pilot trial of a patient-specific cutaneous electrostimulation device (MC5-A Calmare(R)) for chemotherapy-induced peripheral neuropathy. J Pain Symptom Manage 40:883–891. doi:10.1016/j.jpainsymman.2010.03.022
31. Notaro P, Dell'Agnola CA, Dell'Agnola AJ, Amatu A, Bencardino KB, Siena S (2015) Pilot evaluation of scrambler therapy for pain induced by bone and visceral metastases and refractory to standard therapies. Support Care Cancer. doi:10.1007/s00520-015-2952-x
32. Lee SC, Park KS, Moon JY, Kim EJ, Kim YC, Seo H, Kyung J, Lee DJ (2016) An exploratory study on the effectiveness of "Calmare therapy" in patients with cancer-related neuropathic pain: A pilot study. Eur J Oncol Nurs 21:1–7
33. Compagnone C, Tagliaferri F (2015) Chronic pain treatment and scrambler therapy: a multicenter retrospective analysis. Acta Biomed 86:149–156
34. Gustin SM, Peck CC, Wilcox SL, Nash PG, Murray GM, Henderson LA (2011) Different pain, different brain: thalamic anatomy in neuropathic and non-neuropathic chronic pain syndromes. J Neurosci 31:5956–5964. doi:10.1523/JNEUROSCI.5980-10.2011

Palliative Care SOI

Question: How should Statement of Intent #1 Palliative Care be revised to make it more current and more clearly reflect the intent of the HERC?

Question source: Health Evidence Review Commission, Palliative Care and Quality of Life Interdisciplinary Advisory Council

Issue: The current SOI1 Palliative care has outdated language and does not reflect the current standard of care for palliative care. The Palliative Care and Quality of Life Interdisciplinary Advisory Council (PCAC) has created a suggested revisions to the guideline based on current standards of care.

PCAC's objective was to revise the language to assist in "defining benefit plan coverage to maintain quality of life of an individual experiencing a life-threatening condition or serious and progressive illness; ensure patients have access to palliative care regardless of prognosis; ensure the List contains appropriate indications for palliative care; and ensure the List does not contain language that would lead patients, providers or payers to believe that services with curative or life-prolonging intent are inappropriately denied to patients in need of palliative care."

Current Prioritized List

STATEMENT OF INTENT #1: PALLIATIVE CARE

It is the intent of the Commission that palliative care services be covered for patients with a life-threatening illness or severe advanced illness expected to progress toward dying, regardless of the goals for medical treatment and with services available according to the patient's expected length of life (see examples below).

Palliative care is comprehensive, specialized care ideally provided by an interdisciplinary team (which may include but is not limited to physicians, nurses, social workers, etc.) where care is particularly focused on alleviating suffering and promoting quality of life. Such interdisciplinary care should include assessment, care planning, and care coordination, emotional and psychosocial counseling for patients and families, assistance accessing services from other needed community resources, and should reflect the patient and family's values and goals.

Some examples of palliative care services that should be available to patients with a life-threatening/limiting illness,

A. without regard to a patient's expected length of life:
    - Inpatient palliative care consultation; and,
    - Outpatient palliative care consultation, office visits.
B. with an expected median survival of less than one year, as supported by the best available published evidence:
    - Home-based palliative care services (to be defined by DMAP), with the expectation that the patient will move to home hospice care.

C. with an expected median survival of six months or less, as supported by peer-reviewed literature:
   - Home hospice care, where the primary goal of care is quality of life (hospice services to be defined by DMAP).

It is the intent of the Commission that certain palliative care treatments be covered when these treatments carry the primary goal to alleviate symptoms and improve quality of life, without intending to alter the trajectory of the underlying disease.

Some examples of covered palliative care treatments include:

A. 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.
D. Medical equipment and supplies (such as non-motorized wheelchairs, walkers, bandages, and catheters) determined to be medically appropriate for completion of basic activities of daily living, for management of symptomatic complications or as required for symptom control.
E. Acupuncture with intent to relieve nausea.

Cancer treatment with intent to palliate is not a covered service when the same palliation can be achieved with pain medications or other non-chemotherapy agents.

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.

GUIDELINE NOTE 12, 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 in Statement of Intent 1, Palliative Care.

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.

Palliative Care SOI

HERC staff recommendations:

1) Modify SOI 1 as shown below
    a. PCAC recommended revisions to language
    b. For ease of review, the revised wording without highlighting edits is shown below the edited statement of intent
2) Modify GN12 as shown below
    a. PCAC recommended revisions to language
        i. Moves wording from the previous SOI1 which are cancer specific into this guideline for clarity

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 ~~severe advanced illness expected to progress toward dying, regardless of the goals for medical treatment and with services available according to the patient's expected length of life (see examples below).~~ 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.

~~Palliative care is comprehensive, specialized care ideally provided by an interdisciplinary team (which may include but is not limited to physicians, nurses, social workers, etc.) where care is particularly focused on alleviating suffering and promoting quality of life. Such interdisciplinary care should include assessment, care planning, and care coordination, emotional and psychosocial counseling for patients and families, assistance accessing services from other needed community resources, and should reflect the patient and family's values and goals.~~

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- ~~Inpatient palliative care consultation; and,~~
- ~~Outpatient palliative care consultation, office visits.~~

~~B. with an expected median survival of less than one year, as supported by the best available published evidence:~~
- ~~Home-based palliative care services (to be defined by DMAP), with the expectation that the patient will move to home hospice care.~~

~~C. with an expected median survival of six months or less, as supported by peer-reviewed literature:~~
- ~~Home hospice care, where the primary goal of care is quality of life (hospice services to be defined by DMAP).~~

Palliative Care SOI

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~~Some examples of covered palliative care treatments include:~~

- ~~A. 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.~~
- ~~D. Medical equipment and supplies (such as non-motorized wheelchairs, walkers, bandages, and catheters) determined to be medically appropriate for completion of basic activities of daily living, for management of symptomatic complications or as required for symptom control.~~
- ~~E. Acupuncture with intent to relieve nausea.~~

~~Cancer treatment with intent to palliate is not a covered service when the same palliation can be achieved with pain medications or other non-chemotherapy agents.~~

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 to 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.~~

Palliative Care SOI

It is not the intent of the Commission that treatments seeking to prolong life without chance of benefit or have substantial treatment burdens be covered. See Guideline Note 12 TREATMENT OF CANCER WITH LITTLE OF NO BENEFIT

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.

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    D. Chronic Care Management (CPT 99487-99490)
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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 treatments seeking to prolong life without chance of benefit or have substantial treatment burdens be covered. See Guideline Note 12 TREATMENT OF CANCER WITH LITTLE OF NO BENEFIT

GUIDELINE NOTE 12, TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT

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Treatment with intent to prolong survival is not a covered service for patients who have progressive metastatic cancer with

C. 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
D. 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. 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.

Section 9.0

Previously Discussed Items

Vision Training

Question: Should vision training be paired with any diagnosis other than intermittent exotropia and intermittent esotropia?

Question source: HERC staff/VBBS/OHP medical directors

Issue: Vision therapy involves the use of lenses, prisms, and specialized testing and vision training procedures. Vision training, or "eye exercises," are used, not to strengthen the eye muscles, but rather to improve coordination, efficiency, and functioning of the vision system.

Vision therapy (also known as orthoptic and/or pleoptic training) was once on many lines on the Prioritized List. During the biennial review of 2000, it was noted that evidence only supported use of vision therapy for intermittent exotropia and intermittent esotropia. The CPT code for vision therapy (92065 Orthoptic and/or pleoptic training, with continuing medical direction and evaluation) was removed from all lines other than line 473, which is the equivalent of current line 399. It was noted that CPT 92065 now appears on three lines on the Prioritized List, likely due to like splitting and other line changes since 2000. HERC staff was asked to determine whether there were any diagnoses which has evidence to support vision therapy on one or both of these additional lines.

This topic was discussed at the May, 2017 VBBS meeting. At that time, it was brought to the attention of the VBBS that there were two OARs concerning vision therapy that needed to be addressed.

Current Prioritized List status:
CPT 92065:
356 STRABISMUS DUE TO NEUROLOGIC DISORDER (contains strabismus and ophthalmoplegia diagnoses)
375 AMBLYOPIA
399 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN (contains intermittent esotopia and exotopia diagnoses)

Vision Training

OAR 410-140-0140
Vision Services Coverage and Limitations

(1) Providers shall comply with the following rules in addition to the Visual Services program rules to determine service coverage and limitations for OHP clients according to their benefit packages:

(a) General Rules (OAR chapter 410, division 120);

(b) OHP administrative rules (410-141-0480, 410-141-0500, and 410-141-0520);

(c) Health Evidence Review Commission's (HERC) Prioritized List of Health Services (List) (OAR 410-141-0520); and

(d) Referenced guideline notes (The date of service determines the correct version of the administrative rules and HERC List to determine coverage.); and

(e) The Authority's general rules related to provider enrollment and claiming (OAR 943-120-0300 through 1505).

(2) The Division covers ocular prosthesis (e.g., artificial eye) and related services. See OAR 410-122-0640 Eye Prostheses for service coverage and limitations.

(3) The Division covers reasonable services for diagnosing conditions, including the initial diagnosis of a condition that is below the funding line on the HERC List. Once a diagnosis is established for a service, treatment, or item that falls below the funding line, the Division may not cover any other service related to the diagnosis.

(4) Coverage for eligible adults (age 21 and older):

(a) Diagnostic evaluations and medical examinations are not limited if documentation in the physician's or optometrist's clinical record justifies the medical need;

(b) Ophthalmological intermediate and comprehensive exam services are not limited for medical diagnosis;

(c) Vision therapy is not covered; and

(d) Visual services for the purpose of prescribing glasses or contact lenses, fitting fees, or glasses or contact lenses:

(A) One complete examination and determination of refractive state is limited to once every 24 months for pregnant adult women;

(B) Non-pregnant adults are not covered, except when the client:

(i) Has a medical diagnoses of aphakia, pseudoaphakia, congenital aphakia, keratoconus; or

(ii) Lacks the natural lenses of the eye due to surgical removal (e.g., cataract extraction) or congenital absence; or

(iii) Has had a keratoplasty surgical procedure (e.g., corneal transplant) with limitations described in OAR 410-140-0160 (Contact Lens Services and Supplies); and

(iv) Is limited to one complete examination and determination of refractive state once every 24 months.

(5) OHP Plus Children (birth through age 20):

(a) All ophthalmological examinations and vision services, including routine vision exams, fittings, repairs, and materials are covered when documentation in the clinical record justifies the medical need;

(b) Orthoptic and pleoptic training or "vision therapy" is:

(A) Covered when therapy treatment pairs with a covered diagnosis on the HERC List;
(B) Limited to six sessions per calendar year without PA:
(i) The initial evaluation is included in the six therapy sessions;
(ii) Additional therapy sessions require PA (OAR 410-140-0040);
(C) Shall be provided pursuant to OAR 410-140-0280 (Vision Therapy).
(6) Refraction determination is not limited following a diagnosed medical condition (e.g., multiple sclerosis).

410-140-0280
Vision Therapy Services
(1) The Division covers orthoptic and pleoptic training or "vision therapy" as outlined in OAR 410-140-0140 Vision Services Coverage and Limitations.
(2) Providers shall develop a therapy treatment plan and regimen that shall be taught to the client, family, foster parents, and caregiver during the therapy treatments. No extra treatments shall be authorized for teaching.
(3) Therapy that can be provided by the client, family, foster parents, and caregiver is not a reimbursable service.
(4) All vision therapy services including the initial evaluation shall be billed to the Division with the Current Procedural Terminology (CPT) code for orthoptic and pleoptic training.

HSC/HERC history:
HOSC January 2000

Visual training -- The optometrists at Pacific University recommend treating reading disability with visual training. The American Academy of Pediatrics does not endorse this therapy. The Vision Guide at the Office of Medical Assistance Programs limits vision therapy visits to five per year and this service is being reviewed as part of the comprehensive review of ancillary services. At this time the relevant CPT code (92065) is included as part of the medical therapy codes on the medical lines on the Prioritized List (571 lines). Discussion today suggests the code 92065 may be appropriate only for the lines with the diagnoses for intermittent exotropia or intermittent esotropia.

The Subcommittee decided to review the research materials from earlier meetings and form a subcommittee chaired by Dr. Glass to develop formal recommendations for the biennial review.

HOSC February 2000

Vision Therapy
It was decided at last month's meeting that Dr. Glass would convene a task force to review vision therapy. However, research has shown that the Ancillary Services Workgroup considered eliminating this service and found that the fee-for-service program had expenditures of only $2500. Therefore, it has been decided that this is a very small problem

and that all the codes for which the Oregon Optometric Association considers vision therapy efficacious are on Line 473 of the Prioritized List of Health Services. For the 2000 Biennial Review, the plan is to reconfigure the Medical Therapy code ranges to have vision therapy appear on Line 473 only. Darren Coffman will draft a letter to the optometric association explaining this decision.

At this point Dr. Glass teleconferenced into the meeting and reviewed the progress and decisions that had been made. He endorsed the changes that had been recommended and had no further input to the dental recommendations that will be reviewed this afternoon.

Evidence:
No literature was identified examining vision training, orthoptic and/or pleoptic training with amblyopia, ophthalmoplegia, or any other diagnosis appear on lines 356 or 175.

Small case series were identified which supported the use of vision training for patients for intermittent esotropia and exotropia.

Current utilization
For the past 6 months, there were 2,226 paid claims for a total of $237,881.06 for vision training. Only 20 (0.8%) paid claims pair with intermittent esotropia/exotropia. 1471 (66%) paid claims involve diagnostic codes which appear on line 399 but not intermittent esotropia/exotropia.

Vision Training

HERC staff summary:
There is little evidence to support the use of vision therapy for any indication. The best available evidence (small case series) is for intermittent esotropia and exotropia. Current OAR limits vision therapy to is limited to children up through age 20 for 6 sessions without a PA, and for unlimited sessions with a PA, using only the CPT code specific for Orthoptic and/or pleoptic training (i.e. CPT 92065).

Any changes to the Prioritized List would limit those conditions for with vision training could be utilized. Without a change to OAR, vision training would be limited to children through age 20, which staff feels is appropriate. There may be additional benefits for children with different diagnoses through the requirements of EPSDT benefits.

HERC staff recommendations:

1) Remove CPT 92065 (Orthoptic and/or pleoptic training, with continuing medical direction and evaluation) from lines 356 STRABISMUS DUE TO NEUROLOGIC DISORDER and 375 AMBLYOPIA
    a. No evidence for use with any diagnoses appearing on these lines
2) Add a new coding specification to line 399 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN
    a. "CPT 92065 is included on line 399 only for pairing with ICD-10 H50.31 (Intermittent monocular esotropia), H50.32 (Intermittent alternating esotropia), and H50.33 (Intermittent alternating exotropia)."

Back Surgery Guideline
August 2017

Question: How should the back surgery guideline be modified?

Question source: VBBS, HERC staff

Issue: The back surgery guideline was extensively discussed at the May, 2017 VBBS meeting. HERC staff was directed to further refine the guideline wording, with input from Dr. Susan Williams and the OHP medical directors.

At the May meeting, the VBBS made suggestions and approved staff proposals including

1) Add a phrase to one sentence in the guideline: "Surgical correction of spinal stenosis (ICD-10-CM M48.0), with or without spondylolisthesis, is only included on Line 351…"
2) The staff suggestion to add wording specifying that spondylolisthesis must be "demonstrated on flexion/extension films (x-rays) showing at least a 5 to 7 mm translation" was accepted with minor wording changes.
3) The staff suggestion to add "Foraminal or central spinal stenosis causing only radiating pain (e.g. radiculopathic pain) is included only on line 532" was accepted, with an e.g. rather than an i.e. as the only change**.**
4) The ICD-10 codes for radiculopathy were discussed and the decision was they should be added to the upper back surgery line
5) Staff was directed to work on refining the confusing wording of the guideline
6) Later in the meeting, during the discussion of epidural steroid injections, various therapies listed in the current back surgery guideline as not covered were added to the lower surgical line and removed from the guideline list of not covered procedures. Corticosteroid injections for cervical pain was added to the list and a sentence about corticosteroid injections being on the lower back surgery line was added.

HERC staff have worked with OHP medical directors and back surgeons to refine the wording of the guideline. The result to this discussion has been an extensive re-write of the guideline wording. The medical directors and surgeons feel that this wording make the guideline much more clear and usable. Most of this re-writing was a reorganization of previous wording. Some entries have had 'their previous intent changed due to surgical input. Specifically:

1) Changing ">50% of foraminal joints" to ">50% of facet joints per level" based on surgical feedback.
2) The definition of spondylolisthesis to say "at least a 5 to 7 mm translation" on imaging was thought to be confusing. The suggestion was to simply require at least a 5 mm translation.
3) The revised guideline should clarify that spinal stenosis in the cervical spine that causes any neurological dysfunction according to the guideline definition should be eligible for fusion. Spinal stenosis in the thoracic and lumbar spine would need to cause neurogenic claudication. This is due to the fact that spinal stenosis in the cervical spine does not generally cause neurogenic claudication, but rather other symptoms.

Back Surgery Guideline
August 2017

Guideline as of the May 2017 VBBS meeting

GUIDELINE NOTE 37, SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS

Lines 351,532

Spondylolisthesis (ICD-10-CM M43.1, Q76.2) is included on Line 351 only when it results in spinal stenosis with signs and symptoms of neurogenic claudication. Otherwise, these diagnoses are included on Line 532. Decompression and fusion surgeries are both included on these lines for spondylolisthesis.

Surgical correction of spinal stenosis (ICD-10-CM M48.0) is only included on Line 351 for patients with:

1) MRI evidence of moderate to severe central or foraminal spinal stenosis AND
2) A history of neurogenic claudication, or objective evidence of neurologic impairment consistent with MRI findings. Neurologic impairment is defined as objective evidence of one or more of the following:
    a. Markedly abnormal reflexes
    b. Segmental muscle weakness
    c. Segmental sensory loss
    d. EMG or NCV evidence of nerve root impingement
    e. Cauda equina syndrome
    f. Neurogenic bowel or bladder
    g. Long tract abnormalities

Otherwise, these diagnoses are included on Line 532. Only decompression surgery is included on these lines for spinal stenosis; spinal fusion procedures are not included on either line for spinal stenosis unless:

1) the spinal stenosis is in the cervical spine OR
2) spondylolisthesis is present as above OR
3) there is pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of foraminal joints expected to be resected)

The following interventions are not included on these lines due to lack of evidence of effectiveness for the treatment of conditions on these lines, including cervical, thoracic, lumbar, and sacral conditions:

- ~~facet joint corticosteroid injection~~
- prolotherapy
- ~~intradiscal corticosteroid injection~~
- local injections
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- ~~sacroiliac joint steroid injection~~

- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- radiofrequency denervation
- ~~epidural steroid injections~~
- corticosteroid injections for cervical pain

Corticosteroid injections for low back pain with or without radiculopathy are only included on Line 532.

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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Back Surgery Guideline
August 2017

HERC staff recommendations:

1) Add radiculopathy ICD-10 codes to line 351 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS
    a) M47.2 Other spondylosis with radiculopathy
    b) M50.1 Cervical disc disorder with radiculopathy
    c) M51.1 Intervertebral disc disorders with radiculopathy, thoracic, lumbar or sacral
    d) M54.1 Radiculopathy
2) Modify GN 37 as shown below
    a) Note: additions and deletions are not shown due the extensive re-writing of the guideline

GUIDELINE NOTE 37, SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS

Lines 351,532

Spine surgery is included on line 351 only in the following circumstances:

1) Decompressive surgery is included on line 351 to treat debilitating symptoms due to central or foraminal spinal stenosis, and only when the patient meets the following criteria:
    a. Has MRI evidence of moderate or severe central or foraminal spinal stenosis AND
    b. Has neurogenic claudication OR
    c. Has objective neurologic impairment consistent with the MRI findings. Neurologic impairment is defined as objective evidence of one or more of the following:
        i. Markedly abnormal reflexes
        ii. Segmental muscle weakness
        iii. Segmental sensory loss
        iv. EMG or NCV evidence of nerve root impingement
        v. Cauda equina syndrome
        vi. Neurogenic bowel or bladder
        vii. Long tract abnormalities

    Foraminal or central spinal stenosis causing only radiating pain (e.g. radiculopathic pain) is included only on line 532.

2) Spinal fusion procedures are included on line 351 for patients with MRI evidence of moderate or severe central spinal stenosis only when the following conditions are met:
    a. spinal stenosis in the cervical spine (with or without spondylolisthesis) which results in objective neurologic impairment as defined above OR

b. spinal stenosis in the thoracic or lumbar spine caused by spondylolisthesis resulting in signs and symptoms of neurogenic claudication and which correlate with xray flexion/extension films showing at least a 5 mm translation OR
c. pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of facet joints per level expected to be resected)

For all other indications, spine surgery is included on line 532.

The following interventions are not included on these lines due to lack of evidence of effectiveness for the treatment of conditions on these lines, including cervical, thoracic, lumbar, and sacral conditions:

- prolotherapy
- local injections
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- radiofrequency denervation
- corticosteroid injections for cervical pain

Corticosteroid injections for low back pain with or without radiculopathy are only included on Line 532.

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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Services of Low Importance

Issue: At its March 9, 2017 meeting, the HERC adopted changes to the Prioritized List that address treatments with marginal or no clinical benefit, low cost-effectiveness, and/or very high cost. These changes included two new lines and two new guidelines. The guidelines were adopted as blank tables, with HERC staff charged to identify items that should be considered for addition to these tables.

At the May, 2017 VBBS and HERC meetings, the new lines and guidelines were discussed in detail. The following were adopted as criteria for inclusion on one of these lines:

1) Line 500 CONDITIONS FOR WHICH CERTAIN TREATMENTS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS
    a. Marginal clinical benefit: some statistically significant evidence of benefit but not of clinical significance for an important and/or critical outcome
    b. More effective interventions exist
    c. Other effective interventions have a better safety profile
    d. Not cost-effective (consider services with $125,000/QALY as a potential indicator of not being cost-effective, to be weighed with other factors, i.e., risk of treatment harms, burden of the condition)
    e. Significantly less cost-effective than other interventions
2) Line 660 CONDITIONS FOR WHICH CERTAIN TREATMENTS HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS; UNPROVEN TREATMENTS
    a. No clinical benefit: statistical evidence of no benefit
    b. Harms outweigh benefits
    c. Unproven therapies/therapies with insufficient evidence of effectiveness

Services which are prohibited by federal rule (e.g. obesity drugs, cosmetic procedures) will not be included on any part of the Prioritized List.

The guideline 168 and 169 tables will include an English description for the condition (not ICD-10 codes), the CPT code(s) with an English description of the procedure, a rationale statement about why that condition/treatment pair was included, a notation of the last date of review and a link to the relevant minutes. For the rationale column, a statement indicating that the reason was complicated and referring readers to minutes may be reasonable in certain circumstances.

Services of Low Importance

HERC staff recommendations:

1) Adopt the following changes to GN67, GN168 and GN169, effective January 1, 2018.
2) Direct staff to align rationales with rule language and add links to coverage guidances and relevant extracts from meeting materials and minutes.

