Health Evidence Review Commission's Value-based Benefits Subcommittee

November 14, 2019

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
11/14/2019
8:00am - 1:00pm
Clackamas Community College
29373 SW Town Center Loop E,
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
A working lunch will be served at approximately 12:00 PM
All times are approximate

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

III. Straightforward/Consent agenda – Ariel Smits **8:10 AM**
- **A.** Consent table
- **B.** Abnormal pap smear coding cleanup
- **C.** 3D image rendering

IV. Advisory Panel Reports **8:15 AM**
- **A.** Oral Health Advisory Panel
    i. 2020 CDT code review
- **B.** Behavioral Health Advisory Panel
    i. Wraparound services for autism
    ii. Neuropsychological status exams and neuropsychological testing
    iii. Counseling to prevent peripartum mood disorders
- **C.** Genetics Advisory Panel
    i. Recommended changes to the non-prenatal, non-hereditary cancer genetic testing guideline
        1. P450 testing
        2. CALR testing
    ii. Recommended changes to the prenatal genetic testing guideline
    iii. Recommended changes to the hereditary cancer genetic testing guideline

V. 2020 code review **9:00 AM**
- **A.** 2020 CPT code review
    i. Straightforward code placements
        1. Consent code table
            A. Includes BHAP reviewed codes
    ii. Codes requiring discussion
        1. Fat grafting

2. Dry needling
3. Implantable drug delivery devices
4. Preperitoneal pelvic packing
5. Sacroiliac nerve procedures
6. Genicular nerve procedures
7. Oncology
8. Computerized dynamic posturography
9. Myocardial strain imaging using speckle tracking derived assessment
10. Cardiac PET
11. Remote physiologic monitoring

iii. Reviews involving new and existing codes
1. Telephone and email consult guidelines

B. 2020 HCPCS code review

Break **10:30 AM**

VI. Previous discussion items **10:45 AM**

A. Chronic lower extremity venous disease
B. Vestibular rehabilitation

VII. New discussion items **11:15 AM**

A. Indications for intestinal transplantation
B. Breast reconstruction revisions for previous cosmetic procedures
C. Umbilical hernias with non-intestinal obstruction
D. Intracardiac echocardiogram
E. Yttrium 90 embolization mapping
F. Vitamin D screening
G. USPSTF Recommendation Update for GN106
H. Frequency specific microcurrent therapy and similar TENS-like therapies
I. Low level laser therapy
J. Fetal myelomeningocele repair

VIII. Public comment on topics not listed above **12:50 PM**

IX. Next steps **12:55 PM**

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

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on August 8, 2019

For specific coding recommendations and guideline wording, please see the text of the 8/8/2019 VbBS minutes.

RECOMMENDED CODE MOVEMENT (effective 10/1/2019)

- Place the 2019 ICD10-CM codes on various covered and uncovered lines
- Add surgery for varicoceles in children and adolescents to a covered line with a new guideline
- Add the procedure codes for sacral nerve stimulation, artificial urinary sphincter placement, sling procedures for male urinary incontinence to the covered urinary incontinence line. Add sacral nerve stimulation to the uncovered fecal incontinence line.
- Delete the procedure code for urethral bulking injections for urinary incontinence from covered lines and put on the uncovered line for therapies that are less effective than other covered therapies
- Add the testing codes for lead level and the procedure code for lead investigations to covered lines
- Add the procedure code for prolotherapy to an uncovered line
- Add a diagnosis code and procedure code pairing to represent opportunistic salpingectomy to multiple surgical gynecology lines
- Add various procedure codes for partial and full pancreatectomy and islet cell autotransplantation to the uncovered surgical chronic pancreatitis line with a new guideline
- Modify placement of the percutaneous mechanical circulatory support devices (Impella)
- Make various straightforward coding changes

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- Bladder irrigation and a physical therapy procedure were considered for pairing with urinary incontinence but no approved

RECOMMENDED GUIDELINE CHANGES (effective 10/1/2019 unless otherwise noted)

- Edit the lymphedema therapy guideline to allow therapists with LANA-qualifying training to treat OHP patients even if they did not have LANA certification
- Edit the fecal incontinence guideline to include criteria for sacral nerve stimulation
- Clarify the opportunistic salpingectomy guideline
- Edit the guideline on experimental or unproven treatments to include prolotherapy
- Edit the surgical spine guideline to remove reference to prolotherapy as the cpt code is now clearly placed on Line 660
- Adopt a new guideline on the use of Impella devices, allowing them for acute coronary syndrome and cardiogenic shock, and not for elective high-risk percutaneous coronary intervention (PCI)

VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
August 8, 2019
8:00 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair; Mark Gibson; Vern Saboe, DC (via phone until 10 AM, then in person); Gary Allen, DMD; Adriane Irwin, PharmD.