GUIDELINE NOTE 67, ENZYME REPLACEMENT THERAPY

Lines ~~151~~147,~~656~~660

Enzyme replacement therapy for infantile Pompe's disease is included on Line ~~151~~147. All other enzyme replacement therapies are included on Line ~~656~~660.

GUIDELINE NOTE 168, TREATMENTS WITH MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS FOR CERTAIN CONDITIONS

The following treatments are prioritized on Line 500 for the conditions listed here:

Condition	Procedure Code	Treatment	Rationale	Last Review
Stroke	61630	Balloon angioplasty, intracranial (eg, atherosclerotic stenosis), percutaneous	Similar or worse outcomes than standard therapies	March 2016
Bladder incontinence	64566	Posterior tibial neurostimulation	Minimally effective, no evidence of long-term effectiveness	December, 2010
Hearing loss	69710 *HCPCS L8690-L8693*	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone *Auditory osseointegrated device*	Less effective than other therapies	June, 2014, Aug. 2015
Cystic fibrosis, other chronic lung conditions	94669	Mechanical chest wall oscillation	More costly than equally effective therapies	October, 2016

Condition	Procedure Code	Treatment	Rationale	Last Review
Screening for ocular disorders	99177	Photoscreening	More costly than equally effective methods of screening	November, 2015

GUIDELINE NOTE 169, 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:

Condition	Procedure Code	Treatment	Rationale	Last Review
Tissue reconstruction, breast reconstruction	15777	Acellular dermal matrix for soft tissue reinforcement (eg, breast, trunk)	Greater harms than other effective therapies	March, 2015
Spinal conditions	22867-22870	Insertion of interlaminar/ interspinous process stabilization/ distraction device, without fusion, including image guidance when performed, with open decompression, lumbar	Insufficient evidence of effectiveness	November, 2016
All indications	31627	Computer assisted bronchoscopy	Insufficient evidence of effectiveness	December, 2009
All respiratory conditions	31647-31649, 31651	Bronchial valve insertion/removal/replacement	Insufficient evidence of effectiveness	December, 2012
All respiratory conditions	31660-31661	Bronchial thermoplasty	Insufficient evidence of effectiveness	January, 2014
Cardiac conditions	33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant	Insufficient evidence of effectiveness	November, 2016

Services of Low Importance

Condition	Procedure Code	Treatment	Rationale	Last Review
Neonatal polycythemia	36456	Partial exchange transfusion, blood, plasma or crystalloid necessitating the skill of a physician or other qualified health care professional, newborn	No evidence of effectiveness, evidence of possible harm	November, 2016
Sleep apnea	41512	Tongue base suspension	No clinically important benefit	January, 2014
All indications	43252, 88375	Optical endomicroscopy	Insufficient evidence of effectiveness	December, 2012
GI conditions	43284	Laproscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band)	Insufficient evidence of effectiveness	November, 2016
Genitourinary conditions	50705	Ureteral embolization or occlusion	Insufficient evidence of effectiveness	November, 2015
All prostatic conditions	53855	Temporary prostatic stents	Insufficient evidence of effectiveness	October, 2015
Stress incontinence	53860	Transurethral radiofrequency micro-remodeling of the bladder neck and urethra for stress incontinence	Insufficient evidence of effectiveness	December, 2010
Uterine fibroids	58674	Laparoscopy, surgical, ablation of uterine fibroid(s)	Insufficient evidence of effectiveness	November, 2016
Stroke, intracrancial vasospasm	61635	Transcather placement of intravascular stent(s), intracranial (eg, atherosclerotic stenosis), including balloon angioplasty, if performed	Results in significantly worse outcomes than medical management	March 2016

Services of Low Importance

Condition	Procedure Code	Treatment	Rationale	Last Review
Intracranial vasospasm	61640-61642	Balloon dilation of intracranial vasospasm, percutaneous.	Evidence of harm	March, 2016
Spinal conditions	62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc	Insufficient evidence of effectiveness	November, 2016
Neck and thoracic spine conditions	64479-64480	Transforaminal epidural steroid injections	Insufficient evidence of benefit Coverage Guidance Blog	March, 2015
Neck and thoracic spine conditions	64490-64492	Facet joint injections	Insufficient evidence of benefit Coverage Guidance Blog	March, 2015
Neck and thoracic spine pain and radiculopathy	64633-64634	Radiofrequency ablation	Insufficient evidence of benefit Coverage Guidance Blog	March, 2015
Low back pain and radiculopathy	64635-64636	Radiofrequency ablation	Insufficient evidence of benefit Coverage Guidance Blog	November, 2014
Glaucoma	66174-66175	Transluminal dilation of aqueous outflow canal	Insufficient evidence of effectiveness	December, 2010
Angina, coronary artery disease, chest pain, other cardiac conditions	75571	CT coronary calcium scoring	Insufficient evidence of benefit, unclear harms of radiation exposure Coverage Guidance Blog	August 2013
Angina, coronary artery disease, chest	75572	Computed tomography, heart, with contrast material, for		December, 2009

Services of Low Importance

Condition	Procedure Code	Treatment	Rationale	Last Review
pain, other cardiac conditions		evaluation of cardiac structure and morphology		
Angina, coronary artery disease, chest pain, other cardiac conditions	75574	Computed tomography, heart	Insufficient evidence of benefit, unclear harms of radiation exposure Coverage Guidance Blog	August, 2013
Screening for osteoporosis	77086	Vertebral fracture assessment using DXA	Insufficient evidence of effectiveness	October, 2015
Skin conditions	77767	Remote afterloading high dose rate radionuclide skin surface brachytherapy, includes basic dosimetry	Insufficient evidence of effectiveness	October and November 2015
Angina, coronary artery disease, chest pain, other cardiac conditions	78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation	Insufficient evidence of benefit, unclear harms of radiation exposure Coverage Guidance Blog	January, 2015
Angina, coronary artery disease, chest pain, other cardiac conditions	78491-78492	Myocardial imaging, positron emission tomography (PET), perfusion	Insufficient evidence of benefit, unclear harms of radiation exposure Coverage Guidance Blog	January, 2015
Screening for colorectal cancer	81327	SEPT9 (Septin 9) (eg. Colorectal cancer) methylation analysis	Insufficient evidence of effectiveness	November, 2016
Prenatal screening	81422	Fetal chromosomal microdeletion(s) genomic sequence analysis (eg. DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood	Insufficient evidence of effectiveness	November, 2016

Services of Low Importance

Condition	Procedure Code	Treatment	Rationale	Last Review
Diagnosis, risk stratification or evaluation of coronary artery disease	81493	Coronary artery disease, mRNA, gene expression profiling	Insufficient evidence of effectiveness	November, 2015
Cancer tissue test	81504	Biomarker tests for tumor tissue: • Mammaprint, Mammostrat and ImmunoHistoCHemistry 4 (IHC4) for breast cancer • Microsatellite instability (MSI) for colorectal cancer • Urovysion for bladder cancer • Prolaris for prostate cancer • Multiple molecular testing to select targeted cancer therapy	Insufficient evidence of effectiveness. More costly than equally effective therapies for this condition Coverage Guidance Blog	August, 2015
Prostate cancer screening	81539	Oncology (high-grade prostate cancer), biochemical assay of four proteins (Total PSA, Free PSA, Intact PSA, and human kallikrein-2[hk2]), utilizing plasma or serum, prognostic algorithm reported as a probability score	Insufficient evidence of effectiveness	November, 2016
Diagnostic testing	83987	pH; exhaled breath condensate	Insufficient evidence of effectiveness	December, 2009
Diagnostic testing	84145	Procalcitonin (PCT)	Insufficient evidence of effectiveness	December, 2009
Diagnostic testing	84431	Thromboxane metabolite(s)	Insufficient evidence of effectiveness	December, 2009
Diagnostic testing	86305	Human epididymis protein 4 (HE4)	Insufficient evidence of effectiveness	December, 2009

Services of Low Importance

Condition	Procedure Code	Treatment	Rationale	Last Review
Diagnostic testing	88738	Hemoglobin (HGB), quantitative, transcutaneous	Insufficient evidence of effectiveness	December, 2009
Any indication	90880	Hypnotherapy	No clinically important benefit	August, 2015
Gastrointestinal conditions	91112	Gastrointestinal transit and pressure measurement	Insufficient evidence of effectiveness	December, 2012
Any indication	93050	Arterial pressure waveform analysis for assessment of central arterial pressure	Insufficient evidence of effectiveness	November, 2015
Any indication including breast cancer screening	93740	Temperature gradient studies	Insufficient evidence of effectiveness	October, 2015
Sleep apnea, other sleep disorders	95803	Actigraphy	No clinically important benefit	January, 2009
Diagnosis of skin lesions	96931-96935	Reflectance confocal microscopy for non-melanoma skin lesions	Insufficient evidence of effectiveness	November, 2015
Diagnosis of skin lesions	96936	Reflectance confocal microscopy (RCM) for cellular and subcellular imaging of skin.	Insufficient evidence of effectiveness	November, 2016
Musculoskeletal conditions, wounds	97022	Application of a modality; whirlpool	Evidence of harm	May, 2016
Musculoskeletal conditions	97024	Application of a modality; diathermy (eg, microwave)	Insufficient evidence of effectiveness	May, 2016
Musculoskeletal conditions	97028	Application of a modality; ultraviolet	Insufficient evidence of effectiveness	May, 2016
Musculoskeletal conditions	97034	Application of a modality; contrast baths	Insufficient evidence of effectiveness	May, 2016
Musculoskeletal conditions, wounds	97036	Application of a modality; Hubbard tank	Evidence of harm	May, 2016

Services of Low Importance

Condition	Procedure Code	Treatment	Rationale	Last Review
Wounds	97610	Low frequency, non-contact, non-thermal ultrasound	No clinically important benefit	October, 2013
Any indication	D0422 D0423	Collection and preparation of genetic sample material for laboratory analysis and report Genetic test for susceptibility to diseases – specimen analysis	Insufficient evidence of effectiveness	October, 2015
Any indication	D9932-D9935	Cleaning and inspection of removable complete or partial denture, maxillary or mandibular	Insufficient evidence of effectiveness	October, 2015
All conditions except Pompe's disease	S9357	Enzyme replacement therapy	No clinically important benefit	August, 2012

Medications of Low Importance

Question: How should the HERC define medications with marginal benefit or low cost-effectiveness for inclusion on line 500 CONDITIONS FOR WHICH CERTAIN TREATMENTS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS or with no clinical benefit for inclusion on line 660 CONDITIONS FOR WHICH CERTAIN TREATMENTS HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS; UNPROVEN TREATMENTS?

Question source: HERC staff, Pharmacy and Therapeutics (P&T) staff, HSD leadership

Issue: At the March and May, 2017 VBBS and HERC meetings, two new lines were created with accompanying guidelines to define services, surgeries, DME, and other interventions with marginal or no benefit or low cost effectiveness. Medications also fall into the types of interventions meant for inclusion on these lines. P&T is charged with conducting drug class reviews in the maintenance of the fee-for-service preferred drug list and any accompanying prior authorization criteria. In doing so they gain insight into which medications are of marginal or no benefit or whose cost is too high for its health benefit that can be helpful for HERC's prioritization process. HERC staff has been working with the P&T staff to define when a medication would be identified by P&T and referred to the HERC for consideration for inclusion on either line 500 or line 660.

The following principles have been proposed by HERC staff and P&T staff for identification of medications for the marginal/no benefit/low cost-effectiveness lines:

1. P&T will use wholesale acquisition cost (WAC) to determine drug pricing for the purposes of consideration for inclusion on line 500/660. P&T and HERC staff are aware that there is a rebate for the Medicaid program which lowers this cost; however, this rebate price is confidential. WAC is publically available and can be discussed in open meetings. As most drugs have the same rebate percent, WAC is one way to compare relative costs in an open, transparent manner. Additionally, CCOs do not receive the standard Medicaid rebate nor supplemental rebates when purchasing drugs; therefore WAC is a more realistic figure for initial CCO purchase costs.
2. If cost/QALY is known based on good quality studies, then P&T/HERC will generally use a threshold of $150,000/QALY for medications. This is higher than the cost/QALY of $125,000/QALY to be used in consideration for other therapies, but will help take into account the standard Medicaid rebate (i.e. the actual cost/QALY will be more in line with the limit determined for non-drug therapies once the rebate is taken into account). Supplemental rebates are not expected for the new, brand name drugs with few or no alternative treatments that will typically be identified for this process.
3. The P&T and HERC will focus their review and decisions mainly on the clinical benefits, relative costs and harms of medications. Cost-effectiveness may be considered when the drug has evidence of marginal clinical benefit but has costs that are disproportionately high. High cost medications/therapies may also be reviewed if their projected total expenditures could threaten the ability to maintain the funding level of the Prioritized List.
4. If prices go down over time, or there is new evidence of benefit, manufacturers can bring them for review. P&T will be the first body for such review, and P&T will determine if the changes justify reconsideration for prioritization by the HERC.

Medications of Low Importance

Medications which are anticipated to be identified by the P&T for HERC review include the following:

1) Medications with minimal or no clinical benefit
2) Medications with much higher cost than equally effective or more effective therapies
3) Medications whose harms outweigh benefits
4) Medications with low cost-effectiveness. This may be an extremely high cost medication for a rare condition or a more moderately priced drug for a common condition which does not provide significant clinical benefit (or benefit over lower-cost alternatives) for an important patient-centered outcome.
5) Medications that are high cost and affect a large proportion of the OHP population, threatening the ability to maintain the funding level of the Prioritized List

Examples for discussion purposes:

1) Exondys 51 (eteplirsen)—Treatment for Duchenne Muscular Dystrophy (DMD). The FDA has found no clinical benefit for this medication despite giving approval for use. Consider adding to line 660 due to lack of evidence supporting clinical efficacy. Additionally, this is a high cost medication with a WAC of $57,600/month for a 30 kg patient.
2) deflazacort—corticosteroid approved for treatment of Duchenne Muscular Dystrophy (DMD). WAC is $95,000/year. Consider adding to line 500 due to high cost and marginal benefit compared to equally effective but much less expensive alternative corticosteroids (i.e. prednisone).

P&T materials for these medications are included in your packet for review.

<u>HERC staff recommendations</u>

1) Discuss proposed criteria for addition of medications to the marginal/no benefit/low cost-effectiveness lines
    a. Examples of how medication entries would appear in GN168 and GN169 are on the following page
2) Discuss what, if any, additional information the VBBS would require or desire to have when discussing marginal/no benefit/low cost-effectiveness medications.
    a. Would you like P&T staff to come for the discussion?

Medications of Low Importance

GUIDELINE NOTE 168, TREATMENTS WITH MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS FOR CERTAIN CONDITIONS

The following treatments are prioritized on Line 500 for the conditions listed here:

CONDITION	CPT/HCPCS code	TREATMENT	Rationale	Date of Last Review/Link to Meeting Details
Duchenne Muscular Dystrophy		deflazacort	Marginal benefit/low cost-effectiveness compared to equally effective but much less expensive alternative corticosteroids	September, 2017

GUIDELINE NOTE 169, 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:

CONDITION	CPT/HCPCS Code	TREATMENT	Rational	Date of Last Review/Lint to Meeting Minutes
Duchenne Muscular Dystrophy		Exondys 51 (eteplirsen)	No clinically important benefit	September, 2017

Section 10.0

Coverage Guidances

CONTINUOUS GLUCOSE MONITORING IN DIABETES MELLITUS

Draft Coverage Guidance for VbBS and HERC Consideration

August 10, 2017

Oregon Health Authority

OREGON HEALTH & SCIENCE UNIVERSITY

Center For Evidence-based Policy

Background: Diabetes

- More than 29 million Americans are currently living with diabetes mellitus (DM)
  - 86 million Americans have prediabetes
- Diabetes was the seventh leading cause of death in the U.S. in 2013 and increases the risk for:
  - Heart disease
  - Stroke
  - Blindness
  - Kidney disease
  - Amputations

Background: Diabetes Management

- Treatments for diabetes include:
  - Healthy eating
  - Physical activity
  - Blood glucose testing
  - Insulin injections
  - Other oral and injectable medications
- Blood glucose monitoring can be a critical tool for managing diabetes
  - Results from measuring blood glucose levels often inform changes to the patient's treatment plan
  - American Diabetes Association typically recommends an HbA1c target of 7% for adults with diabetes who are not pregnant, but target ranges vary by individual factors

Background: Diabetes Management

Conditions characterized by abnormal blood glucose levels:

- **Hyperglycemia**
  - Abnormally high blood glucose
  - If untreated, can lead to ketoacidosis (i.e., a diabetic coma)
- **Hypoglycemia**
  - Abnormally low blood glucose level (usually defined as <70 mg/dL)
  - If untreated, can lead to seizures or unconsciousness
  - Severe hypoglycemia defined as "An event requiring assistance of another person to actively administer carbohydrate, glucagons, or other resuscitative actions." (ADA Workgroup on Hypoglycemia, 2005)
- **Hypoglycemia unawareness**
  - Blood glucose <70 mg/dL, but patient does not recognize symptoms

Background: Glucose Monitoring

- **Finger-stick test**
  - Most common way to check capillary blood glucose levels
  - Pricking fingertip with a lancing device to obtain blood sample and then using a glucose meter to measure the blood glucose level
- **Continuous glucose monitoring (CGM)**
  - Sensor measures patient's interstitial glucose level in short intervals
- **CGM-augmented insulin pumps**
  - Computerized devices that adjust subcutaneous insulin delivery based on CGM data

Background: Glucose Monitoring

Continuous glucose monitors (CGM):

- Consists of a small sensor inserted under patient's skin to measure glucose levels in interstitial fluid
- Takes readings automatically (typically in one-minute or five-minute intervals)
- Can use either retrospective or real-time monitoring technology
  - Retrospective CGM: data must be downloaded from the device before analysis
  - Real-time CGM: transmitter and receiver connected to the glucose sensor; patient sees measurements instantaneously
    - Option to set alarms to alert patients to hypoglycemia, hyperglycemia, or rapid variations in glucose levels

Background: Glucose Monitoring

- In December 2016, the FDA announced an expansion in the approved uses for Dexcom's G5 Mobile Continuous Glucose Monitoring System
  - Device is now approved as a replacement for the finger-stick test for diabetes treatment decisions in individuals ages two and older
- Previously, all CGM devices were approved only to supplement and not replace finger-stick testing

Scope Statement

- **Population:**

  Children, adolescents, and adults with DM1 or DM2 on insulin therapy, including pregnant women

- **Interventions:**

  Continuous blood glucose monitoring, either retrospective or real-time

- **Comparators:**

  Self-monitoring blood glucose (SMBG) and/or routine HbA1c monitoring

Scope Statement

- **Critical Outcomes:**
  - Severe morbidity (e.g., microvascular and macrovascular complications)
  - Severe hypoglycemia
- **Important Outcomes:**
  - Quality of life
  - Change in HbA1c
  - Ketoacidosis

Scope Statement

Key Questions

1. What is the evidence of effectiveness of CGM in improving outcomes in people with diabetes?
2. What are the indications for retrospective and real-time CGM?
3. Is there evidence of differential effectiveness of CGM based on:
    a. Type 1 vs. Type 2 DM?
    b. Insulin pump (integrated with CGM or standalone) vs. multiple daily insulin injections (MDII)?
    c. Frequency and duration of CGM?
    d. Persistently poor glycemic control?

Evidence Sources: Adults with DM1

Evidence sources for adults with DM1

- Beck et al., 2017
- Benkhadra et al., 2017
- Hommel et al., 2014
- Langendam et al., 2012
- Lind et al., 2017
- National Institute for Health and Care Excellence (NICE) (Guideline 17), 2015
- New et al., 2015
- Riveline et al., 2012
- Tumminia et al., 2015
- van Beers et al., 2016

Evidence Review: Adults with DM1

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*
Severe morbidity *(Critical outcome)*	Insufficient evidence
Severe hypoglycemia *(Critical outcome)*	No difference in severe hypoglycemia at up to six months ●●○○ *(Low confidence)*
Quality of life *(Important outcome)*	No differences in various measures of quality of life ●●●○ *(Moderate confidence)*

Evidence Review: Adults with DM1

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*
Change in HbA1c *(Important outcome)*	No difference in HbA1c with retrospective CGM at up to six months of follow-up MD -0.09%, 95% CI -0.44 to 0.26 ●●●○ (Moderate confidence) Greater improvement in HbA1c with real-time CGM at up to six months of follow-up MD -0.30%, 95% CI -0.47 to -0.12 ●●○○ (Low confidence)
Diabetic ketoacidosis *(Important outcome)*	No difference in ketoacidosis ●●○○ (Low confidence)

Evidence Summary: Adults with DM1

Adults with DM1

- Evidence that real-time CGM results in greater improvements in HbA1c when compared with SMBG
- Some evidence that the greatest improvements in HbA1c are attained in patients who use continuous subcutaneous insulin infusion (CSII or insulin pumps)
- CGM does not reduce severe hypoglycemia or ketoacidosis (but these were rare events in the studies)
- CGM does not improve quality of life
- Insufficient evidence about the effects of CGM on long-term clinical outcomes from diabetes

Adults with DM1

Resource allocation:

CGM adds significant cost to diabetes management, and generally does not eliminate the need for finger-stick testing before insulin dosage changes (one device that does so was approved by the FDA in December 2016). Health care savings that would offset the costs of CGM have not been demonstrated.

Values and preferences:

Blood glucose monitoring techniques that stabilize type 1 diabetes control would generally be highly valued by providers and patients, even if they involve increased attention and care. However, many individuals might prefer established finger-stick monitoring protocols with which they are familiar, given the limited evidence of benefit achieved by using the more complicated and invasive continuous monitoring.

Adults with DM1

Other considerations:

Studies that combine CGM and insulin pump management are appropriate and potentially important, but it is more difficult to establish the incremental benefit provided by CGM when both interventions are studied simultaneously.

Adults with DM1

Rationale:

There is insufficient evidence on long-term clinical outcomes related to the use of CGM, and CGM does not reduce severe hypoglycemia or ketoacidosis (although these were rare events in the studies). We found that use of real-time CGM in adults with DM1 results in greater improvements in HbA1c when compared with SMBG, although it is not clear that the benefits are clinically significant. Some evidence suggests that the greatest improvements in HbA1c are attained in patients who are on insulin pump management. We are recommending that use of CGM be limited to patients most likely to benefit by using criteria and clinical recommendations established by payers and professional societies. Our recommendation is weak because of the limited evidence of benefit.

No improvement in HbA1c levels has been demonstrated with use of retrospective CGM at up to six months of follow-up.

Adults with DM1

DRAFT Coverage Guidance

Real-time continuous glucose monitoring (CGM) is recommended for coverage *(weak recommendation)* in adults with type 1 diabetes mellitus:

- who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit and

- 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).

Retrospective CGM is not recommended for coverage in adults with type 1 diabetes (strong recommendation).

Evidence Summary: Integrated Sensor-Augmented Pump Therapy

Evidence sources for integrated sensor-augmented pump therapy for DM1

- Riemsma et al., 2016

Evidence Summary: Integrated Sensor-Augmented Pump Therapy

Integrated Sensor-Augmented Pump Therapy

- Limited evidence that the use of the MiniMed Veo integrated CSII + CGM system results in fewer overall and nocturnal hypoglycemic events compared to other integrated CSII + CGM systems
- Integrated CSII + CGM systems result in greater improvement in HbA1c at six months when compared to MDII + SMBG, but not when compared to CSII + SMBG (based on indirect comparisons)
- Integrated CSII + CGM systems result in greater patient satisfaction than CSII + SMBG or MDII + SMBG

Integrated Sensor-Augmented Pump Therapy

DRAFT Coverage Guidance

Real-time CGM (including the CGM-enabled insulin pump) is recommended for coverage *(weak recommendation)* in adults with type 1 diabetes on insulin pump management who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit.

Evidence Sources: Children and Adolescents with DM1

Evidence sources for children and adolescents with DM1

- Benkhadra et al., 2017
- Hommel et al., 2014
- Langendam et al., 2012
- NICE (Guideline 18), 2015
- Poolsup et al., 2013
- Riveline et al., 2012

Evidence Review: Children and Adolescents with DM1

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*
Severe morbidity *(Critical outcome)*	Insufficient evidence
Severe hypoglycemia *(Critical outcome)*	No difference in severe hypoglycemia at 6 months RR 0.63, 95% CI 0.27 to 1.46 ●●○○ *(Low confidence)*
Quality of life *(Important outcome)*	Greater parental satisfaction at 6 months MD 0.3 on a scale of 1 to 3, 95% CI 0.21 to 0.39 ●●●● (High confidence)

Evidence Review: Children and Adolescents with DM1

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*
Change in HbA1c *(Important outcome)*	No difference in HbA1c with real-time CGM at six months MD -0.09, 95% CI -0.24 to 0.07 ●●●● (High confidence) No difference in HbA1c with retrospective CGM at six months MD -0.3, 95% CI -0.67 to 0.07 ●●○○ (Low confidence)
Diabetic ketoacidosis *(Important outcome)*	Insufficient evidence

Evidence Summary: Children and Adolescents with DM1

Children with DM1

- Neither real-time nor retrospective CGM result in improvements in HbA1c
- CGM does appear to result in greater parental satisfaction at up to six months
- CGM does not reduce severe hypoglycemia or ketoacidosis (but these were rare events in the studies)
- Insufficient evidence about the effects of CGM on long-term clinical outcomes from diabetes

Children and Adolescents with DM1

Resource allocation:

CGM adds cost to type 1 diabetes management, and offsetting benefits in reducing complications (such as hypoglycemia and ketoacidosis) have not been established.

Values and preferences:

Parents of children with type 1 diabetes would place very high value in the reassurance provided by CGM.

Benefits of CGM may include decreasing the frequency of finger-stick testing, remote access to glucose levels, and lessened nocturnal anxiety, all of which are highly valued by parents (who have primary responsibility for control of diabetes in younger children).

Children and Adolescents with DM1

Other considerations:

CGM studies of children and adolescents with type 1 diabetes generally exclude those younger than eight years of age, and hypoglycemia unawareness is frequent in younger children.

The potential impact of severe or recurrent hypoglycemia on long-term neurocognitive development is a significant concern in children with type 1 diabetes.

Children and Adolescents with DM1

Rationale:

We have high confidence that use of CGM in children with type 1 diabetes results in greater parental satisfaction. Expert testimony confirms that providers, parents, and these young patients highly value the benefits of improved monitoring capability, especially in reducing anxiety related to potential hypoglycemia during attempts to improve HbA1c levels. Although the evidence does not show benefit in critical or important outcomes, we recognize that published CGM studies generally do not include the youngest children with type 1 diabetes and do not address long-term developmental concerns. Our recommendation for coverage is based on strongly expressed values and preferences, and it is a weak recommendation that may be supplemented by further studies of CGM use in this population.

We have low confidence that the use of retrospective CGM results in no clinically significant improvement in HbA1c levels, and there is no evidence of benefit for other critical or important outcomes. Therefore, we recommend noncoverage. The recommendation is strong because of evidence of no benefit.

Children and Adolescents with DM1

DRAFT Coverage Guidance

Real-time CGM is recommended for coverage *(weak recommendation)* in children and adolescents under age 21 with type 1 diabetes who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit.

Retrospective CGM is not recommended for coverage in children and adolescents with type 1 diabetes *(strong recommendation)*.

Evidence Sources: Adults with DM2

Evidence sources for adults with DM2

- NICE (Guideline 28), 2015
- Poolsup et al., 2013
- New et al., 2015
- Sato et al., 2016
- Tang et al., 2014
- Tildesley et al., 2013

Evidence Review: Adults with DM2

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*
Severe morbidity *(Critical outcome)*	Insufficient evidence
Severe hypoglycemia *(Critical outcome)*	Insufficient evidence
Quality of life *(Important outcome)*	No difference in treatment satisfaction compared to SMBG ●○○○ (Very low confidence) Lower treatment satisfaction compared to internet blood glucose monitoring ●○○○ (Very low confidence)

Evidence Review: Adults with DM2

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*
Change in HbA1c *(Important outcome)*	Greater improvement in HbA1c MD -0.31% 95% CI -0.6 to -0.02 ●●○○ *(Low confidence)*
Diabetic ketoacidosis *(Important outcome)*	Not applicable

Evidence Summary: Adults with DM2

Adults with DM2

- Evidence that CGM reduces HbA1c, but magnitude of improvement is smaller than for DM1 and may not be clinically significant
- CGM does not improve treatment satisfaction
- Insufficient evidence about the effects of CGM on hypoglycemia or long-term clinical outcomes from diabetes

Adults with DM2

Resource allocation:

CGM adds cost to type 2 diabetes management. There is insufficient evidence to assess possible offsetting health care savings.

Values and preferences:

Among patients with type 2 diabetes, preferences regarding CGM would be quite variable, even for those on insulin management.

Participant withdrawal because of inconvenience or discomfort was particularly noted in CGM studies of adults with type 2 diabetes.

Adults with DM2

Rationale:

We found insufficient evidence regarding the effects of CGM on long-term clinical outcomes or on severe hypoglycemia in type 2 diabetes, and CGM does not improve treatment satisfaction. We have low confidence that improvements in HbA1c levels seen in type 2 diabetes studies are clinically significant. Evidence was not found that demonstrated improved HbA1c or any other improved outcome with the use of retrospective CGM in adults with DM2. Given the prevalence of type 2 diabetes in the U.S. adult population, use of CGM would add significant cost without known population health benefit. Our recommendation for noncoverage of real-time CGM is a weak recommendation because additional studies could develop evidence that better supports its use in type 2 diabetes.

Adults with DM2

DRAFT Coverage Guidance

Real-time CGM is not recommended for coverage in adults with type 2 diabetes *(weak recommendation)*.

Retrospective CGM is not recommended for coverage in adults with type 2 diabetes *(strong recommendation)*.

Evidence Sources: Children and Adolescents with DM2

Evidence sources for children and adolescents with DM2

- No systematic reviews or randomized controlled trials identified

Evidence Review: Children and Adolescents with DM2

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*
Severe morbidity *(Critical outcome)*	Insufficient evidence
Severe hypoglycemia *(Critical outcome)*	Insufficient evidence
Quality of life *(Important outcome)*	Insufficient evidence
Change in HbA1c *(Important outcome)*	Insufficient evidence
Diabetic ketoacidosis *(Important outcome)*	Not applicable

Evidence Summary: Children and Adolescents with DM2

Children with DM2

- Insufficient evidence to draw conclusions about CGM for any outcomes

Children and Adolescents with DM2

Resource allocation:

CGM adds significant cost to diabetes management, and offsetting benefits in reducing complications (such as hypoglycemia) have not been established.

Values and preferences:

It is unlikely that there would be strong preferences for the use of CGM in children and adolescents with type 2 diabetes, given the extra care and attention that this monitoring entails and the absence of studies establishing clinical benefit.

Children and Adolescents with DM2

Rationale:

No systematic reviews or randomized controlled trials of CGM for children and adolescents with type 2 diabetes were identified in the search. There was insufficient evidence to draw conclusions about CGM for any outcomes in this population. Our recommendation for noncoverage is strong because of lack of evidence supporting the intervention, the additional cost, and the lack of clear values and preferences in favor of the intervention.

Children and Adolescents with DM2

DRAFT Coverage Guidance

Real-time CGM is not recommended for coverage in children and adolescents with type 2 diabetes *(strong recommendation)*.

Retrospective CGM is not recommended for coverage in children and adolescents with type 2 diabetes *(strong recommendation)*.

Evidence Sources: Pregnant Women with Preexisting DM or Gestational Diabetes (GDM)

Evidence sources for diabetes during pregnancy

- NICE (Guideline 3), 2015
- Wei et al., 2015

Evidence Review: Pregnant Women with Preexisting DM or GDM

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*
Severe morbidity *(Critical outcome)*	No differences in maternal, obstetrical, or neonatal outcomes ●○○○ to ●●○○ (Very low to low confidence)
Severe hypoglycemia *(Critical outcome)*	No difference in severe hypoglycemia RR 1.0, 95% CI 0.5 to 2.1 ●●○○ (Low confidence)
Quality of life *(Important outcome)*	Insufficient evidence

Evidence Review: Pregnant Women with Preexisting DM or GDM

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*
Change in HbA1c *(Important outcome)*	Greater improvement in HbA1c at 32 to 36 weeks gestation MD -0.6, 95% CI -0.9 to -0.3 ●●○○ *(Low confidence)* No difference in HbA1c at 36 weeks gestation MD -0.1, 95% CI not calculable, p = 0.63 ●●●○ (Moderate confidence)
Diabetic ketoacidosis *(Important outcome)*	Insufficient evidence

Evidence Summary: Pregnant Women with Preexisting DM or GDM

Pregnant women with diabetes

- Conflicting evidence about the effect of CGM on HbA1c at various time points during pregnancy
- CGM does not reduce severe hypoglycemia
- No differences in any of the studied maternal, obstetrical, or neonatal outcomes

Pregnant Women with Preexisting DM or GDM

Resource allocation:

Outcome improvements for diabetes in pregnancy, especially neonatal outcome improvements, could result in substantial short-term and long-term cost savings. However, thus far, improved outcomes have not been demonstrated, and use of CGM would add significant cost to diabetes management in pregnancy.

Values and preferences:

The value placed on CGM by pregnant women would be highly variable, but would likely be much higher for those with type 1 diabetes. Even in the absence of demonstrated significant clinical outcomes, many obstetrical providers would favor use of monitoring that potentially improves blood sugar control in pregnancy.

Pregnant Women with Preexisting DM or GDM

Rationale:

There is conflicting evidence about the effect of CGM on HbA1c during the third trimester of pregnancy and no evidence regarding the use of these devices earlier in pregnancy or before conception. CGM does not appear to reduce severe hypoglycemia during the third trimester, and there is insufficient evidence to assess effects on quality of life or diabetic ketoacidosis. No benefits have been identified for maternal, obstetrical, or neonatal outcomes. In spite of these limitations, many patients and providers would favor monitoring (particularly in type 1 diabetes) that improves blood sugar control during pregnancy, even with associated additional cost. Despite the cost of these devices and the lack of evidence of clinical outcomes for this population, there is a clear rationale for using CGM to help control blood glucose levels to prevent the known fetal and maternal harms associated with type 1 diabetes during pregnancy or when pregnancy is anticipated.

Pregnant Women with Preexisting DM or GDM

DRAFT Coverage Guidance

CGM is not recommended for coverage during pregnancy for type 2 diabetes or gestational diabetes *(weak recommendation)*.

CGM is recommended for coverage for women with type 1 diabetes who are pregnant or who plan to become pregnant within six months without regard to HbA1c levels *(weak recommendation)*.

Policy Landscape: Guidelines

Review of nine guidelines related to CGM:

- Guidelines consistently recommend that CGM be considered for certain adult patients with DM1, especially for individuals with DM1 who have severe or frequent episodes of hypoglycemia or hypoglycemia unawareness
  - Some recommend patient education or confirmation of adequate patient knowledge prior to CGM use
- Guidelines state that evidence is not as strong for CGM for children with diabetes, persons with DM2, and pregnant women with diabetes
  - Some recommend CGM for children with DM1
  - Some recommend CGM for adults with DM2 who are insulin-dependent

Policy Landscape: Medicaid

Washington Medicaid

- Covers FDA-approved CGM devices for patients ages 18 and younger with prior authorization:
  - Diagnosed with insulin-dependent diabetes
  - Followed by an endocrinologist
  - Had severe episode of hypoglycemia or be enrolled in an IRB-approved trial
- Requires verification of blood glucose with SMBG prior to insulin adjustment

Policy Landscape: Medicare

- Medicare Local Coverage Determination to cover CGM, effective 1/12/2017; applies to all 50 states and DC
  - Patient has been testing blood glucose at least four times a day
  - Patient uses three or more daily injections of insulin or a Medicare-covered CSII pump
  - Patient's insulin treatment regimen requires frequent adjustment based on blood glucose readings
  - Treating practitioner has in-person visit with patient every six months to assess adherence

Policy Landscape: Private Payers

- Regence considers subcutaneous insertion and removal of an implantable interstitial glucose sensor to be investigational medical technology
- Aetna, Cigna, and Moda cover short-term and long-term use of CGM for certain patients when criteria are met
  - Criteria for coverage vary among these providers
  - Examples of criteria include DM1 only, history of ketoacidosis, 3+ daily insulin injections, evidence of patient adherence

Public Comment

- Five public comments were submitted
  - Person with diabetes: favored coverage because of his experience with CGM
  - Group of practitioners: favored coverage of CGM for children with DM1
  - Practitioner: had questions about coverage and implementation
  - Dexcom: favored coverage for DM2
  - Abbott Diabetes Care: favored coverage for DM2

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: CONTINUOUS GLUCOSE MONITORING IN DIABETES MELLITUS

DRAFT for VbBS/HERC meeting materials 8/10/2017

HERC Coverage Guidance

Real-time continuous glucose monitoring (CGM) is recommended for coverage *(weak recommendation)* in adults with type 1 diabetes mellitus:

- who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit and
- 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).

Real-time CGM is recommended for coverage *(weak recommendation)* in children and adolescents under age 21 with type 1 diabetes who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit.

Real-time CGM (including the CGM-enabled insulin pump) is recommended for coverage *(weak recommendation)* in adults with type 1 diabetes on insulin pump management who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit.

Real-time CGM is not recommended for coverage in adults with type 2 diabetes *(weak recommendation)*.

Real-time CGM is not recommended for coverage in children and adolescents with type 2 diabetes *(strong recommendation)*.

Retrospective CGM is not recommended for coverage in patients of any age with type 1 or type 2 diabetes *(strong recommendation)*.

CGM is not recommended for coverage during pregnancy for type 2 diabetes or gestational diabetes *(weak recommendation)*.

CGM is recommended for coverage for women with type 1 diabetes who are pregnant or who plan to become pregnant within six months without regard to HbA1c levels *(weak recommendation)*.

Note: Definitions for strength of recommendation are provided in Appendix A *GRADE-Informed Framework Element Description*.

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 they seek to improve patient experience of care, population health, and the cost-effectiveness of health care. In the era of the Affordable Care Act and health system transformation, reaching these goals may require a focus on population-based health interventions from a variety of sectors as well as individually-focused clinical care. Multisector intervention reports will be developed to address these population-based health interventions or other types of interventions that happen outside of the typical clinical setting.

The HERC selects topics for its reports to guide public and private payers based on the following principles:

- 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 reports are based on a review of the relevant 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. For some conditions, the HERC has reviewed evidence and identified effective interventions, but has not made coverage recommendations because many of these policies are implemented in settings beyond traditional healthcare delivery systems.

GRADE-INFORMED FRAMEWORK

The 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 carrying out the steps involved in developing recommendations. There are several elements that determine the strength of a recommendation, as listed in the table below. The 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. Otherwise, the level of confidence in the estimate is determined by the HERC based on the assessment of two independent reviewers from the Center for Evidence-based Policy. Unless otherwise noted, estimated resource allocation, values and preferences, and other considerations are assessments of the HERC.

Coverage question: Should continuous glucose monitoring be recommended for coverage in adults with type 1 diabetes mellitus?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other Considerations**
Severe morbidity *(Critical outcome)*	Insufficient evidence	CGM adds significant cost to diabetes management, and generally does not eliminate the need for finger-stick testing before insulin dosage changes (one device that does so was approved by the FDA in December 2016). Health care savings that would offset the costs of CGM have not been demonstrated.	Blood glucose monitoring techniques that stabilize type 1 diabetes control would generally be highly valued by providers and patients, even if they involve increased attention and care. However, many might prefer established finger-stick monitoring	Studies that combine CGM and insulin pump management are appropriate and potentially important, but it is more difficult to establish the incremental benefit provided by CGM when both interventions are studied simultaneously.
Severe hypoglycemia *(Critical outcome)*	No difference in severe hypoglycemia at up to six months ●●○○ *(Low confidence)*			
Quality of life *(Important outcome)*	No differences in various measures of quality of life ●●●○ *(Moderate confidence)*			
Change in HbA1c *(Important outcome)*	No difference in HbA1c with retrospective CGM at up to six months of follow-up (MD -0.09%, 95% CI -0.44 to 0.26) ●●●○ *(Moderate confidence)*			

Coverage question: Should continuous glucose monitoring be recommended for coverage in adults with type 1 diabetes mellitus?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other Considerations**
	Greater improvement in HbA1c with real-time CGM at up to six months of follow-up (MD -0.30%, 95% CI -0.47 to -0.12) ●●○○ *(Low confidence)*		protocols with which they are familiar, given the limited evidence of benefit achieved by using the more complicated and invasive continuous monitoring.	
Diabetic ketoacidosis *(Important outcome)*	No difference in ketoacidosis ●●○○ *(Low confidence)*			
Rationale: There is insufficient evidence on long-term clinical outcomes related to the use of CGM, and CGM does not reduce severe hypoglycemia or ketoacidosis (although these were rare events in the studies). We found that use of real-time CGM in adults with DM1 results in greater improvements in HbA1c when compared with SMBG, although it is not clear that the benefits are clinically significant. Some evidence suggests that the greatest improvements in HbA1c are attained in patients who are on insulin pump management. We are recommending that use of CGM be limited to those most likely to benefit by using criteria and clinical recommendations established by payers and professional societies. Our recommendation is weak because of the limited evidence of benefit. No improvement in HbA1c levels has been demonstrated with use of retrospective CGM at up to six months of follow-up.				
Recommendation: Real-time CGM is recommended for coverage *(weak recommendation)* in adults with type 1 diabetes mellitus: • who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit and • 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). Real-time CGM (including the CGM-enabled insulin pump) is recommended for coverage *(weak recommendation)* in adults with type 1 diabetes on insulin pump management who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit. Retrospective CGM is not recommended for coverage in adults with type 1 diabetes (strong recommendation).				

Coverage question: Should continuous glucose monitoring be recommended for coverage in adults with type 2 diabetes mellitus?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other Considerations**
Severe morbidity *(Critical outcome)*	Insufficient evidence	CGM adds cost to type 2 diabetes management. There is insufficient evidence to assess possible offsetting health care savings.	Among patients with type 2 diabetes, preferences regarding CGM would be quite variable, even for those on insulin management. Participant withdrawal because of inconvenience or discomfort was particularly noted in CGM studies of adults with type 2 diabetes.	
Severe hypoglycemia *(Critical outcome)*	Insufficient evidence			
Quality of life *(Important outcome)*	No difference in treatment satisfaction compared to SMBG ●○○○ *(Very low confidence)* Lower treatment satisfaction compared to internet blood glucose monitoring ●○○○ *(Very low confidence)*			
Change in HbA1c *(Important outcome)*	Greater improvement in HbA1c (MD -0.31% 95% CI -0.6 to -0.02) ●●○○ *(Low confidence)*			
Diabetic ketoacidosis *(Important outcome)*	Not applicable			

Rationale: We found insufficient evidence regarding the effects of CGM on long-term clinical outcomes or on severe hypoglycemia in type 2 diabetes, and CGM does not improve treatment satisfaction. We have low confidence that improvements in HbA1c levels seen in type 2 diabetes studies are clinically significant. Evidence was not found that demonstrated improved HbA1c or any other improved outcome with the use of retrospective CGM in adults with DM2. Given the prevalence of type 2 diabetes in the U.S. adult population, use of CGM would add significant cost without known population health benefit. Our recommendation for noncoverage of real-time CGM is a weak recommendation because additional studies could develop evidence that better supports its use in type 2 diabetes.

Recommendation: Real-time CGM is not recommended for coverage in adults with type 2 diabetes *(weak recommendation)*. Retrospective CGM is not recommended for coverage in adults with type 2 diabetes *(strong recommendation)*.

Coverage question: Should continuous glucose monitoring be recommended for coverage in children and adolescents with type 1 diabetes mellitus?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource allocation	Values and Preferences	Other Considerations
Severe morbidity *(Critical outcome)*	Insufficient evidence	CGM adds cost to type 1 diabetes management, and offsetting benefits in reducing complications (such as hypoglycemia and ketoacidosis) have not been established.	Parents of children with type 1 diabetes would place very high value in the reassurance provided by CGM. Benefits of CGM may include decreasing the frequency of finger-stick testing, remote access to glucose levels, and lessened nocturnal anxiety, all of which are highly valued by parents (who have primary responsibility for control of diabetes in younger children).	CGM studies of children and adolescents with type 1 diabetes generally exclude those younger than eight years of age, and hypoglycemia unawareness is frequent in younger children. The potential impact of severe or recurrent hypoglycemia on long-term neurocognitive development is a significant concern in children with type 1 diabetes.
Severe hypoglycemia *(Critical outcome)*	No difference in severe hypoglycemia at 6 months (RR 0.63, 95% CI 0.27 to 1.46) ●●○○ *(Low confidence)*			
Quality of life *(Important outcome)*	Greater parental satisfaction at 6 months (MD 0.3 on a scale of 1 to 3, 95% CI 0.21 to 0.39) ●●●● *(High confidence)*			
Change in HbA1c *(Important outcome)*	No difference in HbA1c with real-time CGM at six months (MD -0.09, 95% CI -0.24 to 0.07) ●●●● *(High confidence)* No difference in HbA1c with retrospective CGM at six months (MD -0.3, 95% CI -0.67 to 0.07 ●●○○ *(Low confidence)*			
Diabetic ketoacidosis *(Important outcome)*	Insufficient evidence			

Coverage question: Should continuous glucose monitoring be recommended for coverage in children and adolescents with type 1 diabetes mellitus?
Rationale: We have high confidence that use of CGM in children with type 1 diabetes results in greater parental satisfaction. Expert testimony confirms that providers, parents, and these young patients highly value the benefits of improved monitoring capability, especially in reducing anxiety related to potential hypoglycemia during attempts to improve HbA1c levels. Although the evidence does not show benefit in critical or important outcomes, we recognize that published CGM studies generally do not include the youngest children with type 1 diabetes and do not address long-term developmental concerns. Our recommendation for coverage is based on strongly expressed values and preferences, and it is a weak recommendation that may be supplemented by further studies of CGM use in this population. We have low confidence that the use of retrospective CGM results in no clinically significant improvement in HbA1c levels, and there is no evidence of benefit for other critical or important outcomes. Therefore, we recommend noncoverage. The recommendation is strong because of evidence of no benefit.
Recommendation: Real-time CGM is recommended for coverage *(weak recommendation)* in children and adolescents under age 21 with type 1 diabetes who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit. Retrospective CGM is not recommended for coverage in children and adolescents with type 1 diabetes *(strong recommendation).*

Coverage question: Should continuous glucose monitoring be recommended for coverage in children and adolescents with type 2 diabetes mellitus?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other Considerations**
Severe morbidity *(Critical outcome)*	Insufficient evidence	CGM adds significant cost to diabetes management, and offsetting benefits in reducing complications (such as hypoglycemia) have not been established.	It is unlikely that there would be strong preferences for the use of CGM in children and adolescents with type 2 diabetes, given the extra care	
Severe hypoglycemia *(Critical outcome)*	Insufficient evidence			
Quality of life *(Important outcome)*	Insufficient evidence			

Coverage question: Should continuous glucose monitoring be recommended for coverage in children and adolescents with type 2 diabetes mellitus?				
Change in HbA1c *(Important outcome)*	Insufficient evidence		and attention that this monitoring entails and the absence of studies establishing clinical benefit.	
Diabetic ketoacidosis *(Important outcome)*	Not applicable			
Rationale: No systematic reviews or randomized controlled trials of CGM for children and adolescents with type 2 diabetes were identified in the search. There was insufficient evidence to draw conclusions about CGM for any outcomes in this population. Our recommendation for noncoverage is strong because of lack of evidence supporting the intervention, the additional cost, and the lack of clear values and preferences in favor of the intervention.				
Recommendation: Real-time CGM is not recommended for coverage in children and adolescents with type 2 diabetes *(strong recommendation).* Retrospective CGM is not recommended for coverage in children and adolescents with type 2 diabetes *(strong recommendation)*.				