Members Absent: Holly Jo Hodges, MD

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

Also Attending: Adam Obley (Center for Evidence-based Policy); Erik Schulwolf, Stacey Bunk, Kirk Klinger, Sarah Klinger, Shannon Kjellsen, Channing Wyles, and Chris Hennessy (Abiomed); Megan Kaley, Jaime Musgrave and Mary Hiady (Providence Health Systems); Rika Bierek (OMA); Miranda Milla (COHO); Monte Madsen and Matt Yern (Medtronic); Ed Boyle, MD and Andrew Gentile MD (Inova Vein Center); Casey Seideman, MD and Brian Duty, MD (OHSU); Mike Bolen (MDT); Carolyn Bonnin; Erin Hanussak; Kevin Bonnin, Rocky Dallum (Tonkon Torp); Jason Wollmuth (Providence Heart Institute); Allen Gabriel, MD (via phone); Katina Kirby and Paula Stewart, MD (LANA, via phone)

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

  The meeting was called to order by Kevin Olson, Chair, at 8:10 am and roll was called. A quorum of members was present at the meeting. Minutes from the May 16, 2019 VbBS meeting were reviewed and approved as submitted.

  Smits reviewed the errata; there were no comments.

- **Topic: Straightforward/Consent Agenda**

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

  Recommended Actions:
  1) Add CPT 58541-58544 (Supracervical hysterectomy) to line 464 UTERINE PROLAPSE; CYSTOCELE
  2) Add CPT 68720 (Dacryocystorhinostomy (fistulization of lacrimal sac to nasal cavity)) to line 393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN
  3) Remove CPT 95012 (Nitric oxide expired gas determination) from line 9 ASTHMA
     a. Advise HSD to add 95012 to the Diagnostic Procedures File
  4) Add 97535 (Self-care/home management training (eg, activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes) to line 421 LYMPHEDEMA

5) Advise HSD to add CPT 99091 (Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days) to the Ancillary File
6) Add ICD-10 D48.7 (Neoplasm of uncertain behavior of other specified sites) to Line 372 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS and Line 200 CANCER OF SOFT TISSUE
7) Add CPT 81227 (CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)) to line 252 MULTIPLE SCLEROSIS AND OTHER DEMYELINATING DISEASES OF CENTRAL NERVOUS SYSTEM
    a. Remove CPT 81227 from line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
    b. Modify GN173 as shown in Appendix A

MOTION: To approve the recommendations stated in the consent agenda. CARRIES 5-0.

- **Topic: 2019 ICD-10-CM code placement**

Discussion: There was minimal discussion regarding the staff recommended placements. Staff noted that ICD-10 Z71.84 (Encounter for health counseling related to travel) could not be placed on the Excluded File as recommended; this file is reserved for procedure codes. The suggested placement was the "Diagnoses Not Covered" file; the VbBS agreed to this modification.

Recommended Actions:
1) 2019 ICD-10 code placements as shown in Appendix C

MOTION: To recommend the code placements as modified. CARRIES 5-0.

- **Topic:** Non-LANA certification for lymphedema providers

Discussion: Smits reviewed the topic summary.

Testimony was heard from Dr. Paula Stewart and Katina Kirby from LANA. Dr. Stewart testified that LANA data shows that there are 60 LANA-certified providers in Oregon. They both testified regarding the need for safety for patients getting treatment for lymphedema. They feel that a minimum of a 135-hour course is required to assure patient safety.

Olson wondered about whether setting 135-hour course completion was a reasonable standard for rural communities. The LANA representatives noted that LANA is aware of the issue of lack of coverage for rural communities and has initiatives to try to address this which are ongoing.

Testimony was heard from Megan Kaley, a LANA certified therapist for Providence. She testified in support of the suggested changes. All Providence lymphedema therapists would fall under the new guideline, and so could now see OHP patients. Providence as a group supports this change. She

argued about the need to have a breadth of knowledge to see these patients. Providers can cause harm if not treating correctly. Any therapist can screen for lymphedema, but only certain therapists are qualified to treat the disease.

It was noted that affordability of the LANA exam has been a barrier to LANA certification. Dr. Stewart testified that the cost of the exam has been cut in half to help this year, and they are trying to get a grant to help defray the cost on an ongoing basis. LANA has some costs to administer the exam, so cannot cut the exam price further. Training costs $2500-3000 and takes 9+ days of time, which is another barrier.

Irwin suggested adding a time requirement to the guideline for patients to become LANA certified after training. Smits noted that the current guideline wording has this provision, and it is causing issues for CCOs. LANA and Ms. Kaley spoke against adding such a time provision.