Coverage question: Should continuous glucose monitoring be recommended for coverage in pregnant women with preexisting or gestational diabetes mellitus?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other Considerations**
Severe morbidity *(Critical outcome)*	No differences in maternal, obstetrical, or neonatal outcomes ●○○○ to ●●○○ *(Very low to low confidence)*	Outcome improvements for diabetes in pregnancy, especially neonatal outcome improvements, could result in substantial	The value placed on CGM by pregnant women would be highly variable, but would likely be much higher for	
Severe hypoglycemia *(Critical outcome)*	No difference in severe hypoglycemia (RR 1.0, 95% CI 0.5 to 2.1) ●●○○ *(Low confidence)*			

Coverage question: Should continuous glucose monitoring be recommended for coverage in pregnant women with preexisting or gestational diabetes mellitus?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other Considerations**
Quality of life *(Important outcome)*	Insufficient evidence	short-term and long-term cost savings. However, thus far improved outcomes have not been demonstrated, and use of CGM would add significant cost to diabetes management in pregnancy.	those with type 1 diabetes. Even in the absence of demonstrated significant clinical outcomes, many obstetrical providers would favor use of monitoring that potentially improves blood sugar control in pregnancy.	
Change in HbA1c *(Important outcome)*	Greater improvement in HbA1c at 32 to 36 weeks gestation (MD -0.6, 95% CI -0.9 to -0.3) ●●○○ *(Low confidence)* No difference in HbA1c at 36 weeks gestation (MD -0.1, 95% CI not calculable, p=0.63) ●●●○ *(Moderate confidence)*			
Diabetic ketoacidosis *(Important outcome)*	Insufficient evidence			
Rationale: There is conflicting evidence about the effect of CGM on HbA1c during the third trimester of pregnancy and no evidence regarding the use of these devices earlier in pregnancy or before conception. CGM does not appear to reduce severe hypoglycemia during the third trimester, and there is insufficient evidence to assess effects on quality of life or diabetic ketoacidosis. No benefits have been identified for maternal, obstetrical, or neonatal outcomes. In spite of these limitations, many patients and providers would favor monitoring (particularly in type 1 diabetes) that improves blood sugar control during pregnancy, even with associated additional cost. Despite the cost of these devices and the lack of evidence of clinical outcomes for this population, there is a clear rationale for using CGM to help control blood glucose levels to prevent the known fetal and maternal harms associated with type 1 diabetes during pregnancy or when pregnancy is anticipated.				
Recommendation: CGM is not recommended for coverage during pregnancy for type 2 diabetes or gestational diabetes *(weak recommendation)*.				

CGM is recommended for coverage for women with type 1 diabetes who are pregnant or who plan to become pregnant within six months without regard to HbA1c levels *(weak recommendation)*.

Note: GRADE framework elements are described in Appendix A. A GRADE Evidence Profile is provided in Appendix B.

EVIDENCE OVERVIEW

Clinical Background

Diabetes mellitus is a metabolic disorder in which blood sugar (glucose) levels are elevated as a result of the body either failing to produce sufficient insulin or to use its own insulin properly (Centers for Disease Control and Prevention [CDC], 2015). Although the rate of new cases of diabetes in the United States has started to decline, diabetes remains a major public health issue: more than 29 million Americans are currently living with diabetes and 86 million Americans are living with prediabetes (CDC, 2016). Diabetes was the seventh leading cause of death in the U.S. in 2013 (CDC, 2016). Diabetes complications and associated conditions include heart disease, stroke, blindness, kidney disease, and amputations. More than 20% of health care expenditures are allocated to persons with diabetes (CDC, 2016).

There are several types of diabetes. Type 1 diabetes (DM1) accounts for 5% of diabetes cases and is typically diagnosed in children and young adults (American Diabetes Association [ADA], 2017d). In DM1, the immune system attacks cells in the pancreas that produce insulin. People with DM1 are thus reliant on daily insulin injections to stay alive (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2016).

In children, DM1 has been associated with mild impairment in neurocognitive functioning across several domains; in particular, severe hypoglycemia is associated with statistically significant impairment in short-term verbal memory (Naguib, Kulinskaya, Lomax, & Garralda, 2009). Additionally, psychological distress is common among parents of children with DM1 and higher levels of psychological distress are associated with poorer diabetes management (Whittemore, Jaser, Chao, Jang, & Grey, 2012).

Type 2 diabetes (DM2) accounts for approximately 90% to 95% of diabetes cases (CDC, 2015). DM2 can develop at any age as a result of the body failing to make or use insulin properly, but is most common in adults (NIDDK, 2016).

Gestational diabetes (GDM) develops in 2% to 10% of pregnancies and can cause health issues for mothers and their babies if untreated (CDC, 2015).

Diabetes is typically treated with healthy eating, physical activity, medications to lower blood glucose levels, insulin injections, and blood glucose testing. It is important for people with diabetes to take responsibility for their daily care and maintain blood glucose levels within target range (CDC, 2015).

Indications

Blood glucose monitoring is a critical tool for patients in managing their diabetes. Target ranges for levels of blood glucose are individualized based on duration of diabetes, age and life expectancy, comorbid conditions, known cardiovascular disease or advanced microvascular complications, hypoglycemia unawareness, and individual patient considerations. The ADA typically recommends an HbA1c target of 7% (i.e., 154 mg/dL average glucose) for adults with diabetes who are not pregnant. Results from measuring blood glucose levels often inform changes to the patient's treatment plan, especially if blood glucose levels are abnormally high or low or fluctuating rapidly (ADA, 2017a).

Hypoglycemia is a condition characterized by abnormally low blood glucose levels (usually defined as below 70 mg/dL), which can lead to a seizure or unconsciousness if left untreated. Individual reactions to hypoglycemia vary; signs and symptoms include shakiness, anxiety, irritability, confusion, rapid heartbeat, dizziness, nausea, hunger, headache, and fatigue. Hypoglycemia unawareness is when blood glucose levels fall below 70 mg/dL, but there are no symptoms (ADA, 2017c). Hyperglycemia or high blood glucose occurs when the body has too little insulin or when the body cannot use insulin properly. If left untreated, hyperglycemia can lead to ketoacidosis (i.e., a diabetic coma), a life-threatening condition requiring immediate treatment (ADA, 2017b).

Given the importance of blood glucose testing and insulin administration to the management of diabetes, multiple technologies are available to aid persons with diabetes in maintaining their blood glucose levels within a safe range. The most common way to check glucose levels is the finger-stick test, which involves pricking a fingertip with a lancing device to obtain a blood sample and then using a glucose meter to measure the blood glucose level (NIDDK, 2008). More recently developed technologies include insulin pumps, which are computerized devices that can deliver a steady flow of insulin; continuous glucose monitoring (CGM) devices; and CGM-enabled insulin pumps (United States Food and Drug Administration [FDA], 2016b).

Technology Description

CGM systems consist of a small sensor inserted under the patient's skin to measure glucose levels in the interstitial fluid. The device automatically takes readings, typically in one-minute or five-minute intervals (NIDDK, 2008). CGM devices can be categorized into two primary types: retrospective and real-time. In retrospective CGM, data must be downloaded from the device before analysis. Real-time CGM systems, approved by the FDA in 2005, consist of a transmitter and receiver connected to the glucose sensor, which enables the patient to see measurements instantaneously. Real-time CGM also allows for the option to set alarms, which can alert patients to hypoglycemia, hyperglycemia, or rapid variations in glucose levels (Golden et al., 2012).

The accuracy of CGM systems has improved during the last decade and measurement error has been reduced from approximately 20% to 10% (Rodbard, 2016). In December 2016, the FDA announced its expansion of approved use for one CGM system, the Dexcom's G5 Mobile Continuous Glucose Monitoring System; the device is now approved as a replacement for the finger-stick test for diabetes treatment decisions for individuals ages two and older. Previously, all approved CGM devices including the Dexcom system were approved only to supplement and not replace finger-stick testing (FDA, 2016a).

Key Questions and Outcomes

The following key questions (KQ) guided the evidence search and review described below. For additional details about the review scope and methods, please see Appendix C.

1. What is the evidence of effectiveness of CGM in improving outcomes in people with diabetes?
2. What are the indications for retrospective and real-time CGM?

3. Is there evidence of differential effectiveness of CGM based on:
    a. Type 1 vs. Type 2 DM?
    b. Insulin pump (integrated with CGM or standalone) vs. multiple daily insulin injections (MDII)?
    c. Frequency and duration of CGM?
    d. Persistently poor glycemic control?

Critical outcomes selected for inclusion in the GRADE table are severe morbidity (e.g., microvascular and macrovascular complications) and severe hypoglycemia. Important outcomes selected for inclusion in the GRADE table are quality-of-life, change in HbA1c, and ketoacidosis.

Evidence Review

Adults with DM1

Langendam et al., 2012

This is a high-quality systematic review of 22 randomized controlled trials (RCTs) of CGM in patients with DM1. The review included studies of adults and children and studies of real-time and retrospective CGM. Seven of the studies involved only patients with poorly controlled diabetes (HbA1c >8.0%). The authors noted several concerns regarding risk of bias in the studies, including inadequate allocation concealment, lack of blinding, and industry sponsorship or involvement.

The main comparison for the review examined the use of CGM-augmented insulin pump therapy to self-monitoring blood glucose (SMBG) with MDII in insulin pump-naïve patients (all age groups). For this comparison, there were no statistically significant differences in severe hypoglycemia at six months (risk ratio [RR] with CGM 3.26, 95% CI 0.38 to 27.82, very low-quality evidence); ketoacidosis at six months (RR with CGM 2.45, 95% CI 0.1 to 58.45, very low-quality evidence), or quality of life at six months as measured by the SF-36 (very low-quality evidence). Patients treated with CGM-augmented insulin pump therapy had greater improvement in HbA1c at six months (-0.7% compared to -0.1 to -0.2% in the control groups, moderate-quality evidence).

The overall meta-analytic estimates for the effects of real-time CGM in patients with DM1 (adults and children) were as follows:

- There was low-quality evidence of no difference in severe hypoglycemia at six months (7.9% with CGM vs. 7.5% with controls, RR 1.05, 95% CI 0.63 to 1.77).
- There was low-quality evidence of no difference in ketoacidosis at six months (2% with CGM vs. 2.3% with controls, RR 0.85, 95% CI 0.32 to 2.26).
- There was very low-quality evidence of no differences in patient or parental quality of life at six months.
- There was moderate-quality evidence that CGM reduced HbA1c more than controls at six months (mean difference -0.2%, 95% CI -0.1% to -0.4%).

The following observations were made about retrospective CGM systems in adults:

- One study found no difference in the change in HbA1c between study arms and another study found a statistically non-significant difference in favor of GCM (-0.3%, 95% CI -0.9% to 0.3%).
- One study found no difference in severe hypoglycemia (one event in each group).

The following observations were made about real-time CGM systems in adults:

- At three months, the mean difference in change in HbA1c ranged from -0.12 to -1.12 in favor of CGM (five trials, two with statistically significant improvements).
- At six months, the mean difference in change in HbA1c ranged from -0.05 to -1.10 in favor of CGM (three trials, two with statistically significant improvements).
- At 12 months, the mean difference in change in HbA1c was -0.6 based on a single trial with a statistically significant improvement.
- For a single trial that reported on the categorical outcome of >0.5% reduction in HbA1c at six months, the RR was 4.25 (95% CI 1.76 to 10.22, 46% vs. 11% absolute risk) in favor of CGM.
- In four trials that examined severe hypoglycemia at three to 12 months, there were no statistically significant differences between the groups.
- Of four trials that investigated ketoacidosis at three to 12 months, there were no statistically significant differences between the groups.
- In two trials that reported on quality of life at six months, there were no statistically significant differences between the groups.

The authors included several pre-specified subgroup analyses. No studies involved patients with impaired awareness of hypoglycemia. Among the seven studies that enrolled patients with poorly controlled DM1 (HbA1c >8.0%), the three retrospective CGM studies reached conflicting conclusions, and the four real-time CGM studies offered "limited evidence" for improved glycemic control. In one study that examined protocol adherence, patients who used the CGM sensor at least 70% of the time had greater improvements in HbA1c than CGM users who demonstrated lower adherence (mean change in HbA1c at six months of -0.96% vs. -0.81%).

Benkhadra et al., 2017

This is a high-quality systematic review and individual patient data meta-analysis of RCTs of real-time CGM in adults and children with DM1. The authors identified 11 trials and judged the overall risk of bias in these trials to be moderate (mostly stemming from concerns about allocation concealment, blinding, and industry sponsorship). The patient characteristics were similar at baseline; the average baseline HbA1c was 8.2% in adults and 8.3% in children and adolescents.

The meta-analytic estimates were stratified by age. For participants over the age of 15, CGM resulted in a greater reduction in HbA1c compared to controls (mean difference -0.356%, 95% CI -0.551% to -0.160%, $p<0.001$). For participants ages 12 and under or ages 13 to 15, there were no statistically significant differences in HbA1c between the CGM and control groups. Severe hypoglycemia was not assessed in this review, but the meta-analysis found no statistically significant differences in the incidence of any hypoglycemic event (glucose <70 mg/dL) in the overall population or any of the

stratified age groups. A sensitivity analysis that excluded two trials of older real-time CGM technology did not alter the conclusions.

National Institute for Health and Care Excellence (Guideline 17), 2015

This is a good-quality systematic review commissioned by the National Institute for Health and Care Excellence to inform the 2015 update of the comprehensive guideline on diagnosis and management of DM1 in adults. The authors identified 11 parallel RCTs and three crossover RCTs that compared retrospective or real-time CGM to SMBG. The authors assessed GRADE ratings for the outcomes.

For trials comparing retrospective CGM to SMBG, there was moderate-quality evidence of no statistically significant difference in HbA1c at up to six months of follow-up (mean difference -0.09, 95% CI -0.44 to 0.26), and low-quality evidence of no statistically significant difference in severe hypoglycemia.

For trials comparing real-time CGM to SMBG, there was very low-quality evidence of a statistically significant improvement in HbA1c at up to six months of follow-up (mean difference -0.30%, 95% CI -0.47 to -0.12). There was very low-quality evidence of no statistically significant difference between real-time CGM and SMBG with respect to severe hypoglycemia at up to six months follow-up (12 fewer events per 1,000 patients with CGM, 95% CI -37 to 63 per 1,000). There was moderate-quality evidence of no significant difference between real-time CGM and SMBG with respect to overall and various subscale measures of quality of life.

Beck et al., 2017

This is a moderate-quality RCT of real-time CGM (using the Dexcom G4 Platinum system) in adults with DM1 using MDII. The trial was conducted at 24 endocrinology practices in the United States. Adults over age 25 with DM1 were eligible to participate in the trial if their HbA1c level was between 7.5% and 10% and they had not used a CGM device in the preceding three months. There was a two week run-in period during which eligible participants were required to demonstrate 85% adherence to use of the CGM sensor in addition to twice-daily calibration with a blood glucose meter. Fourteen eligible participants were excluded from randomization during the run-in period. Ultimately, 158 adults were randomly assigned (2:1 randomization) to CGM or continued SMBG. Randomization was stratified by HbA1c level. The authors did not describe blinding of patients, clinicians, or outcomes assessors. The primary outcomes were changes in HbA1c at 12 and 24 weeks as measured by a central laboratory.

The groups were generally similar at baseline, and the average HbA1c in both groups was 8.6%. A greater proportion of patients in the control group had reported at least one episode of severe hypoglycemia in the previous 12 months (17% vs. 8%). At 24 weeks, the mean change in HbA1c was greater in the CGM group (-0.6%, 95% CI -0.8% to -0.3%, $p<0.001$). The percentage of patients achieving HbA1c of <7.0% at 24 weeks was 18% in the CGM group and 4% in the control group ($p=0.01$). There were two episodes of severe hypoglycemia in each group, and no episodes of ketoacidosis in either group. In the exploratory analyses, age, baseline HbA1c, education level, and type of study site (community or academic) did not have significant interactions with the 24-week HbA1c treatment effect.

Hommel et al., 2014

This is a report on quality of life, treatment satisfaction, medical resource use, and indirect costs from a fair-quality randomized crossover trial of real-time CGM in adults and children with DM1 treated with continuous subcutaneous insulin infusion (CSII). Patients ages 6 to 70 were eligible to participate in the study if they had DM1 for more than one year and had been on CSII for more than six months with suboptimal control (defined as HbA1c 7.5% to 9.5%). Patients were required to pass a five-question multiple-choice test concerning pump therapy and general understanding of diabetes to be eligible. During a four week run-in period, eligible patients wore the CGM system (MiniMed Paradigm) for two weeks, followed by two weeks during which blinded CGM data was collected. At the end of the run-in period, eligible patients were required to pass a 10-question test about sensor use in order to enter the trial. Ultimately, 153 patients were randomized in a 1:1 ratio to six months of sensor ON or sensor OFF, followed by a four-month washout period before crossing over to the other arm. Patients had clinical follow-up every six weeks during the study periods. Blinding of patients, clinicians, or outcomes assessors was not described in the report.

The groups were similar at baseline and the average HbA1c values were 8.5% and 8.3% for the OFF/ON and ON/OFF sequence, respectively. For adult participants, overall treatment satisfaction (measured by the Diabetes Treatment Satisfaction Questionnaire [DTSQ]) was higher in the sensor ON arm (p=0.012). There were no statistically significant differences between the sensor ON and sensor OFF groups with respect to diabetes-related hospitalizations (p=0.21). In a per-protocol analysis, children with >70% adherence during the sensor ON period had significantly fewer missed school days compared to the sensor OFF group (0.38 vs. 1.24 days per child per six months, p=0.005).

Lind et al., 2017

This is a fair-quality open-label randomized crossover trial of real-time CGM conducted at 15 clinical sites in Sweden. Patients over the age of 18 with DM1 for at least one year were eligible if they had HbA1c >7.5% and were being treated with MDII; patients receiving treatment with CSII were excluded. All eligible patients were subject to a six-week run-in period, which included two weeks of masked CGM data collection. Patients who “did not believe they would wear the sensor more than 80% of the time” or who did not perform a sufficient number of calibrations were excluded. Ultimately, 161 patients were randomized to real-time CGM or SMBG (four times daily) for 26 weeks, followed by a 17-week washout period, and then crossover to the other arm for an additional 26 weeks. The trial was not blinded.

The groups were similar at baseline, and the average HbA1c was 8.5% at the time of randomization. Nineteen patients (12%) had incomplete follow-up and were excluded from the analysis. The patients with incomplete follow-up were more likely to be younger, have a higher baseline HbA1c, and to have had an episode of severe hypoglycemia in the preceding year compared to those with complete follow-up. For the primary outcome of change in HbA1c, patients in the CGM arm had statistically significantly greater improvements than those in the control arm (mean difference -0.43%, 95% CI -0.57 to -0.29). Severe hypoglycemia was rare, occurring in five patients in the control arm and one patient in the CGM arm (numeric data only). Mean well-being (measured by the WHO-5 scale) and treatment satisfaction (measured by DTSQ) were statistically significantly higher in the CGM arm.

New et al., 2015

This is a fair-quality randomized controlled trial comparing real-time CGM with alarms, real-time CGM without alarms, and SMBG. Adults ages 18 to 65 with DM1 or DM2 treated with MDII or CSII and who had not used a CGM system in the preceding six months were eligible. After a 20 day run-in period during which masked CGM was performed, patients with at least 50% adherence to sensor use (n=145) were randomized to CGM with alarms, CGM without alarms, and SMBG (1:1:1, stratified by type of diabetes). The trial was not blinded.

The groups were similar at baseline, and the average HbA1c was around 8.2%. Most participants (about 85%) had DM1. Although they were not the primary outcomes, HbA1c and quality of life measures were reported. Severe hypoglycemia and ketoacidosis were not reported. There were no statistically significant differences between the three groups with respect to change in HbA1c. As for quality of life measures, only the comparison of CGM with alarms versus SMBG for the physical component score of the Short-Form-8 Health Survey reached statistical significance (favoring CGM with alarms, p=0.024). There were no differences in the Diabetes Distress Scale Score between the groups.

Riveline et al., 2012

This is a poor-quality randomized trial comparing patient-led real-time CGM, physician-driven real-time CGM, and SMBG in adults and children with DM1 treated with MDII or CSII. Eligible patients were between 8 and 60 years old, had HbA1c ≥ 8.0%, and were performing SMBG at least twice daily. Eligible participants were subject to a 10-day run-in period to assess suitability for CGM use. Randomization technique and allocation concealment were not described. Of 257 eligible participants, 60 failed the screening during run-in, and these patients were more likely to be younger, have a lower educational level, and have a history of ketoacidosis compared to the group that was randomized. Ultimately, 197 patients were randomized, but 19 were excluded from the analysis because of missing HbA1c data.

The groups were generally similar at baseline, although the patient-led CGM group included a greater number of patients with an episode of severe hypoglycemia in the previous year. At 12 month follow-up, the reduction in HbA1c was similar in the two CGM groups. The combined CGM groups had greater improvement in HbA1c (-0.48%, 95% CI -0.63 to -0.33) than the SMBG group (0.02%, 95% CI -0.18 to 0.23). However, the improvement in HbA1c in the combined CGM groups was only present in patients on CSII (-0.67%, 95% CI -1.01 to -0.33); for patients on MDII, the difference in HbA1c between the combined CGM groups and the SMBG group was not statistically significant (-0.28%, 95% CI -0.67 to 0.10). After adjustment for age and a history of severe hypoglycemia in the previous year, there were no differences in episodes of severe hypoglycemia between the groups. For quality of life outcomes, patients in the combined CGM groups had statistically significant improvements in the physical component score of the SF-36 and the treatment satisfaction scale of the Diabetes Quality of Life (DQoL) score compared to those in the SMBG group; there were no statistically significant differences between the CGM and the SMBG groups on the global DQoL or mental component of the SF-36.

Tumminia et al., 2015

This is a poor-quality single-center randomized crossover trial of adults with DM1 treated with MDII or CSII. Twenty patients with DM1 (10 on MDII and 10 on CSII) and HbA1c >8.0% were randomly assigned

to real-time CGM or SMBG for six months, followed by a two-month washout period and crossover to the other arm for an additional six months. The randomization technique and allocation concealment are not well described. The trial was not blinded.

It is unclear whether the groups were similar at baseline because the authors only reported baseline characteristics by the use of MDII or CSII. For their analysis, the authors excluded six patients (30%) who did not use CGM at least 40% of the time during the prescribed portion of the study. Among the remaining 14 patients, the improvement in HbA1c was greater during the CGM period of the study (-0.78%) than during the SMBG portion of the study (-0.14%). Both the MDII-treated patients and the CSII-treated patients had greater improvement during the CGM period compared to the SMBG period. There were no episodes of severe hypoglycemia during the study. One patient on CSII was hospitalized for ketoacidosis during the SMBG portion of the study.

van Beers et al., 2016

This is a fair-quality open-label randomized crossover trial of CGM compared to SMBG in adults with DM1 and impaired hypoglycemia awareness who were treated with MDII or CSII. After a six-week run-in period that included diabetes education and a two-week period of masked CGM, patients were randomly assigned to CGM or SMBG for 16 weeks, followed by a 12-week washout period and crossover to the other arm for an additional 16 weeks. The authors described appropriate randomization techniques and allocation concealment. Ultimately, 52 patients were randomized. The average HbA1c at randomization was 7.5%.

Two secondary outcomes that were reported are relevant to this summary. The number of patients with at least one severe hypoglycemic event was 19% in the CGM phase compared to 35% in the SMBG phase (OR 0.48, 95% CI 0.2 to 1.04, p=0.062). There was no difference in HbA1c at the study endpoint between the CMG and SMBG phases (7.3% in both groups). Although the data were not presented in the paper, the authors observed no difference in quality of life measures between the CGM and SMBG phases.

Adults with DM2

National Institute for Health and Care Excellence (Guideline 28), 2016

This is a good-quality systematic review commissioned by the National Institute for Health and Care Excellence (NICE) to inform the 2016 update of the comprehensive guideline on diagnosis and management of DM2 in adults. The authors identified two RCTs with 165 total patients that compared SMBG with CGM to conventional SMBG alone. One trial was conducted in the United States and one was conducted in South Korea. The average HbA1c at baseline was 8.3% in one study and 8.9% in the other. Patients in these trials could be on oral antidiabetic medications, insulin, or both. In the meta-analysis of these two trials, the authors found very low-quality evidence that SMBG with CGM results in a statistically significant improvement in HbA1c at up to 52-weeks follow-up with a mean difference of -0.46% (95% CI -0.87 to -0.06). No other important or critical outcomes were reported.

Poolsup et al., 2013

This is a good-quality systematic review and meta-analysis of randomized trials of CGM in children with DM1 or adults with DM2. The authors identified four RCTs comparing CGM to SMBG in adults with DM2

(total n=228). Although all studies used a real-time CGM monitor, two studies used the data retrospectively. Two of the trials were judged as high quality and two were deemed low quality. All of the participants in the studies had a baseline HbA1c >8%. Two of the studies only included patients on oral antidiabetic agents, and the other two studies included patients on oral agents, insulin, or both. The authors found no indication of publication bias and there was limited heterogeneity, with an $I^2 = 0\%$. In the fixed-effects meta-analysis, CGM resulted in statistically significantly improvement in HbA1c with a mean difference of -0.31% (95% CI -0.6 to -0.02). Because of the small number of trials, sensitivity analysis comparing retrospective and real-time GGM was not performed. No other important or critical outcomes were reported.

New et al., 2015

The description of this trial can be found above. Overall, 15% of the patients in this trial had DM2. However, the results for glycemic control as measured by HbA1c were not separately reported by the type of diabetes.

Sato et al., 2016

This is a poor-quality open-label randomized controlled trial of retrospective CGM compared to usual care (including SMBG) for adults with DM2. All patients (n=34) wore a CGM system for the duration of the trial. In the intervention group, the information from the CGM device was interpreted by the study team, which subsequently provided counseling and treatment guidance to the patient and treating clinician; in the control group, patients and physicians were blinded to the CGM data and based clinical decisions on HbA1c and SMBG information. The authors did not describe the randomization technique or allocation concealment. Patients, treating clinicians, and study personnel were not blinded. It is unclear whether patients in each arm had similar numbers of clinical encounters during the study. There were baseline differences between the two groups with respect to gender distribution and age; the average baseline HbA1c in both groups was 8.2%. There were no statistically significant differences in change in HbA1c between the two groups; at up to eight months follow-up, the mean HbA1c was 8.2% in the CGM group and 7.9% in the control group. However, the average total daily insulin dose increased by 2.2 IU in the CGM group compared to 0.2 IU in the control group. Severe hypoglycemia was not measured, but the authors noted that the time spent at a glucose level of <70 mg/dL was “almost” 0% in both groups. There was no statistically significant difference in treatment satisfaction between the two groups.

Tang et al., 2014

This is a fair-quality parallel randomized controlled trial comparing real-time CGM to internet-blood glucose monitoring (IBGM) in adults with DM2. The primary outcomes for this trial were related to treatment satisfaction. Fifty-seven patients were initially enrolled and randomized, but seven patients in the CGM group dropped out immediately after randomization. Five additional patients withdrew from the CGM group; some cited inconvenience or discomfort from their treatment. Five patients in the IBGM group withdrew during the study. Thus, 40 patients with HbA1c >7.0% treated with insulin or insulin with oral agents were randomized to real-time CGM or to three times daily SMBG and facilitated internet communication with their provider. The groups were similar at baseline. The primary outcome

was treatment satisfaction as measured by the DTSQ. Fifteen patients in the CGM group and 17 patients in the IBGM group completed the survey at trial completion. Overall, treatment satisfaction was statistically significantly higher in the IBGM group compared to the CGM group ($p<0.001$). Although glycemic outcomes were not a primary endpoint in this study, there was no statistically significant difference in the change in HbA1c between the CGM and IBGM groups at six months follow-up (-0.9% vs. -1.07%, $p=0.312$).

Tildesley et al., 2013

This is a report from the trial described immediately above with respect to glycemic control outcomes measured at six months. Only the seven patients who dropped out of the CGM group immediately after randomization were excluded from the analysis. Available data for the remaining 50 participants was analyzed in an intention-to-treat fashion. The baseline mean HbA1c in the CGM group was 8.80% and improved to 7.49% at six months; in the IBGM group, the baseline mean HbA1c was 8.79% and improved to 7.96% at six months. The between-group difference in change in HbA1c was not statistically significant ($p=0.08$). There were no episodes of severe hypoglycemia in either group.

Children and Adolescents with DM1

Langendam et al., 2012

A description of this systematic review and meta-analysis and results from the combined group of adults and children can be found above.

The following observations were made about retrospective CGM systems in children:

- In five trials, the mean difference in change in HbA1c ranged from -0.5% to 0.1%, with wide confidence intervals around the estimates due to small sample sizes.
- In four trials that reported severe hypoglycemia, events were rare, occurring in two children in a CGM group and one child in an SMBG group.
- In one trial that reported on quality of life, there were no significant differences between the CGM and SMBG groups on the DCCT quality of life questionnaire.

The following observations were made about real-time CGM systems in children:

- In one trial, the mean difference in change in HbA1c was -0.2% (95% CI -0.3% to 0.0%) at three months. At six and 12 months, the difference in HbA1c between CGM and SMBG was not statistically significant.
- In one trial with a categorical outcome of HbA1c improvement of -0.5% at three months, that goal was achieved in 46% of patients in the CGM group compared to 28% of patients in the SMBG group (RR 1.68, 95% CI 1.02 to 2.78). The results were sustained at six months, with the goal achieved in 54% in the CGM group and 31% in the SMBG group (RR 1.73, 95% CI 1.10 to 2.72).
- In one trial, improvements in HbA1c were only observed in children with sensor use >60% of the time.

- Severe hypoglycemia and ketoacidosis were both rare events in these trials. In one trial, there were five severe hypoglycemic events in the CGM arm compared to seven events in the SMBG arm at six months (RR 0.74, 95% CI 0.25 to 2.19).
- In two studies that reported on quality of life outcomes, there were no statistically significant differences between the groups on the PedsQL or WHO-5 questionnaires.

The following observations were made about real-time CGM systems in adolescents:

- In two trials, the mean difference in change in HbA1c at three months was -0.3% (95% CI -0.8% to 0.1%) and -0.2% (95% CI-0.4% to 0.0%).
- In one trial with a categorical outcome of HbA1c improvement of -0.5% at three months, there was no difference between the CGM and SMBG groups (36% and 37%, respectively).
- Severe hypoglycemia and ketoacidosis were both rare events in these trials. In one trial, there were three severe hypoglycemic events in the CGM arm compared to five events in the SMBG arm (RR 0.56, 95% CI 0.14 to 2.22).

National Institute for Health and Care Excellence (Guideline 18), 2016

This is a good-quality systematic review and meta-analysis commissioned by NICE to inform the 2016 update of the comprehensive guideline on diagnosis and management of DM1 in children and adolescents. The authors identified seven RCTs comparing CGM and SMBG (five from the Langendam review and two additional trials). The authors assessed GRADE ratings for the outcomes. The results for children and adolescents with a diagnosis of DM1 at least one year before study enrollment were reported separately from those of children with a recent diagnosis of DM1 (within one year of study enrollment).

Among children and adolescents with DM1 diagnosed at least one year before study enrollment:

- There was high-quality evidence of no statistically significant difference between real-time CGM and SMBG with respect to HbA1c at six months (MD -0.09, 95% CI -0.24 to 0.07).
- There was low-quality evidence of no statistically significant difference between retrospective CGM and SMBG with respect to HbA1c at six months (MD -0.3, 95% CI -0.67 to 0.07).
- There was low-quality evidence of no statistically significant difference between CGM and SMBG with respect to severe hypoglycemia at six months (RR 0.63, 95% CI 0.27 to 1.46).
- There was high-quality evidence of statistically significantly greater parental satisfaction with CGM compared to SMBG at six months (MD 0.3 on a scale of 1 to 3, 95% CI 0.21 to 0.39).

Among children and adolescents with a recent diagnosis of DM1 (within one year of study enrollment):

- There was moderate-quality evidence of no statistically significant difference between real-time CGM and SMBG with respect to HbA1c at six months (MD -0.10, 95% CI -0.46 to 0.66).
- There was moderate-quality evidence of no statistically significant difference between real-time CGM and SMBG with respect to HbA1c at 12 months (MD -0.10, 95% CI -0.46 to 0.66).
- There was low-quality evidence of no statistically significant difference between CGM and SMBG with respect to the rate of severe hypoglycemia at 12 months (-4.6%, 95% CI -5.1% to 5.5%).

- There was high-quality evidence of no statistically significant differences between CGM and SMBG with respect to parental satisfaction at six or 12 months.

Benkhadra et al., 2017

The description of this systematic review and individual patient data meta-analysis can be found above. In the stratified meta-analysis, real-time CGM was not found to produce statistically significant improvements in HbA1c in participants age ≤12 or age 13 to 15.

Poolsup et al., 2013

The description of this systematic review and meta-analysis can be found above. The authors identified 10 RCTs (total n=817) comparing CGM to SMBG in children with DM1. Seven of the studies were judged to be high quality and three studies low quality. The authors stated that there was significant heterogeneity in the study results. Overall, CGM was not better than SMBG with respect to HbA1c (pooled mean difference -0.13%, 95% CI -0.38% to 0.11%, p=0.27). When the five trials of real-time CGM were considered separately, CGM resulted in greater improvement in HbA1c compared to usual care (pooled mean difference -0.18%, 95% CI -0.35% to -0.02%, p=0.02). There were no statistically significant differences among subgroups in baseline HbA1c or trial quality.

Hommel et al., 2014

The description of this trial can be found above. The results for children included in the trial are as follows. Pediatric quality of life was measured by the PedsQL scale and its subscales using both the child's self-rating and the parent's proxy rating. There were no statistically significant differences in the child's self-rated quality (overall or in any subscale) between the sensor ON and sensor OFF periods. There were statistically significant improvements in the parent's proxy ratings, but the magnitude of the differences was not deemed to be clinically relevant. Additionally, in a per-protocol analysis, children with >70% adherence during the sensor ON period had significantly fewer missed school days compared to the sensor OFF group (0.38 vs. 1.24 days per child per six months, p=0.005).

Riveline et al., 2012

This description of this trial can be found above. Overall, 14% of the patients in this trial were age 18 and younger. However, the results were not stratified by age.

Children and Adolescents with DM2

No systematic reviews or randomized controlled trials of CGM for children and adolescents with DM2 were identified in the search.

Diabetes During Pregnancy

National Institute for Health and Care Excellence (Guideline 3), 2015

This is a good-quality systematic review and meta-analysis commissioned by NICE to inform the 2015 update of the comprehensive guideline on diagnosis and management of diabetes in pregnant women. The authors identified five studies comparing CGM to SMBG (three RCTs and two within-participant studies). Two of the included studies enrolled pregnant women with DM1, two studies enrolled

pregnant women with either DM1 or DM2, and one study enrolled women with GDM. Four of the studies used retrospective CGM and one used real-time CGM. In the SMBG groups, women measured capillary blood glucose between four and eight times each day. The authors assessed the GRADE rating for the outcomes.

There was low-quality evidence from one study that CGM resulted in greater improvement in HbA1c at 32 to 36 weeks gestation (MD -0.6, 95% CI -0.9 to -0.3). There was moderate-quality evidence from one study of no statistically significant difference between CGM and SMBG with respect to HbA1c at 36 weeks gestation (MD -0.1, 95% CI not calculable, p=0.63). There was moderate-quality evidence from one study of no statistically significant difference between CGM and SMBG with respect to severe hypoglycemia (RR 1.0, 95% CI 0.5 to 2.1).

There was low- to very low-quality evidence of no statistically significant differences between CGM and SMBG with respect to the risk of Caesarean delivery, preterm birth, miscarriage, early neonatal death, need for neonatal intensive care unit admission, or large for gestational age.

Wei et al., 2015

This is a high-quality open-label randomized controlled trial comparing CGM to SMBG in women with GDM. At the outset of the trial, 117 women with GDM at 24 to 28 weeks gestation were randomized to CGM or SMBG; four participants in the CGM arm were lost to follow-up or dropped out, and seven participants in the SMBG group were found to be ineligible after randomization. Ultimately, 51 participants received CGM (24 during the second trimester and 27 during the third trimester), and 55 participants were managed by SMBG. Follow-up and insulin management were standardized across all groups.

The groups were similar at baseline. There were no statistically significant differences in any obstetrical or neonatal outcomes (including perinatal death, Caesarean delivery, preterm birth, gestational age at delivery, five-minute Apgar scores, macrosomia, neonatal hypoglycemia, or large or small for gestational age). As expected in women with GDM, the baseline HbA1c values were relatively low (5.7% and 5.8% in the CGM and SMBG groups respectively). There were no statistically significant differences in the change in HbA1c between the CGM and SMBG groups during the trial.

Integrated Sensor-Augmented Pump Therapy for DM1

Riemsma et al., 2016

This is a good-quality health technology assessment of integrated sensor-augmented pump therapies for adults and children with DM1. The authors included 19 RCTs that compared integrated sensor-augmented pump therapy with CSII + SMBG, CSII + CGM (non-integrated), MDII + SMBG, and MDII + CGM. Both head-to-head data and indirect comparisons (through network meta-analysis) were presented when appropriate. The results were separated by adults and children with DM1. Eleven of the trials were deemed to be at high risk of bias, four trials had an unclear risk of bias, and four trials had a low risk of bias (overall assessment of high risk of bias for the body of literature). Follow-up periods ranged from three to 24 months.

The head-to-head comparison of the MiniMed Veo pump to other integrated CSII + CGM systems in adults at three months follow-up produced the following findings:

- There was no significant difference in the change in HbA1c (difference 0.05%, 95% CI -0.05 to 0.15).
- There were statistically significantly fewer overall and nocturnal hypoglycemic events in the MiniMed Veo group ($p<0.001$), but severe hypoglycemia was not specifically reported.
- There were no cases of diabetic ketoacidosis in either group.
- Quality of life measures were not reported.

The head-to-head comparison of integrated CSII + CGM systems to non-integrated CSII + CGM in adults at six months follow-up produced the following finding:

- There was no statistically significant difference in the change in HbA1c (difference -0.0364%, SE 0.1412, p=0.80)

The head-to-head comparison of CSII + CGM to MDII + SMBG in adults at three months produced the following findings:

- One study found no statistically significant difference in the change in HbA1c (difference -0.68%, p=0.071).
- One study found a statistically significant difference in change in HbA1c in favor of CSII + CGM (-0.97%, p=0.02).
- There were no statistically significant differences in the number of hypoglycemic events or diabetic ketoacidosis.

The head-to-head comparison of CSII + CGM to MDII + SMBG in adults at six months produced the following findings:

- There was a statistically significant difference in the change in HbA1c in favor of CSII + CGM (-1.1%, 95% CI -1.47 to -0.73).
- There was no statistically significant difference in the number of hypoglycemic events.
- There was a small but statistically significant improvement in quality of life as measured by the SF-36 in favor of CSII + CGM (difference 7.9, 95% CI 0.5 to 15.3).

The head-to-head comparison of CSII + CGM to MDII + SMBG in adults at 12 months produced the following findings:

- There was a statistically significant difference in the change in HbA1c in favor of CSII + CGM (-0.6%, 95% CI –0.8 to -0.4).
- There was no statistically significant difference in the rate of severe hypoglycemic events.
- There was a small but statistically significant improvement in quality of life as measured by the SF-36 in favor of CSII + CGM (difference 3, 95% CI 1.36 to 4.64).

Indirect comparisons between studies in adults are summarized in the tables below. Cells in bold indicate that the difference is statistically significant.

Indirect comparisons for change in HbA1c at three months in adults

Intervention	Integrated CSII + CGM WMD (95% CI)	CSII + SMBG WMD (95% CI)	MDII + SMBG WMD (95% CI)
MiniMed Veo	0.04 (-0.07 to 0.15)	0.41 (-0.31 to 1.13)	-0.43 (-0.95 to 0.1)
Integrated CSII + CGM		0.37 (-0.34 to 1.08)	-0.47 (-0.98 to 0.04)
CSII + CGM			**-0.84 (-1.33 to -0.35)**

Indirect comparisons for diabetic ketoacidosis at three months in adults

Intervention	Integrated CSII + CGM RR (95% CI)	CSII + SMBG RR (95% CI)	MDII + SMBG RR (95% CI)
MiniMed Veo	No events	No events	No events
Integrated CSII + CGM		0.26 (0.01 to 8.53)	0.32 (0.04 to 2.86)
CSII + CGM			1.25 (0.08 to 19.22)

Indirect comparisons for severe hypoglycemia at three months in adults

Intervention	CSII + SMBG RR (95% CI)	MDII + SMBG RR (95% CI)
Integrated CSII + CGM	0.33 (0.03 to 3.87)	0.19 (0.02 to 1.51)
CSII + SMBG		0.63 (0.17 to 2.31)

Indirect comparisons for change in HbA1c at six months in adults

Intervention	CSII + SMBG WMD (95% CI)	MDII + SMBG WMD (95% CI)
Integrated CSII + CGM	-0.05 (-0.31 to 0.21)	**-1.1 (-1.46 to -0.74)**
CSII + SMBG		-0.10 (-0.52 to 0.32)

Indirect comparisons for quality of life (by DTSQ) at six months in adults

Intervention	CSII + SMBG WMD (95% CI)	MDII + SMBG WMD (95% CI)
Integrated CSII + CGM	**5.90 (2.22 to 9.58)**	**8.60 (6.28 to 10.92)**
CSII + SMBG		2.70 (-0.16 to 5.56)

The head-to-head comparison of MiniMed Veo to CSII + SMBG in children and adolescents at six months produced the following finding:

- There was no statistically significant difference in the change in HbA1c (0.07, 95% CI -0.2 to 0.3).

The head-to-head comparison of integrated CSII + CGM to CSII + SMBG in children and adolescents at six months produced the following finding:

- There was no statistically significant difference in the change in HbA1c (0.4894, SE 0.2899, p=0.10).

The head-to-head comparison of integrated CSII + CGM to MDII + SMBG in children and adolescents at 12 months produced the following findings:

- There was a statistically significant change in HbA1c in favor of integrated CSII + CGM (-0.5, 95% CI -0.8 to -0.2).
- There were no statistically significant differences in severe hypoglycemia, DKA, or quality of life (as measured by the PedsQL scale).

The indirect comparison between studies in children is shown in the table below.

Indirect comparisons for change in HbA1c at six months in children

Intervention	Integrated CSII + SMBG WMD (95% CI)	CSII + SMBG WMD (95% CI)
MiniMed Veo	0.38 (-0.16 to 0.92)	-0.04 (-0.26 to 0.18)
Integrated CSII + SMBG		-0.42 (-0.92 to 0.08)

EVIDENCE SUMMARY

Adults with DM1

There is evidence that real-time CGM in adults with DM1 results in greater improvements in HbA1c when compared with SMBG. Some evidence suggests that the greatest improvements in HbA1c are attained in patients who use CSII. CGM does not reduce severe hypoglycemia or ketoacidosis, but these were rare events in the studies. CGM does not improve quality of life. There was insufficient evidence about the effects of CGM on long-term clinical outcomes from diabetes.

Adults with DM2

There is evidence that CGM in adults with DM2 reduces HbA1c. CGM does not improve treatment satisfaction. There was insufficient evidence about the effects of CGM on hypoglycemia or long-term clinical outcomes from diabetes.

Children with DM1

Neither real-time nor retrospective CGM results in improvements in HbA1c in children with DM1. CGM does appear to result in greater parental satisfaction at up to six months. CGM does not reduce severe

hypoglycemia or ketoacidosis, but these were rare events in the studies. There was insufficient evidence about the effects of CGM on long-term clinical outcomes from diabetes.

Children with DM2

There was insufficient evidence to draw conclusions about CGM for any outcomes in this population.

Pregnant Women

There is conflicting evidence about the effect of CGM on HbA1c at various time points during pregnancy. CGM does not reduce severe hypoglycemia. There were no differences in any of the studied maternal, obstetrical, or neonatal outcomes.

Integrated Sensor-Augmented Pump Therapy

There was limited evidence that the use of the MiniMed Veo integrated CSII + CGM system results in fewer overall and nocturnal hypoglycemic events compared to other integrated CSII + CGM systems. Based on indirect comparisons, integrated CSII + CGM systems result in greater improvement in HbA1c at six months when compared to MDII + SMBG, but not when compared to CSII + SMBG. Integrated CSII + CGM systems result in greater patient satisfaction than CSII + SMBG or MDII + SMBG.