The LANA representatives were asked about the pass/fail rate of the LANA exam; they noted is was generally in the high 80% pass range. LANA allows 3 attempts to pass the exam, then requires applicants to get additional training before attempting the exam again.

The VbBS agreed with the staff suggested guideline change but requested that the topic be revisited in 1-2 years. HERC staff will ask CCOs to report back in a year or two to tell us how many non-LANA certified therapists are being used by the CCO patients and whether the loosened criteria are still necessary.

Recommended Actions:
1) Modify GN 43 as shown in Appendix A

MOTION: To recommend the guideline note changes as presented. CARRIES 5-0.

- **Topic:** Repair of varicoceles in children and adolescents

Discussion: Smits reviewed the summary document. Dr. Casey Seidman, from OHSU pediatric urology, testified in favor of the staff recommendation. Gibson asked whether a 20% testicular size difference was significant enough to justify surgery. Seidman replied that the 20% number was based on what was used in studies. Gibson asked what was the implication of small testicular size. Seidman replied that smaller testicles are associated with lower testicular function, including hormonal function. Small size is used as a surrogate measure for testicular function. Seidman noted that testicle size typically catches up within a year from surgery. It was noted that this surgery is not for fertility purposes, but rather for developmental purposes.

Recommended Actions:
1) Add ICD-10 I86.1 (Scrotal varices) to line 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
2) Add the following treatment CPT codes to line 327
    a. CPT 36470 (Injection of sclerosant; single incompetent vein (other than telangiectasia))
    b. CPT 37241-37242 (Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital

or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles))
    c. CPT 55530-55550 (Excision of varicocele or ligation of spermatic veins for varicocele)
3) Add a new guideline as shown in Appendix B to lines 327 and 545 SUBLINGUAL, SCROTAL, AND PELVIC VARICES

MOTION: To recommend the code and guideline note changes as presented. CARRIES 5-0.

- **Topic:** General incontinence procedures

Discussion: There was no discussion about these items.

Recommended Actions:
1) Do not add CPT 51700 or 97112 to line 453 URINARY INCONTINENCE

- **Topic:** Sacral nerve stimulation

Discussion: Smits reviewed the summary document. Duty was asked if sacral nerve stimulation therapy is lifelong; he replied that it was as long as there was no need to remove the device due to malfunction or other issues.

Recommended Actions:
1) Add the following CPT codes to lines 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION, 453 URINARY INCONTINENCE and 526 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS
    1. CPT 64561 Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
    2. CPT 64581 Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
    3. CPT 64590 Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
    4. HCPCS A4290, C1767, C1778, C1787, C1897, L8679-L8689 (Implantable pulse generator, implantable electrodes, patient programmer, transmitter)
2) Modify GN129 as shown in Appendix A
3) Adopt a new guideline note for lines 327 and 453 as shown in Appendix B

MOTION: To recommend the code and guideline note changes as presented. CARRIES 5-0.

- **Topic:** Artificial urinary sphincter (AUS)

Discussion: Smits introduced the summary document. Gibson was concerned with the low quality of evidence. Duty noted that this device is not well studied due to being standard of care. Revision rate is high over time. Duty noted that this treatment results in a dramatic improvement in quality of life. There is no other very effective treatment for severe urinary incontinence.

Staff recommendations were approved with the slight modification, substituting "men" for "members" in the proposed new guideline.

Recommended Actions:

1) Remove the CPT codes for insertion/removal/reinsertion of artificial urinary sphincters (CPT 53445-53449; HCPCS C1815) from lines 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES, 87 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM, and 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
2) Add CPT codes for insertion of AUS to line 453 URINARY INCONTINENCE
    a. CPT 53445 Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff
    b. CPT 53447 Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session
    c. CPT 53449 Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff
    d. HCPCS C1815 Prosthesis, urinary sphincter (implantable)
3) Add a new guideline to line 453 as shown in Appendix B

MOTION: To recommend the code and guideline note changes as modified. CARRIES 5-0.

- **Topic:** Sling procedure for male urinary incontinence

Discussion: Smits reviewed the summary document. Duty was asked about how the evidence for male sling procedures compared to the evidence for the female sling. Duty replied that the male procedure has been around a lot less time than the female procedure. For men, the procedure is used mostly for moderate incontinence. Severe incontinence is generally treated with artificial urinary sphincters.

Recommended Actions:

1) Add CPT 53440 (Sling operation for correction of male urinary incontinence (eg, fascia or synthetic)) and 53442 (Removal or revision of sling for male urinary incontinence (eg, fascia or synthetic)) to line 453 URINARY INCONTINENCE
2) Remove CPT 53440 and 53442 from lines 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES, 87 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM, and 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION

MOTION: To recommend the code as presented. CARRIES 5-0.