POLICY LANDSCAPE

Quality measures

A search of the National Quality Measures Clearinghouse did not identify any measures directly related to CGM for diabetes.

Payer coverage policies

Private Payers

Coverage policies for CGM for patients with diabetes were assessed for Aetna, Cigna, Moda, and Regence. Aetna, Cigna, and Moda cover short-term and long-term use of CGM for certain patients when set criteria are met. Regence considers subcutaneous insertion and removal of an implantable interstitial glucose sensor to be investigational medical technology.

Coverage for Short-Term Use of CGM

Aetna defines short-term use of CGM as 72 hours to one week, and covers no more than two short-term CGM periods within a 12-month period. Cigna and Moda both define short-term use as 72 hours or less. Cigna permits no more than six separate sessions in a 12-month period.

Aetna covers short-term CGM for diagnostic use for persons with diabetes who have hypoglycemia unawareness or repeated hypoglycemia and hyperglycemia at the same time each day. Cigna provides coverage for short-term CGM for persons with difficult-to-control insulin-treated diabetes, including patients who have hypoglycemic or hyperglycemic episodes unresponsive to therapy adjustments, in addition to patients with asymptomatic nocturnal hypoglycemia. Moda specifies coverage for short-

term CGM for persons with diabetes and at least one of the following: HbA1c values greater than 6.0 and less than 8.5; wide variations in blood glucose levels at least four times per day and insulin administration at least three times per day; unexplained frequent hypoglycemic episodes in people with diabetes who take insulin; repeated hypoglycemic or hyperglycemic episodes at the same time each day; episodes of ketoacidosis or hospitalizations for uncontrollable glucose; preconception or pregnancy with a history of suboptimal glycemic control; and patients who are initiating insulin or an insulin pump regimen for the first time.

Coverage for Long-Term Use of CGM

Aetna covers long-term therapeutic use of CGM as an adjunct to finger-stick testing of blood glucose for adults ages 25 and older with DM1 and for certain younger persons with DM1 who have two or more episodes of severe hypoglycemia in a period of 30 days, despite frequent self-monitoring and appropriate insulin adjustments. Cigna covers long-term use of CGM as necessary for persons with diabetes who have at least one of the following: a history of diabetic ketoacidosis; a positive autoantibody test; fasting C-peptide level ≤110% of the lower limit of normal according to the lab measurement method and a concurrently obtained fasting glucose ≤225 mg/dL; or renal insufficiency with a creatinine clearance ≤50 ml/minute and a fasting C-peptide level ≤200% of the lower limit of normal according to the lab measurement method. Moda may cover long-term use of CGM for persons ages 7 and older who have diabetes and either use an insulin pump or receive at least three daily insulin injections who have a history of hypoglycemic unawareness or wide fluctuations in blood glucose levels requiring four or more finger sticks per day and frequent insulin dosage adjustments. Moda requires the patient to complete a comprehensive diabetic program with a written statement from the ordering physician indicating the patient's readiness for CGM, in addition to evidence of the patient's compliance and understanding of the previous diabetic regimen.

Coverage for CGM Replacement

Cigna covers the replacement of an existing CGM device or component as medically necessary for persons with diabetes when provided documentation confirming need for replacement (i.e., device is malfunctioning, is no long under warranty, and cannot be repaired), as well as evidence of an evaluation by the health care provider managing the patient's diabetes, including a recommendation for continued use of CGM.

Medicaid

Washington Medicaid covers FDA-approved CGM devices for patients ages 18 and younger who have received prior authorization and an invoice. Before requesting prior authorization for CGM, patients should be diagnosed with insulin-dependent diabetes, be followed by an endocrinologist, and have one or more severe episodes of hypoglycemia or be enrolled in an Institutional Review Board-approved trial. Washington Medicaid does not cover closed-loop systems and requires verification of blood glucose with SMBG prior to insulin adjustment. Washington Medicaid covers short-term SMBG use for a 72-hour monitoring period with expedited prior authorization.

Medicare

No Medicare National Coverage Determination was identified for CGM for patients with diabetes. One Medicare Local Coverage Determination (LCD) was identified (effective 1/12/2017), which applies to all 50 states and Washington D.C. CGM is covered by Medicare with the following requirements:

- The beneficiary has been using a BGM and performing testing four or more times a day
- The beneficiary is insulin-treated with three or more daily injections of insulin or a Medicare-covered CSII pump
- The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of BGM or CGM testing results
- Within six months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate diabetes control and determined that the requirements above are met

The LCD requires the treating practitioner to have an in-person visit with the beneficiary every six months to assess adherence to the CGM regimen and diabetes treatment plan.

On January 12, 2017, the Centers for Medicare & Medicaid Services issued Ruling 1682R, defining which CGM devices are covered under the durable medical equipment benefit. Medicare covers CGM devices that have been approved by the FDA to replace blood glucose monitors for diabetes treatment decisions. To date, the Dexcom G5 is the only device to receive such FDA approval. Medicare does not cover CGM devices approved by the FDA for use as adjunctive devices to complement, but not replace, information obtained from blood glucose monitors.

Professional Society Guidelines

Recommendations from nine guidelines that address CGM for persons with diabetes are outlined below. The guidelines consistently recommend that CGM be considered for certain patients with DM1, especially for individuals with DM1 who have severe or frequent episodes of hypoglycemia or hypoglycemia unawareness.

The guideline "American Diabetes Association Standards of Medical Care in Diabetes—2016" makes the following recommendations regarding CGM for persons with diabetes (ADA, 2016):

- CGM can be a useful tool to lower HbA1c in selected adults ages 25 and older with DM1 when used properly and in conjunction with intensive insulin regimens.
- CGM may help lower HbA1c in children, teens, and younger adults; however, evidence for these groups is not as strong as for adults and success correlates with adherence to ongoing use of the device.
- CGM may be useful as a supplement to SMBG for persons with hypoglycemia unawareness or frequent hypoglycemia episodes.
- Patient readiness for CGM should be assessed on a case-by-case basis because adherence to CGM varies by individual.
- Robust diabetes education, training, and support for CGM are necessary for its optimal implementation and continuous use.

- Access to CGM should be continued after turning 65 years of age for patients who have been using CGM successfully.

The "American Association of Clinical Endocrinologists and American College of Endocrinology 2016 Outpatient Glucose Monitoring Consensus Statement" makes the following recommendations regarding CGM for persons with diabetes (Bailey et al., 2016):

- CGM is recommended for adults and children with DM1, particularly for individuals with a history of severe hypoglycemia and hypoglycemia unawareness, and to assist in correcting hyperglycemia in patients not within target range for blood glucose level.
- Before CGM use, patients should have knowledge of the basics of sensor insertion, calibration, and real-time data interpretation. More in-depth training and more frequent follow-up is recommended for CGM users who are children.
- Current evidence is limited for CGM use for patients with DM2 who are receiving insulin or sulfonylureas; trials assessing the use of CGM for these patients are ongoing.
- No recommendation is provided regarding the use of CGM for persons with DM2 who have a low risk of hypoglycemia.
- Evidence is unclear regarding the benefits of CGM in pregnant persons with preexisting diabetes; additional studies are ongoing. CGM should primarily be considered a teaching tool when used during pregnancy, and should be used to evaluate peak postprandial blood glucose, fine-tune insulin dosing, and identify foods associated with blood glucose fluctuations. Additionally, CGM can be used as a supplement to blood glucose monitoring during pregnancy, in particular for monitoring nocturnal hypoglycemia or hyperglycemia and postprandial hyperglycemia.

The guideline "2016 Continuous Glucose Monitoring: A Consensus Conference of the American Association of Clinical Endocrinologists and American College of Endocrinology" makes the following recommendations regarding CGM for persons with diabetes (Fonesca, et al., 2016):

- Current evidence supports the use of CGM for children and adults with DM1.
- CGM may also benefit patients with insulin-dependent DM2 and pregnant women with diabetes.

The guideline "2016 Diabetes Technology—Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline" makes the following recommendations regarding CGM for persons with diabetes (Peters, et al., 2016):

- Real-time CGM is recommended for adults with well-controlled DM1 and for adults with DM1 who have HbA1c levels above target. Patients should be willing and able to use a CGM device on a nearly daily basis.
- Short-term use of real time CGM is suggested for adult patients with DM2 who have HbA1c levels greater or equal to 7% and are both willing and able to use a CGM device.
- Education, training, and ongoing support to help achieve and maintain individualized glycemic goals is suggested for adults with diabetes using CGM.

The NICE 2016 guideline, "Type 1 Diabetes in Adults: Diagnosis and Management," which is based on a NICE systematic review discussed in the evidence overview of this coverage guidance, makes the following recommendations regarding CGM for persons with diabetes (NICE, 2016b):

- Do not offer real-time CGM routinely to adults with DM1.
- Consider real-time CGM for adults with DM1 who are willing to commit to using it at least 70% of the time and calibrate it as needed, and who have at least one of the following (despite optimized use of insulin therapy and conventional blood glucose monitoring): more than one episode a year of severe hypoglycemia that has no obviously preventable cause; complete hypoglycemia unawareness; frequent asymptomatic hypoglycemia that interferes with daily activities; extreme fear of hypoglycemia; or hyperglycemia that persists despite frequent testing (but only continue CGM if HbA1c can be sustained at 7% or below, or if there has been a fall in HbA1c of 2.5% or more).
- For adults with DM1 using CGM, the principles of flexible insulin therapy should be applied with either multiple daily injections of insulin or continuous subcutaneous insulin infusion therapy.
- Real-time CGM should be provided by a center with expertise in CGM use as a tool to optimize HbA1c levels and reduce the frequency of hypoglycemic episodes.

Guidelines Specific to Diabetes in Children and Adolescents

The International Society for Pediatric and Adolescent Diabetes 2014 Clinical Practice Consensus Guideline, "Assessment and Monitoring of Glycemic Control in Children and Adolescents with Diabetes," makes the following recommendations regarding CGM for persons with diabetes (Rewers, et al., 2014):

- CGM may particularly benefit individuals with hypoglycemic unawareness because CGM devices can be set to alert patients when glucose is below a specified range or when glucose falls at a rapid rate. However, it is currently recommended that CGM values are confirmed by SMBG for real-time adjustments of insulin dosing.

The NICE 2016 guideline, "Diabetes (Type 1 and Type 2) in Children and Young People: Diagnosis and Management," which is based on a NICE systematic review discussed in the evidence overview of this coverage guidance, makes the following recommendations regarding CGM for persons with diabetes (NICE, 2016a):

- Offer ongoing real-time CGM monitoring with alarms to children and young people with DM1 who have at least one of the following: frequent severe hypoglycemia, impaired awareness of hypoglycemia associated with adverse consequences (e.g., seizures or anxiety), or inability to recognize or communicate about symptoms of hypoglycemia.
- Consider ongoing real-time CGM for neonates, infants, and preschool children; children and young people who undertake high levels of physical activity; and children and young people who have comorbidities (i.e., anorexia nervosa) or who are receiving treatment (e.g., corticosteroids) that impedes control of blood glucose levels.
- Consider intermittent CGM to improve blood glucose control in children and young people who have hyperglycemia that persists despite insulin adjustment and additional support.

Guidelines Specific to Diabetes during Pregnancy

The 2013 "Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline" makes the following recommendations regarding CGM for persons with diabetes (Blumer, et al., 2013):

- It is suggested that CGM be used during pregnancy for women with overt or gestational diabetes when SMBG is not sufficient to assess glycemic control.

The NICE 2015 guideline, "Diabetes in Pregnancy: Management from Preconception to the Postnatal Period," which is based on a NICE systematic review discussed in the evidence overview of this coverage guidance, makes the following recommendations regarding CGM for persons with diabetes (NICE, 2015):

- Do not offer CGM routinely to pregnant women with diabetes.
- Consider CGM for pregnant women on insulin therapy who either have severe hypoglycemia or unstable blood glucose levels, or to gain information about changes in blood glucose levels.
- Ensure available support for pregnant women using CGM from a health care professional with expertise in CGM use.

REFERENCES

Evidence Sources

Benkhadra, K., Alahdab, F., Tamhane, S., Wang, Z., Prokop, L. J., Hirsch, I. B., ... Murad, M. H. (2016). Real time continuous glucose monitoring in type 1 diabetes: A systematic review and individual patient data meta-analysis. *Clinical Endocrinology.* DOI: 10.1111/cen.1329.

Beck, R. W., Riddlesworth, T., Ruedy, K., Ahmann, A., Bergenstal, R., Haller, S., ... Price, D. (2017). Effect of continuous glucose monitoring on glycemic control in adults with type 1 diabetes using insulin injections: The DIAMOND randomized clinical trial. *JAMA, 317*(4), 371-378. DOI: 10.1001/jama.2016.19975.

Hommel, E., Olsen, B., Battelino, T., Conget, I., Schutz-Fuhrmann, I., Hoogma, R., ... Bolinder, J. (2014). Impact of continuous glucose monitoring on quality of life, treatment satisfaction, and use of medical care resources: Analyses from the SWITCH study. *Acta Aiabetologica, 51*(5), 845-851. DOI: 10.1007/s00592-014-0598-7.

Langendam, M., Luijf, Y. M., Hooft, L., Devries, J. H., Mudde, A. H., & Scholten, R. J. (2012). Continuous glucose monitoring systems for type 1 diabetes mellitus. *The Cochrane Database of Systematic Reviews, 1*, Cd008101. DOI: 10.1002/14651858.CD008101.pub2.

Lind, M., Polonsky, W., Hirsch, I. B., Heise, T., Bolinder, J., Dahlqvist, S., ... Hellman, J. (2017). Continuous glucose monitoring vs conventional therapy for glycemic control in adults with type 1 diabetes treated with multiple daily insulin injections: The GOLD randomized clinical trial. *JAMA, 317*(4), 379-387. DOI: 10.1001/jama.2016.19976.

National Institute for Health and Care Excellence. (2016a). *Diabetes (type 1 and type 2) in children and young people: Diagnosis and management.* Retrieved from

https://www.nice.org.uk/guidance/ng18/resources/diabetes-type-1-and-type-2-in-children-and-young-people-diagnosis-and-management-1837278149317

National Institute for Health and Care Excellence. (2016b). *Type 1 diabetes in adults: Diagnosis and management.* Retrieved from https://www.nice.org.uk/guidance/ng17/resources/type-1-diabetes-in-adults-diagnosis-and-management-1837276469701

National Institute for Health and Care Excellence. (2016c). *Type 2 diabetes in adults: Management.* Retrieved from https://www.nice.org.uk/guidance/ng28/resources/type-2-diabetes-in-adults-management-1837338615493

National Institute for Health and Care Excellence. (2015). *Diabetes in pregnancy: Management from preconception to the postnatal period.* Retrieved from https://www.nice.org.uk/guidance/ng3/resources/diabetes-in-pregnancy-management-from-preconception-to-the-postnatal-period-51038446021

New, J. P., Ajjan, R., Pfeiffer, A. F., & Freckmann, G. (2015). Continuous glucose monitoring in people with diabetes: The randomized controlled Glucose Level Awareness in Diabetes Study (GLADIS). *Diabetic Medicine: A Journal of the British Diabetic Association*, *32*(5), 609-617. DOI: 10.1111/dme.12713.

Poolsup, N., Suksomboon, N., & Kyaw, A. M. (2013). Systematic review and meta-analysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in diabetes. *Diabetology & Metabolic Syndrome*, *5*, 39. DOI: 10.1186/1758-5996-5-39.

Riemsma, R., Corro Ramos, I., Birnie, R., Buyukkaramikli, N., Armstrong, N., Ryder, S., ... Kleijnen, J. (2016). Integrated sensor-augmented pump therapy systems [the MiniMed® Paradigm™ Veo system and the Vibe™ and G4® PLATINUM CGM (continuous glucose monitoring) system] for managing blood glucose levels in type 1 diabetes: A systematic review and economic evaluation. *Health Technology Assessment, 20*(17), v-xxxi, 1-251. DOI: 10.3310/hta20170

Riveline, J. P., Schaepelynck, P., Chaillous, L., Renard, E., Sola-Gazagnes, A., Penfornis, A., ... Hanaire, H. (2012). Assessment of patient-led or physician-driven continuous glucose monitoring in patients with poorly controlled type 1 diabetes using basal-bolus insulin regimens: A 1-year multicenter study. *Diabetes Care*, *35*(5), 965-971. DOI: 10.2337/dc11-2021.

Sato, J., Kanazawa, A., Ikeda, F., Shigihara, N., Kawaguchi, M., Komiya, K., ... Watada, H. (2016). Effect of treatment guidance using a retrospective continuous glucose monitoring system on glycaemic control in outpatients with type 2 diabetes mellitus: A randomized controlled trial. Journal of International Medical Research, 44(1), 109-121. DOI: 10.1177/0300060515600190.

Tang, T. S., Digby, E. M., Wright, A. M., Chan, J. H. M., Mazanderani, A. B., Ross, S. A., ... Tildesley, H. D. (2014). Real-time continuous glucose monitoring versus internet-based blood glucose monitoring in adults with type 2 diabetes: A study of treatment satisfaction. *Diabetes Research and Clinical Practice*, *106*(3), 481-486. DOI: 10.1016/j.diabres.2014.09.050.

Tildesley, H. D., Wright, A. M., Chan, J. H., Mazanderani, A. B., Ross, S. A., Tildesley, H. G., ... White, A. S. (2013). A comparison of internet monitoring with continuous glucose monitoring in insulin-requiring type 2 diabetes mellitus. *Canadian Journal of Diabetes, 37*(5), 305-308. DOI: 10.1016/j.jcjd.2013.05.006

Tumminia, A., Crimi, S., Sciacca, L., Buscema, M., Frittitta, L., Squatrito, S., ... Tomaselli, L. (2015). Efficacy of real-time continuous glucose monitoring on glycaemic control and glucose variability in type 1 diabetic patients treated with either insulin pumps or multiple insulin injection therapy: A randomized controlled crossover trial. *Diabetes Metabolism Research and Reviews*, *31*(1), 61-68. DOI: 10.1002/dmrr.2557.

van Beers, C. A., DeVries, J. H., Kleijer, S. J., Smits, M. M., Geelhoed-Duijvestijn, P. H., Kramer, M. H., ... Serne, E. H. (2016). Continuous glucose monitoring for patients with type 1 diabetes and impaired awareness of hypoglycaemia (IN CONTROL): A randomised, open-label, crossover trial. *Lancet Diabetes & Endocrinology, 4*(11), 893-902. DOI: 10.1016/s2213-8587(16)30193-0.

Wei, Q., Sun, Z., Yang, Y., Yu, H., Ding, H., & Wang, S. (2016). Effect of a CGMS and SMBG on maternal and neonatal outcomes in gestational diabetes mellitus: A randomized controlled trial. *Scientific Reports*, *6,* 19920. DOI: 10.1038/srep19920.

Other Citations

American Diabetes Association. (2017a). *Checking your blood glucose*. Retrieved from http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/checking-your-blood-glucose.html

American Diabetes Association. (2017b). *Hyperglycemia (high blood glucose levels)*. Retrieved from http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/hyperglycemia.html

American Diabetes Association. (2017c). *Hypoglycemia (low blood glucose levels)*. Retrieved from http://www.diabetes.org/living-with-diabetes/treatment-and-care/blood-glucose-control/hypoglycemia-low-blood.html

American Diabetes Association. (2017d). *Type 1 diabetes*. Retrieved from http://www.diabetes.org/diabetes-basics/type-1/?referrer=http://www.diabetes.org/diabetes-basics/statistics/

American Diabetes Association. (2016). Standards of medical care in diabetes—2016. *The Journal of Clinical and Applied Research and Education, 39*(Supplement 1), S1-S112. Retrieved from http://care.diabetesjournals.org/content/suppl/2015/12/21/39.Supplement_1.DC2/2016-Standards-of-Care.pdf

Bailey, T. S., Grunberger, G., Bode, B. W., Handelsman, Y., Hirsch, I. B., Jovanovic, L., ... Walsh, J. (2016). American Association of Clinical Endocrinologists and American College of Endocrinology 2016 outpatient glucose monitoring consensus statement. *Endocrine Practice, 22*(2), 231-261. DOI: 10.4158/ep151124.cs

Blumer, I., Hadar, E., Hadden, D. R., Jovanovic, L., Mestman, J. H., Murad, M. H., & Yogev, Y. (2013). Diabetes and pregnancy: An Endocrine Society clinical practice guideline. *The Journal of Clinical Endocrinology and Metabolism, 98*(11), 4227-4249. DOI: 10.1210/jc.2013-2465.

Centers for Disease Control and Prevention. (2016). *Working to reverse the US epidemic at a glance*. Retrieved from https://www.cdc.gov/chronicdisease/resources/publications/aag/diabetes.htm

Centers for Disease Control and Prevention. (2015). *Basics about diabetes*. Retrieved from https://www.cdc.gov/diabetes/basics/diabetes.html

Fonseca, V. A., Grunberger, G., Anhalt, H., Bailey, T. S., Blevins, T., Garg, S. K., ... Tamborlane, W. (2016). Continuous glucose monitoring: A consensus conference of the American Association of Clinical Endocrinologists and American College of Endocrinology. *Endocrine Practice, 22*(8), 1008-1021. DOI: 10.4158/ep161392.cs.

Golden, S. H., Brown, T., Yeh, H. C., Maruthur, N., Ranasinghe, P., Berger, Z., … Bass, E. B. (2012). Methods for insulin delivery and glucose monitoring: Comparative effectiveness. Comparative Effectiveness Review No. 57. AHRQ Publication No. 12-EHC036-EF. Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from https://www.effectivehealthcare.ahrq.gov/ehc/products/242/749/CER57_Insulin-Delivery_FinalReport_20120703.pdf

Naguib, J., Kulinskaya, E., Lomax, C., & Garralda, M. (2009). Neurocognitive performance in children with type 1 diabetes—A meta-analysis. *Journal of Pediatric Psychology, 34*(3), 271-282. DOI: 10.1093/jpepsy/jsn074.

National Institute of Diabetes and Digestive and Kidney Diseases. (2016). *Diabetes overview*. Retrieved from https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes

National Institute of Diabetes and Digestive and Kidney Diseases. (2008). *Continuous glucose monitoring*. Retrieved from https://www.niddk.nih.gov/health-information/diabetes/overview/managing-diabetes/continuous-glucose-monitoring

Peters, A. L., Ahmann, A. J., Battelino, T., Evert, A., Hirsch, I. B., Murad, M. H., ... Wolpert, H. (2016). Diabetes technology—Continuous subcutaneous insulin infusion therapy and continuous glucose monitoring in adults: An Endocrine Society clinical practice guideline. *The Journal of Clinical Endocrinology and Metabolism, 101*(11), 3922-3937. DOI: 10.1210/jc.2016-2534.

Rewers, M. J., Pillay, K., de Beaufort, C., Craig, M. E., Hanas, R., Acerini, C. L., & Maahs, D. M. (2014). ISPAD Clinical Practice Consensus Guidelines 2014. Assessment and monitoring of glycemic control in children and adolescents with diabetes. *Pediatric Diabetes, 15*(Supplement 20), 102-114. DOI: 10.1111/pedi.12190.

Rodbard, D. (2016). Continuous glucose monitoring: A review of successes, challenges, and opportunities. *Diabetes Technology and Therapeutics, 18*(2), S13-S13. DOI: 10.1089/dia.2015.0417

United States Food and Drug Administration. (2016a). *FDA expands indication for continuous glucose monitoring systems, first to replace fingerstick testing for diabetes treatment decisions*. Retrieved from http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm534056.htm

United States Food and Drug Administration. (2016b). *More choices available for diabetes management*. Retrieved from http://www.fda.gov/forconsumers/consumerupdates/ucm424219.htm

Whittemore, R., Jaser, S., Chao, A., Jang, M., & Grey, M. (2012) Psychological experience of parents of children with type 1 diabetes: A systematic mixed-studies review. *The Diabetes Educator, 38*(4), 562-579. DOI: 10.1177/0145721712445216.

Suggested citation: Obley, A., Hackett, R., Mosbaek, C., King, V., & Shaffer, W. (2017). *Coverage guidance: Continuous glucose monitoring in diabetes mellitus*. Portland, OR: Center for Evidence-based Policy, Oregon Health & Science University.

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[1]

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

[1] Includes risk of bias, precision, directness, consistency and publication bias

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.

APPENDIX B. GRADE EVIDENCE PROFILE

Quality Assessment (Confidence in Estimate of Effect) Adults with T1DM							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Severe morbidity							
0							Insufficient evidence
Severe hypoglycemia							
3	RCTs	Serious risk of bias	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Very low confidence in estimate of the effect ●○○○
Quality of life							
1	RCT	Serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	Moderate confidence in the estimate of the effect ●●●○
Change in HbA1c							
Retrospective CGM 2	RCTs	Serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	Moderate confidence in the estimate of the effect ●●●○
Real-time CGM 6	RCTs	Serious risk of bias	**	No serious indirectness	Serious imprecision	None	Low confidence in estimate of the effect ●●○○

Quality Assessment (Confidence in Estimate of Effect) Adults with T1DM							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Diabetic ketoacidosis							
5	RCTs	Serious risk of bias	No serious inconsistency	No serious indirectness	Serious Imprecision	None	Low confidence in estimate of the effect ●●○○

** The original assessment in the NICE review was very serious inconsistency due to a high level of statistical heterogeneity. Subsequent RCTs of RT-CGM in type 1 diabetics have shown similar improvements in HbA1c that overlap with the 95% CI of the meta-analytic estimate from NICE. Thus we regard concerns over inconsistency as less serious based on the additional studies

Quality Assessment (Confidence in Estimate of Effect) Adults with T2DM							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Severe morbidity							
0							Insufficient evidence
Severe hypoglycemia							
0							Insufficient evidence
Quality of life							
Treatment satisfaction 2	RCTs	Serious	No serious inconsistency	Serious indirectness	Serious imprecision	None	Very low confidence in estimate of the effect ●○○○

Quality Assessment (Confidence in Estimate of Effect) Adults with T2DM							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Change in HbA1c							
4	RCTs	Serious	No serious inconsistency	No serious indirectness	Serious imprecision	None	Low confidence in estimate of the effect ●●○○
Diabetic ketoacidosis							
0							Not applicable

Quality Assessment (Confidence in Estimate of Effect) Children and adolescents with T1DM							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Severe morbidity							
0							Insufficient evidence
Severe hypoglycemia							
2	RCTs	No serious risk of bias	No serious inconsistency	No serious indirectness	Very serious imprecision	None	Low confidence in estimate of the effect ●●○○
Quality of life							
1	RCT	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	High confidence in the estimate of the effect ●●●●

Quality Assessment (Confidence in Estimate of Effect) Children and adolescents with T1DM							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Change in HbA1c							
Retrospective CGM 2	RCTs	Serious risk of bias	No serious inconsistency	No serious indirectness	Serious imprecision	None	Low confidence in estimate of the effect ●●○○
Real-time CGM 2	RCTs	No serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	High confidence in the estimate of the effect ●●●●
Diabetic ketoacidosis							
0							Insufficient evidence

Quality Assessment (Confidence in Estimate of Effect) Children and adolescents with T2DM							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Severe morbidity							
0							Insufficient evidence
Severe hypoglycemia							
0							Insufficient evidence
Quality of life							
0							Insufficient evidence
Change in HbA1c							
0							Insufficient evidence

Quality Assessment (Confidence in Estimate of Effect) Children and adolescents with T2DM							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Diabetic ketoacidosis							
0							Not applicable

Quality Assessment (Confidence in Estimate of Effect) Pregnant women							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Severe morbidity							
Maternal, obstetrical, and neonatal outcomes 1 to 3	RCTs	Serious risk of bias (all studies)	Varies by outcome	Varies by outcome	Varies by outcome	Varies by outcome	Very low to low confidence in estimate of the effect ●○○○ to ●●○○
Severe hypoglycemia							
1	RCT	Serious risk of bias	No serious inconsistency	No serious indirectness	Serious imprecision	None	Moderate confidence in the estimate of the effect ●●●○

Quality Assessment (Confidence in Estimate of Effect) Pregnant women							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Quality of life							
1	RCT	Serious	No serious inconsistency	No serious indirectness	No serious imprecision	None	Moderate confidence in the estimate of the effect ●●●○
Change in HbA1c							
At 32 to 36 weeks gestation 1	RCT	Serious risk of bias	No serious inconsistency	Serious indirectness	No serious imprecision	None	Low confidence in estimate of the effect ●●○○
At 36 weeks gestation 1	RCT	Serious risk of bias	No serious inconsistency	No serious indirectness	No serious imprecision	None	Moderate confidence in the estimate of the effect ●●●○
Diabetic ketoacidosis							
0							Insufficient evidence

APPENDIX C. METHODS

Scope Statement

Populations

Children, adolescents, and adults with type 1 or type 2 diabetes mellitus (DM) on insulin therapy, including pregnant women

Population scoping notes: *None*

Interventions

Continuous blood glucose monitoring, either retrospective or real time

Intervention exclusions: *None*

Comparators

Self-monitoring blood glucose (SMBG) and/or routine HbA1c monitoring

Outcomes

Critical: Severe morbidity (e.g., microvascular and macrovascular complications), severe hypoglycemia

Important**:** Quality-of-life, change in HbA1c, ketoacidosis

Considered but not selected for the GRADE table: Myocardial infarction, cerebrovascular accident, amputations, neuropathy, retinopathy, nephropathy (we chose to generalize these into "severe morbidity" to simplify consideration), diabetes-related hospitalizations, emergency department visits

Key Questions

KQ1: What is the evidence of effectiveness of CGM in improving outcomes in people with diabetes?

KQ2: What are the indications for retrospective and for real-time CGM?

KQ3: Is there evidence of differential effectiveness of CGM based on:

a. Type 1 vs. Type 2 DM?
b. Insulin pump (integrated with CGM or standalone) vs. multiple daily insulin injections (MDII)?
c. Frequency and duration of CGM?
d. Persistently poor glycemic control?

Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, technology assessments, and clinical practice guidelines meeting the criteria for the PICO above. Searches of core sources were limited to citations published after 2012.

The core sources searched included:

Agency for Healthcare Research and Quality (AHRQ)
Blue Cross/Blue Shield Health Technology Assessment (HTA) program
BMJ Clinical Evidence
Canadian Agency for Drugs and Technologies in Health (CADTH)
Cochrane Library (Wiley Interscience)
Hayes, Inc.
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 the search terms for Diabetes Mellitus and continuous glucose monitoring. 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 review selected for each indication.

Searches for clinical practice guidelines were limited to those published since 2010. A search for relevant clinical practice guidelines was also conducted, using the following sources:

Australian Government National Health and Medical Research Council (NHMRC)
Centers for Disease Control and Prevention (CDC) – Community Preventive Services
Choosing Wisely
Institute for Clinical Systems Improvement (ICSI)
National Guidelines Clearinghouse
New Zealand Guidelines Group
NICE
Scottish Intercollegiate Guidelines Network (SIGN)
United States Preventive Services Task Force (USPSTF)
Veterans Administration/Department of Defense (VA/DOD)

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, or clinical practice guidelines.

APPENDIX D. APPLICABLE CODES

CODES	DESCRIPTION
CPT Codes	
83036	Hemoglobin; glycosylated (A1C)
83037	Hemoglobin; glycosylated (A1C) by device cleared by FDA for home use
95250-1	Glucose monitoring by SQ device
97802-97804	Medical nutrition therapy
98960-98962	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
99078	Physician educational services rendered to patients in a group setting (eg, prenatal, obesity, or diabetic instructions)
HCPCS Level II Codes	
A4230-2	Insulin infusion pump supplies
A4233-6	Batteries for home blood glucose monitors
A4253	Blood Glucose test strips, box of 50
A4255	Platforms for home blood glucose monitor, 50/box
A4256	Calibrator solutions/chips
A4258	Spring-powered device for lancet, each
A4259	Lancets, per box of 100
A9274	External ambulatory insulin delivery system, disposable
A9276	Disposable sensor, CGM system
A9277	External transmitter, CGM system
A9278	External receiver, CGM system
E0607	Blood glucose monitor
E0784	Insulin infusion pump
E2100	Blood glucose monitor with voice synthesizer
E2101	Blood glucose monitor with integrated lancer
G0108-G0109	Diabetes outpatient self-management training services
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 (including additional hours needed for renal disease)
S1030-1	Continuous non-invasive glucose monitoring device, purchase/rental
S9140	Diabetic management program, follow-up visit to non-MD provider
S9141	Diabetic management program, follow-up visit to MD provider

Note: Inclusion on this list does not guarantee coverage

Coverage Guidance: Continuous Glucose Monitoring in Diabetes Mellitus

Question: How should the draft Coverage Guidance **Continuous Glucose Monitoring in Diabetes Mellitus** be applied to the Prioritized List?

Question source: HERC Staff, HTAS

Issue:
The HTAS approved the following draft "box language":

Real-time continuous glucose monitoring (CGM) is recommended for coverage *(weak recommendation)* in adults with type 1 diabetes mellitus:

- who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit and
- 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).

Real-time CGM is recommended for coverage *(weak recommendation)* in children and adolescents under age 21 with type 1 diabetes who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit.

Real-time CGM (including the CGM-enabled insulin pump) is recommended for coverage *(weak recommendation)* in adults with type 1 diabetes on insulin pump management who have received or will receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit.

Real-time CGM is not recommended for coverage in adults with type 2 diabetes *(weak recommendation)*.

Real-time CGM is not recommended for coverage in children and adolescents with type 2 diabetes *(strong recommendation)*.

Retrospective CGM is not recommended for coverage in patients of any age with type 1 or type 2 diabetes *(strong recommendation)*.

CGM is not recommended for coverage during pregnancy for type 2 diabetes or gestational diabetes *(weak recommendation)*.

CGM is recommended for coverage for women with type 1 diabetes who are pregnant or who plan to become pregnant within six months without regard to HbA1c levels *(weak recommendation)*.

Rationale for Recommendations

The accuracy of real-time continuous glucose monitoring systems, approved by the FDA since 2005, has improved during the last decade and measurement error has been reduced from approximately 20% to 10%. In December 2016, the FDA announced its expansion of approved use for one CGM system as a replacement for finger-stick testing for diabetes treatment decisions for individuals ages two and older. Previously, all approved CGM devices were approved only to supplement and not replace finger-stick testing.

Use of real-time CGM in adults with type 1 diabetes results in greater improvements in HbA1c when compared with self-monitoring of blood glucose, although it is not clear that the benefits are clinically significant. Some evidence suggests that the greatest improvements in HbA1c are attained in patients who are on insulin pump management. There is insufficient evidence on long-term clinical outcomes related to the use of CGM, and CGM does not reduce severe hypoglycemia or ketoacidosis (although these were rare events in the studies). We are recommending that use of CGM be limited to those most likely to benefit by using criteria and clinical recommendations established by payers and professional societies.

We have high confidence that use of CGM in children with type 1 diabetes results in greater parental satisfaction. Expert testimony confirms that providers, parents, and these young patients highly value the benefits of improved monitoring capability, especially in reducing anxiety related to potential hypoglycemia during attempts to improve HbA1c levels. Although the evidence does not show benefit in critical or important outcomes, we recognize that published CGM studies generally do not include the youngest children with type 1 diabetes and do not address long-term developmental concerns. Our recommendation for CGM coverage in children and adolescents is based on strongly expressed values and preferences.

In adults with type 2 diabetes, we found insufficient evidence regarding the effects of CGM on long-term clinical outcomes or on severe hypoglycemia, and CGM does not improve treatment satisfaction. We have low confidence that improvements in HbA1c levels seen in type 2 diabetes studies are clinically significant. Given the prevalence of type 2 diabetes in the U.S. adult population, use of CGM would add significant cost without known population health benefit.

No systematic reviews or randomized controlled trials of CGM for children and adolescents with type 2 diabetes were identified in the literature search. There is insufficient evidence to draw conclusions about CGM for any outcome in this population.

There is conflicting evidence about the effect of CGM on HbA1c during the third trimester of pregnancy and no evidence regarding the use of these devices earlier in

pregnancy or before conception. CGM does not appear to reduce severe hypoglycemia during the third trimester, and there is insufficient evidence to assess effects on quality of life or diabetic ketoacidosis. No benefits have been identified for maternal, obstetrical, or neonatal outcomes. In spite of these limitations, many patients and providers would favor monitoring (particularly in type 1 diabetes) that improves blood sugar control during pregnancy, even with associated additional cost. Despite the cost and the lack of evidence of clinical outcomes, there is a clear rationale for using CGM to help control blood glucose levels, to prevent the known fetal and maternal harms associated with type 1 diabetes during pregnancy or when pregnancy is anticipated.

No clinically significant improvement in HbA1c levels has been demonstrated with use of retrospective CGM in adults or children with type 1 or type 2 diabetes.

Current Prioritized List Status: Codes

CODES	DESCRIPTION	
CPT Codes		**Current Code Placement**
83036	Hemoglobin; glycosylated (A1C)	Diagnostic Procedures File
83037	Hemoglobin; glycosylated (A1C) by device cleared by FDA for home use	Services Recommended for Non-coverage File
95250-1	Glucose monitoring by SQ device	8 TYPE 1 DIABETES MELLITUS
97802-97804	Medical nutrition therapy	Approximately 40 lines, including 8 and 30
98960-98962	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 min	1 PREGNANCY 8 TYPE 1 DIABETES MELLITUS 30 TYPE 2 DIABETES MELLITUS
99078	Physician educational services rendered to patients in a group setting (eg, prenatal, obesity, or diabetic instructions)	600+ lines
HCPCS Level II Codes		
G0108-G0109	Diabetes outpatient self-management training services	1,8,30
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 (including additional hours needed for renal disease)	1,8,30
A9276	Disposable sensor, CGM system	*(HERC generally does not recommend placement of DME codes, though they are reimbursed as ancillary services based on HERC recommendations. K0553 and K0554 are new codes introduced in 2017 for the Dexcom G5 system)*
A9277	External transmitter, CGM system	
A9278	External receiver, CGM system	
K0553	Supply allowance for therapeutic CGM	
K0554	Receiver (monitor), dedicated, for use with therapeutic CGM	
S1030-1	Continuous non-invasive glucose monitoring device, purchase/rental	*(This device was not reviewed in the coverage guidance and is generally considered experimental)*
S9140	Diabetic management program, follow-up visit to non-MD provider	1,8,30
S9141	Diabetic management program, follow-up visit to MD provider	1,8,30

Current Prioritized List Guideline:

GUIDELINE NOTE 108, CONTINUOUS BLOOD GLUCOSE MONITORING

Line 8

Services related to real-time continuous blood glucose monitoring (for long-term use) or retrospective glucose monitoring (for short-term use) are included on Line 8 only when insulin pump management is being considered, initiated, or utilized and only when the patient has at least one of the following despite compliance with treatment:

- HbA1c levels greater than 8.0%, or
- recurrent hypoglycemia with at least three events in the past six months.

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/herc/Pages/blog-continuous-glucose-monitoring.aspx

HERC Staff Recommendations:

1) Revise Guideline Note 108 as below:

GUIDELINE NOTE 108, CONTINUOUS ~~BLOOD~~ GLUCOSE MONITORING

Line 8

~~Services related to real-time continuous blood glucose monitoring (for long-term use) or retrospective glucose monitoring (for short-term use) are included on Line 8 only when insulin pump management is being considered, initiated, or utilized and only when the patient has at least one of the following despite compliance with treatment:~~

- ~~HbA1c levels greater than 8.0%, or~~
- ~~recurrent hypoglycemia with at least three events in the past six months.~~

Real-time continuous glucose monitoring (CGM) is included on line 8 for

1) adults with type 1 diabetes mellitus not on insulin pump management
    a. who have received or will receive diabetes education specific to the use of CGM AND
    b. who have used the device for at least 50% of the time at their first follow-up visit AND
    c. 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).
2) adults with type 1 diabetes on insulin pump management (including the CGM-enabled insulin pump)
    a. who have received or will receive diabetes education specific to the use of CGM AND
    b. who have used the device for at least 50% of the time at their first follow-up visit.
3) women with type 1 diabetes who are pregnant or who plan to become pregnant within six months without regard to HbA1c levels
4) children and adolescents under age 21 with type 1 diabetes
    a. who have received or will receive diabetes education specific to the use of CGM AND
    b. 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/herc/Pages/blog-continuous-glucose-monitoring.aspx

2) Add an entry to GN168 as shown below

GUIDELINE NOTE 168, TREATMENTS WITH MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS FOR CERTAIN CONDITIONS
The following treatments are prioritized on Line 500, CONDITIONS FOR WHICH CERTAIN TREATMENTS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS, for the conditions listed here:

CONDITION	CPT/HCPCS Code	TREATMENT	Rational	Date of last Review
Diabetes mellitus	95250-95251	Retrospective (professional) continuous glucose monitoring	Limited evidence of clinical utility	August, 2017

HERC Coverage Guidance: Continuous Glucose Monitoring in Diabetes Mellitus
Disposition of Public Comments

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Commenters

Identification	Stakeholder
A	Bruce Boston, MD; Kara Connelly, MD; Ines Guttmann Bauman, MD; Kelly Keller, PA; Lisa Madison, MD; Lindsey Nicol, MD; Melinda Pierce, MD; Joan Kono, RN CSN-PP CDE *[Submitted May 5, 2017]*
B	John Thomas Maluski *[Submitted May 21, 2017]*
C	Tracy Ann, RN *[Submitted May 24, 2017]*
D	Tomas C. Walker, DNP, APRN, CDE, on behalf of Dexcom, Inc. *[Submitted May 24, 2017]*
E	Duncan Williams, on behalf of Abbott Diabetes Care *[Submitted May 25, 2017]*

Public Comments

ID/#	Comment	Disposition
A1	Benefits of continuous glucose meters (CGMs) in childhood type 1 diabetes Our main goal of treatment in children with type 1 diabetes, as in adults, is to normalize blood sugars as much as possible without dangerous hypoglycemia. A secondary goal is to allow the child and family to have minimal disruption to normal life, by reducing the burden of disease management, and to foster in the child the development of healthy coping skills for this lifelong chronic illness. Management of pediatric type 1 diabetes is more challenging than adult type 1 diabetes. Insulin requirements for pediatric patients change frequently due to growth and puberty	*Thank you for your comments. The commenter's statements regarding the evidence for CGM in children are consistent with the findings of the evidence review. The current coverage guidance provides for the use of CGM in children with type 1 diabetes.*

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	and frequent changes in activity levels. Children are less able to sense hypoglycemia, particularly in the toddler age group. Frequent capillary blood glucose (CBG) testing has for years formed the mainstay of modern diabetes management, used to monitor the effect of insulin dosing, protect against hypoglycemia, and calculate insulin doses. In recent years, CGM's, specifically CGM's that allow real time and remote monitoring of blood sugars (RT-CGM), are rapidly gaining traction as an important tool for diabetes management. 1. Glycemic control Improved glycemic control, as judged by HbA1c, is used as a proxy for glycemic control and has clearly been shown to be associated with reduction in long term diabetes complications. As concluded by the HERC committee meta-analysis, CGMs have been shown to significantly lower HbA1c in adults. Significant lowering of HbA1c in children and young adults with type 1 diabetes using CGM has not clearly been demonstrated as yet, although most studies show trends towards improved HbA1c. It seems most likely that this difference is due to the difficulties in performing clinical studies in childhood: relatively low numbers of subjects and reduced adherence to CGMs in the pediatric patient age group. In addition, these studies were generally performed with older CGM devices: newer devices are more accurate and we are finding a much greater uptake and adherence to CGM technology in our pediatric age group in recent years. 2. Reduction in hypoglycemic events CGM technology, with real time display of glucose values, offers great promise with respect to the detection and prevention of hypoglycemia. Children are at particularly high risk of hypoglycemia due to high insulin sensitivity, variable insulin needs, and variable activity levels. Furthermore, they have poor awareness of hypoglycemia, and in the youngest age	

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	ranges, they or their caregivers are often not able to detect any warning signs of hypoglycemia. This often leads families to prefer their child run higher blood sugars than optimal, particularly at night, negatively impacting HbA1c. Nevertheless, severe hypoglycemia is a rare event in modern diabetes management. Rates of severe hypoglycemia in children using RT-CGMs have been shown to be reduced in some studies, and unchanged, with improved HbA1c, in others. Importantly, studies have also shown a reduction in 'time in hypoglycemic range' in children wearing RT-CGMs. 3. Improved quality of life/psychosocial adaptation Caring for a child with diabetes imposes a substantial burden on families. Parents of children diagnosed very young, in particular, may wake every night for years to check their child's blood sugar, out of fear of hypoglycemia. Burnout, particularly in teens and parents of teens, is high. CGM monitoring of blood sugars, particularly overnight, brings substantial peace of mind to families who are able to use the technology correctly. The ability to remotely monitor their child's blood sugar whilst they are at school is another tremendous benefit to families, and the use of CGM has been shown to reduce missed days at school. 4. Partial replacement for capillary blood glucose (CBG) testing RT-CGM accuracy has improved to the point where one of the most popular CGM devices (Dexcom G5) has an error rate comparable to standard blood glucose meters. This has led the FDA to recently approve Dexcom readings to replace CBG testing for insulin dose calculation in children >2 years and adults. Thus, RT-CGM is likely to reduce the burden of painful, intrusive, and repetitive blood sugar testing that we currently require of our patients. Reduction in use of test strips may result in a cost benefit for insurance, in addition. Summary	

ID/#	Comment	Disposition
	For these reasons, we believe that RT CGM technology should be an option available to all children with type 1 diabetes in Oregon. The main US professional endocrine societies (AACE, ADA, Endocrine society) all support the use of CGM in this age group. Children with type 1 diabetes are a particularly vulnerable group, and the ability to monitor blood sugars in real time offers substantial benefit, not least of which is peace of mind for the family. Patient selection is extremely important. Not all families are able to benefit from CGM: for some the additional data CGM systems provide can be overwhelming and confusing, despite education, and others find that the child cannot tolerate wearing the device. The decision regarding who may benefit from CGM is best individualized and left to an experienced pediatric diabetes provider. Education on how to use CGM effectively is also extremely important for successful outcomes, and should be provided by a trained pediatric diabetes educator. A trial of use may also be helpful. Overall, adherence is improving rapidly with improvements in sensor size and application, and CGM data may well reduce the frequency of CBG pokes, providing some cost offset. Very young children with type 1 diabetes are potentially a group who may benefit the most from RT-CGMs because of rapid blood sugar variation and lack of glycemic awareness. Unfortunately studies in this group are limited. The pace of improvement of the technology is rapid, with the development of partial 'closed loop' systems for those patients on pumps, allowing insulin delivery to be suspended when a rapid fall in blood sugar is detected, and/or adjustment of insulin basal rates based on blood sugar trend. This 'next generation' of integrated pumps and RT-CGM systems is likely to evolve rapidly over the coming few years.	
B1	I am a retired Federal Government secondary school teacher having taught at Chemawa Indian School in Salem, Oregon and Osan American High School in Pyongtaek, Republic of Korea.	*Thank you for your comments. This coverage guidance recommends coverage, although it will not affect coverage for Medicare recipients. It may, however,*

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	I am merely providing an anecdotal narrative of my personal experience with Type 1 Diabetes and the use of an insulin pump with a continuous glucose monitor. I was diagnosed with Type 1 Diabetes in July, 2007 at the age of 62. I had never been tested as pre-diabetic in my life. My pancreas basically stopped and its function became virtually nil per a C-peptide test. Following my diagnosis of Type 1 Diabetes, I tested my blood glucose (BG) approximately 4 times daily. I injected Insulin Lispro (Humalog) and Insulin Lantus in order to control my diabetes. I had great difficulty in maintaining an HbA1C test in acceptable areas (in the 7's). I started using the Medtronic Paradigm Insulin Pump with a Continuous Glucose Monitor (CGM) in early 2008. My doctor informed me that I was extremely "brittle" and probably one of her most difficult cases in attaining BG control. I have used the Medtronic Insulin Pump with a CGM since that time until the present. My HbA1C tests are for the most part always in the mid to upper 6 range. I have never been to the emergency room or hospitalized for uncontrolled diabetes, even though my BG will range on a weekly basis, from the 300s to the 60s. For the most part I operate between 100 and 200 BG. If I miss dosing even for one meal I will easily reach a BG of 400. And, if I miscalculate a meal I can go into the 60's. Yet, I keep control of my diabetes because the CGM provides me an early warning in order to take action to treat my diabetes. I believe I would be very helpless without the CGM, being required to provide a finger stick test several times daily in order to keep the same type control I reach with my CGM. I currently test 3 to 4 times daily in order to recalibrate my CGM. I have met other diabetics who use a pump but do not have a CGM. They are required to test as many as 7 to 8 times daily. Since my diabetes diagnosis I have suffered squamous cell throat cancer which had metastasized to my lymph system. I am fully recovered. I have had a heart attack and have had a stent emplaced, and I am recovered. I have had total knee replacement. And, I suffer	*influence coverage for the Oregon Health Plan and other payers.*

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	from an auto-immune disease, dermatomyositis, for which I receive an infusion of Rituxin every 6 months. The surgery and treatment for these problems required that my diabetes was under control. Thanks to my CGM and proper HbA1C numbers, the doctors had no hesitation in performing their actions on me. Because I am on Medicare, age 72, I do not receive insurance coverage for the CGM, only the pump and infusion equipment. I purchase my own CGM's in order to live a lifestyle that allows me to exercise several days each week and to perform other activities that provide me pleasure. I fully endorse the use of the CGM.	
C1	How is the 50% compliance determined and in what time period? 3-6-12 month follow-up? Some long term diabetics only see endocrinology once a year. Are the provider's determining compliance with a download? I have never seen CGM download on authorization requests. (I do DME authorization review for CareOregon.) These are expensive items to only have for 3 months as vendors do not rent them, but expect full payment. Is this DM equipment held to the 5 year DME rule? Currently DME providers are billing for 2 receivers and 1 transmitter every 12 months. Will there be additions to fee schedule?	*Thank you for your comments. Adherence can be determined using data from the CGM device. Providers can download data from CGM receivers that includes usage data and glucose levels. The subcommittee believed that adherence should be assessed by a clinician at an appropriate and patient-centered follow-up interval after the initiation of CGM.* *Implementation issues that are determined by individual health plans are not included in this coverage guidance, such as CGM device purchase versus rental agreements, authorization frequency for CGM supplies, and fee schedules.*
D1	On behalf of Dexcom, Inc., I'm writing to express my appreciation for the diligence applied to developing coverage guidance for continuous glucose monitoring (CGM) and the opportunity to provide comment. We concur with many of the recommendations; however, certain portions of the assessment reflect outdated information. With this letter, I'd like to address the use of obsolete CGM technology in systematic reviews and meta-	*Thank you for your comments.*

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	analyses (SRMAs) and the "no-coverage" recommendation for adults with type 2 diabetes (T2D) and provide new information regarding Medicare coverage for CGM.	
D2	Obsolete Technology in Meta-Analyses The Commission's review was heavily dependent upon SRMAs that include obsolete and discontinued CGM systems with relatively poor accuracy, as measured by the mean absolute relative difference (MARD) between CGM and contemporaneous blood glucose values. Several referenced sources, including the 2012 Cochrane Review,[1] base their conclusions on systems with MARD values in the 16-26% range, which is significantly worse than the 9% MARD of the Dexcom G5 Mobile System that was approved in 2015. In general, findings from SRMAs for medical devices can be limited as technological advancements preclude differentiation of past and current devices.[2] Findings from older SRMAs may significantly underestimate the potential benefits of the latest devices. We appreciate the Commission's inclusion of the recently published DIAMOND[3] and GOLD[4] randomized controlled trials. The DIAMOND trial examined the impact of the CGM use in adults with T1D using multiple daily injections (MDI) with A1c values from 7.5% to 9.9%. Subjects randomized to CGM had excellent compliance (93% used it 6 or 7 days/week), and experienced a mean A1c decrease of 1 percentage point from baseline to week 24, compared to a 0.4 percentage point reduction in the control group (P <.001). Benefits were observed across all subsets including those subjects with lower education, poorer numeracy skills, and higher baseline A1c levels. These data are complemented by those from the GOLD study that was conducted in Sweden. Again, use of CGM was shown to result in lower A1c values and reduced hypoglycemia in people with T1D using MDI. The DIAMOND study also included a cohort of 158 patients with T2D who were using MDI. As with subjects with T1D, subjects with T2D used CGM 6.7±0.9 days/week, were highly satisfied with the technology, and significantly reduced their A1c values.[5] In summary, clinical outcomes from studies such as DIAMOND and GOLD that use up-to-date CGM	*Thank you for your comments. The evidence review acknowledges that the accuracy of CGM devices has improved over time.* *The results from the type 2 diabetes cohort of the DIAMOND study remain unpublished (citation 5 is an oral abstract). Based on the oral abstract, the between-group difference in A1c after 24 weeks was -0.3% (95% CI -0.5% to 0.0%) in favor of CGM over the control arm. This finding is similar to the meta-analytic estimate of A1c improvement for patients with type 2 diabetes cited in the coverage guidance.*

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	systems show clinically meaningful and statistically significant benefits for patients with either T1D or T2D. These favorable results are likely to extend to larger populations with access to tools and technologies in the rapidly-evolving category of therapeutic CGM.	

D3	Real-time CGM is not recommended for coverage in adults with T2D
	
	The Commission's recommendation of non-coverage for adults with T2D poses risks for patients on intensive insulin therapy (IIT). Large RCTs have shown that IIT increases the risk of severe hypoglycemia by 2- to 3-fold in patients with T1 and T2D.[6-8] Incorporating CGMs into the management of insulin-treated T2 patients would reduce hypoglycemia and result in safer and potentially better overall control, as hypoglycemia remains an important risk of therapy intensification.[9]
	
	Considerable data have emerged on the incidence, risk, and costs arising from hypoglycemia among patients with T1D or insulin-treated T2D.[5,10-13] Based on the accumulated evidence, professional societies have published guidelines recommending CGM for patients with either T1D or T2D who are at risk for hypoglycemia, as follows:
	
	• ADA Standards of Care 2017[14]
	  ○ CGM is recommended in patients with T1D and those with hypoglycemia unawareness or frequent hypoglycemia.
	• AACE and ACE Outpatient Glucose Monitoring Consensus Statement[15]
	  ○ CGM usage has improved diabetes outcomes by reducing hypoglycemia and should be used in all patients who have severe hypoglycemia.
	• Endocrine Society Clinical Practice Guideline 2016[16]
	  ○ We recommend RT-CGM devices for adult patients with T1DM who have A1c levels above target or well-controlled T1D.
	• AACE and ACE CGM Consensus Conference 2016[17]
	  ○ Participants unanimously agreed that RT-CGM should be available to all insulin-using patients regardless of diabetes type.
		IIT may increase the risk of hypoglycemia, but data on CGM from RCTs and systematic reviews of RCTs have not demonstrated a reduction in the incidence of severe hypoglycemia.
		
		The professional society statements are noted. The AACE and ACE CGM Consensus Conference acknowledge that their conclusion is "based entirely on studies conducted in T1D." They also acknowledge uncertainty about the benefits for patients with hypoglycemia unawareness: "Few studies have been conducted in patients with hypoglycemia unawareness due to challenges recruiting a suitable patient population, but it is likely that this population would also benefit from CGM…"

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D4	<u>Medicare</u> On January 12, 2017, CMS announced the benefit category of non-adjunctive CGMs.[18] The ruling classified CGMs into "therapeutic" and "non-therapeutic" systems, with the former defined as those that can be used to replace fingerstick blood glucose testing for diabetes treatment decisions. Such systems are classified as durable medical equipment (DME) within the scope of Medicare Part B. Currently, *Dexcom G5 Mobile is the only device which meets the therapeutic CGM device classification.* On May 18, 2017, a Glucose Monitors Local Coverage Determination (LCD) and Related Policy Article was revised[19] to reflect the CMS ruling. Per the LCD, therapeutic CGMs may be covered by Medicare when all of the following are met: • The beneficiary has diabetes and, • Has been using a BGM and performing frequent (four or more times a day) testing; and, • Is insulin-treated with MDI or a Medicare-covered CSII pump; and, • The insulin regimen requires frequent adjustment on the basis of BGM or CGM testing results; and, • Within six months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria are met; and, • Every six months following the initial prescription of CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM and treatment plan.	*The subcommittee is aware of the CMS designation of the Dexcom G5 Mobile device as therapeutic CGM and the related LCD. We have updated the coverage guidance to include the new LCD.*

ID/#	Comment	Disposition
D5	Based on the above, we respectfully request that the Health Evidence Review Commission: 1) Place greater emphasis on clinical outcomes associated with recently published RCTs which use currently available devices. 2) Update the assessment to reflect CMS Ruling 1682R, revised LCD for glucose monitors and coverage criteria for therapeutic CGM. 3) Align with Medicare and recommend therapeutic CGM for people with either T1D or T2D who are on ITT.	*See responses to D2, D3, and D4 above.*
E1	On behalf of Abbott Diabetes Care, I am pleased to submit comments in response to the above-referenced draft coverage guidance. In the draft guidance, the Commission recommends (weak recommendation) coverage of real-time continuous glucose monitoring ("CGM") in adults with Type I Diabetes Mellitus ("T1DM"): • Who receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit; and, • Who have baseline HbAlc levels greater than or equal to 8.0%, frequent or severe hypoglycemia, or impaired awareness of hypoglycemia. We strongly support this recommendation. By contrast, the Commission recommends against coverage for real-time CGM for adults with Type 2 Diabetes Mellitus ("T2DM") and for professional CGM for patients with T1DM and T2DM. We respectfully disagree with these latter recommendations as explained below. 1. Real-Time CGM Should be Covered for T2DM with Multiple Daily Insulin Injections ("MDI")	*Thank you for your comments.* *As noted above, the results from the type 2 cohort of the DIAMOND study remain unpublished (citation 1 is an oral abstract). Based on the oral abstract, the between-group difference in A1c after 24 weeks was -0.3% (95% CI -0.5% to 0.0%) in favor of CGM over the control arm. This finding is similar to the meta-analytic estimate of A1c improvement for patients with type 2 diabetes cited in the coverage guidance.* *The initial six-month results of the REPLACE study (citation 2) were published after the coverage guidance was drafted. The trial was designed as an open-label unmasked RCT with 2:1 randomization (n=224). Patients with less than 50% adherence during a blinded run-in period were excluded before randomization. There was higher loss to follow-up in the control group (17%) compared to the CGM group (6%). Comparisons of sensor-derived glycemic measures between the two*

ID/#	Comment	Disposition
	There is new evidence, published after the HERC report, supporting the use of real-time CGM in adult patients with T2DM. a. DIAMOND Study The DIAMOND study was a 24-week randomized controlled trial conducted at 25 clinics across the United States and Canada that evaluated CGM versus a control group in T2DM with MDL 158 patients were randomly assigned to CGM or standard care. The mean HbA1c decreased from 8.5+0.6% (baseline) to 7.7+0.7% at 24 weeks with CGM versus 8.5+0.7% to 8.0+0.9% in the control group (adjusted difference= - 0.3%, 95% confidence interval -0.5% to -0.0%, p=0.02). The CGM group reported a high degree of satisfaction. Overall, a high percentage of adults with T2DM requiring MDI used CGM on a daily/near-daily basis for 24 weeks with a significant reduction in HbA1c and increased time-in-range ("TIR") compared with the control group.[1] b. REPLACE[2] The REPLACE study was a randomized, controlled study in adults with T2DM on intensive insulin therapy from 26 diabetes centers. 224 participants were randomly assigned (2:1) to the Abbott FreeStyle Libre™ Flash Glucose Monitoring System for self-management or to the self-monitoring of blood glucose ("SMBG") control group. Participants in the intervention group who successfully completed the 6-month trial continued into a 6- month open-access phase. At the end of the 1 2-month period, "time in hypoglycemia [sensor glucose <3.9 mmol/L (70 mg/dL)] was reduced by 50% compared to baseline [-0.70 ± 1.85/24 h (mean ± standard deviation)" and nocturnal hypoglycemia was reduced by 52%p=0.0002 (for both results) in favor of the intervention group. Overall, the use of flash glucose-sensing technology was "associated with a sustained reduction in hypoglycemia and safely and effectively replaced SMBG."[3]	*groups represent only the final two weeks of the study period (days 194–208), during which the control group participants wore a blinded sensor. There was no correction for multiple testing of secondary endpoints including the sensor-derived glycemic measures. Abbott Diabetes Care sponsored and funded the trial and was also involved in data collection and results reporting. All but one of the authors disclosed receiving personal fees from Abbott Diabetes care, and an employee of Abbot Diabetes Care provided "statistical support." There was no difference in the primary endpoint of change in A1c between the CGM and control groups at the end of six months. Secondary endpoints of time in hypoglycemia, nocturnal hypoglycemia, and frequency of hypoglycemic events (at various thresholds) were all reduced in the CGM arm, but severe hypoglycemia was not reported. (Patients with a history of severe hypoglycemia were excluded from the trial). CGM was associated with improved total treatment satisfaction as measured by the DTSQ (13.1 vs. 9.0 on a -18 to 18 point scale, with higher scores reflecting greater satisfaction), but there were no statistically significant differences in the perceived hypoglycemia or perceived hyperglycemia components of the DTSQ.* *Citation 3 is a six month open-access extension of the REPLACE trial and the outcomes were mainly sensor-derived glycemic measures compared to baseline values.*

ID/#	Comment	Disposition
	These two studies published within the last three months provide substantial evidence to support coverage for real-time CGM for adults with T2DM with MDI. c. Medicare Coverage In January 2017, after HERC drafted its guidance, CMS published an administrative ruling that "therapeutic continuous glucose monitors (CGM) are covered under the Durable Medical Equipment benefit."[4] A coverage article and corresponding LCD outline the criteria for coverage under Medicare.[5,6] II. Professional (Retrospective) CGM Should be Covered for T1DM or T2DM with MDI Vigersky, et al. conducted a review of the role of CGM for patients with T2DM.[7] He noted "[p]rofessional and real-time CGM has been used primarily in patients with T1D and most of the evidence for its benefit is in that group...However, there has been growing evidence that those with T2D may benefit from the use of this technology by COM's ability to uncover previously unknown hypoglycemia...." This review presented results from 7 studies, including 5 RCTs, which showed 3-7 days of professional CGM result in improvement in HbA1C (0.6%-2.3%) in patients with T2DM. Medicare and many private payers cover professional (retrospective) CGM in patients with T1DM.[8] Some payers also provide coverage for professional CGM in T2DM with MDI especially to document hypoglycemia.[9] The systematic review and the coverage policies in support of professional CGM support coverage for professional CGM for T1DM and T2DM with MDI. We appreciate the opportunity to submit comments on this draft coverage guidance.	*As noted above, the subcommittee is aware of the CMS designation of the Dexcom G5 Mobile device as therapeutic CGM and the related LCD.* *The manuscript by Vigersky and Srivastava (citation 7) is not a systematic review and no methods are described. The relevant evidence table included in the review is entitled "Studies demonstrating improved HbA1c." This leads to the question of whether additional studies exist that do not demonstrate improved HbA1C.*

References Provided by Commenters

ID/#	References
D	1. Langendam M, Luijf YM, Hooft L, Devries JH, Mudde AH, Scholten RJ. Continuous glucose monitoring systems for type 1 diabetes mellitus. Cochrane Database Syst Rev. 2012;1:CD008101. 2. Price D, Graham C, Parkin CG, Peyser TA. Are Systematic Reviews and Meta-Analyses Appropriate Tools for Assessing Evolving Medical Device Technologies? J Diabetes Sci Technol. 2015;10(2):439-446. 3. Beck RW, Riddlesworth T, Ruedy K, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Adults With Type 1 Diabetes Using Insulin Injections: The DIAMOND Randomized Clinical Trial. JAMA. 2017;317(4):371-378. 4. Lind M, Polonsky W, Hirsch IB, et al. Continuous Glucose Monitoring vs Conventional Therapy for Glycemic Control in Adults With Type 1 Diabetes Treated With Multiple Daily Insulin Injections: The GOLD Randomized Clinical Trial. JAMA. 2017;317(4):379-387. 5. Bergenstal R, Riddlesworth T, Ruedy K, Kollman C, Price D, Beck R. Patients with Type 2 Diabetes Using Multiple Daily Insulin Injections Have High Adherence and Benefit From CGM: A Prospective, Randomized Controlled Trial. Diabetes Technol Ther. 2017;19(S1):A11. 6. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med. 1993;329(14):977-986. 7. UK Prospective Diabetes Study Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet. 1998;352(9131):837-853. 8. Action to Control Cardiovascular Risk in Diabetes Study Group. Effects of intensive glucose lowering in type 2 diabetes. N Engl J Med. 2008;358(24):2545-2559. 9. Cryer PE. The barrier of hypoglycemia in diabetes. Diabetes. 2008;57(12):3169-3176. 10. Foos V, Varol N, Curtis BH, et al. Economic impact of severe and non-severe hypoglycemia in patients with Type 1 and Type 2 diabetes in the United States. J Med Econ. 2015;18(6):420-432. 11. Cariou B, Fontaine P, Eschwege E, et al. Frequency and predictors of confirmed hypoglycaemia in type 1 and insulin-treated type 2 diabetes mellitus patients in a real-life setting: results from the DIALOG study. Diabetes Metab. 2015;41(2):116-125. 12. Geller AI, Shehab N, Lovegrove MC, et al. National estimates of insulin-related hypoglycemia and errors leading to emergency department visits and hospitalizations. JAMA Intern Med. 2014;174(5):678-686. 13. Schopman JE, Geddes J, Frier BM. Prevalence of impaired awareness of hypoglycaemia and frequency of hypoglycaemia in insulin-treated type 2 diabetes. Diabetes Res Clin Pract. 2010;87(1):64-68. 14. American Diabetes A. 6. Glycemic Targets. Diabetes Care. 2017;40(Suppl 1):S48-S56. 15. Bailey TS, Grunberger G, Bode BW, et al. American Association of Clinical Endocrinologists and American College of Endocrinology 2016 Outpatient Glucose Monitoring Consensus Statement. Endocr Pract. 2016;22(2):231-261. 16. Peters AL, Ahmann AJ, Battelino T, et al. Diabetes Technology-Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2016;101(11):3922-3937.

ID/#	References
	17. Fonseca VA, Grunberger G, Anhalt H, et al. Continuous Glucose Monitoring: A Consensus Conference of the American Association of Clinical Endocrinologists and American College of Endocrinology. Endocr Pract. 2016;22(8):1008-1021. 18. Centers for Medicare and Medicaid Services. Ruling No.: [CMS-1682-R]. 2017. Available at: https://www.cgsmedicare.com/jb/pubs/news/2017/03/cope2581.html. Accessed May 24, 2017. 19. CGS Administrators L. Glucose Monitors LCD and Revised Policy Article. 2017; https://www.cgsmedicare.com/jb/pubs/news/2017/05/cope3241.html. Accessed May 18, 2017.
E	1. Bergenstal R, Riddlesworth T, Ruedy K, Kollman C, PriceD, Beck RW. Patients with type 2 diabetes using multiple daily insulin injections have high adherence and benefit from CGM: a prospective, randomized controlled trial. Paper presented at: 1Oth International Conference on Advanced Technology and Therapeutics (ATID); February 15-18, 2017; Paris, France. 2. REPLACE is the randomized controlled trial, "Novel Glucose-sensing Technology as a Replacement for Blood Glucose Monitoring for the Management of Insulin-treated Type 2 Diabetes" Page 1 DM_HC I080089-3 023560.0691 3. Haak T, Hanaire H , Ajjan R, Hermanns N, Riveline J, Rayman G. Use of Flash Glucose-Sensing Technology for 12 months as a Replacement for Blood Glucose Monitoring in Insulin-treated Type 2 Diabetes. Diabetes Ther. 2017 Apr II. doi: I0.1 007/s 13300-017-0255-6. 4. The ruling (CMS-1862-R) articulates CMS policy concerning the classification of continuous glucose monitoring systems as durable medical equipment under Part B of the Medicare program. 5. Glucose Monitor - Policy Article CA52464). 6. Local Coverage Determination by CGS Administrators and Noridian Healthcare Solutions, Glucose Monitors (L33822). 7. Vigersky R, and Shrivasta v M . Role of continuous glucose monitoring for type 2 in diabetes management and research. Journal of Diabetes and its Complications. 31.1 (2017): 280-287. 8. "Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes", UnitedHealthcare Commercial Medical Policy, April I, 20 1 7. "Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid", Medical policy adopted by a number of Blues plans including Blue Shield of California, HCSC (BlueCross BlueShield of IL, TX, OK, N M, and MT), Blue Cross of Idaho, BlueCross BlueShield of Alabama, and others. "Continuous Interstitial Glucose Monitoring", Anthem Medical Policy, 2017. ''Home Blood Glucose Monitors", Cigna Medical Coverage Policy, 2017. 9. See the above policies from United, HCSC, and CIGNA among others.