- **Topic:** Urethral bulking injections for urinary incontinence

  Discussion: Smits introduced the summary document. Duty noted that these injections work best for less severe disease. Duty did not feel that these injections are highly used; most use is in a palliative situation for patients that cannot undergo surgery.

  The subcommittee members discussed that the evidence shows that these injections don't work well. They elected to not cover these injections. The decision was to place the CPT code for this procedure on line 500 as less effective than other available treatments.

  Recommended Actions:

  1) Remove CPT 51715 (Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck) from lines 87 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM, 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION, 432 HYPOSPADIAS AND EPISPADIAS.
  2) Add CPT 51715 to line 500 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS
  3) Add entry for CPT 51715 in Guideline Note 172 as shown in Appendix A

  MOTION: To recommend the guideline note change as modified. CARRIES 5-0.

- **Topic:** Chronic lower extremity venous disease (CLEVD)

  Discussion: Smits introduced the summary document. Dr. Ed Boyle, a surgeon from Bend, testified, as did Monty Madison from Medtronic. Dr. Boyle testified about his experience with patients with CLEVD. Currently OHP only covers stage C6 (active ulceration). All other payers cover lower stages of disease. CLEVD causes skin cracks and recurrent cellulitis that costs a lot to treat, including hospitalizations. He recommended treating more patients (stages C2-C6) with less severe disease, which he feels would reduce complications and costs. Dr. Boyle recommended adding coverage for refractory lower extremity edema, skin changes, and other objective criteria. He agreed that pain is subjective and should not be a coverage criteria. He noted that superficial thrombophebiltis is not benign, as it can result in DVT and PE in some cases.

  It was noted that NICE has guidance on this topic, which was not reviewed.

  Madison noted that CLEVD has a 4% annual progression rate, and early treatment results in decreased risk of progression, increased QOL in patients and reduced cost for treating complications. Treatment has shifted from inpatient surgery to outpatient endovascular procedures.

  The VbBS decided that they would like to review the NICE evidence review and guidance prior to making a decision on this topic.

  Recommended Actions:
  1) This topic was tabled to the fall VbBS meeting

- **Topic:** Lead screening and investigation

  Discussion: There was minimal discussion of this topic.

  Recommended Actions:
  1) Add ICD-10 R78.71 (Abnormal lead level in blood) to lines 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS and 103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
     a. Advise HSD to remove ICD-10 R78.71 from the Diagnostic Workup File
  2) Add HCPCS T1029 (Comprehensive environmental lead investigation, not including laboratory analysis, per dwelling) to lines 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS, and 103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
     a. Advise HSD to remove HCPCS T1029 from the Ancillary File

  MOTION: To recommend the code changes as presented. CARRIES 5-0.

- **Topic:** Telephone and email visit guidelines

  Discussion: This topic was tabled until the next VbBS meeting

- **Topic:** Vestibular rehabilitation

  Discussion: Livingston presented an issue summary. Public testimony was received from Jaime Musgrave and Mary Hiady, both physical therapists at Providence. They spoke to the importance of treating patients at risk of falls with physical therapy, including in those patients who had not yet fallen, but a fall risk assessment screening test such as the STEADI was positive. They also requested codes such as 95992 (Epley maneuver) pair on the dysfunction line 292 in case vertigo was contributing to the increased fall risk. Subcommittee members suggested further work to address the issue of being at risk for falls, and an option of a guideline to clarify coverage intent.

  Recommended Actions:
  1) Staff to bring back this topic to the next VbBS meeting

- **Topic:** Prolotherapy

  Discussion: There was minimal discussion on this topic.

  Recommended Actions:
  1) Place M0076 Prolotherapy on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
  2) Add entry for HCPCS code M0076 to Guideline Note 173 as shown in Appendix A
  3) Modify GN37 as shown in Appendix A

  MOTION: To recommend the code and guideline note changes as presented. CARRIES 5-0.

- **Topic:** Opportunistic salpingectomy guideline clarification

  Discussion: Livingston reviewed the summary document. Subcommittee members and staff clarified the intent of the guideline is to allow opportunistic salpingectomy if done, but not to pay extra for it, given its uncertain benefit for cancer prevention. However, ensuring that claims for sterilization are not denied is one intent of the clarifying language. Opportunistic salpingectomy can be done in lieu of bilateral tubal sterilization, though with the intent to pay no more than the indicated procedure (bilateral tubal ligation).

  Recommended Actions:
  1) Add the following ICD-10-CM code to multiple surgical OB/GYN lines (1, 25, 37, 51, 61, 63, 133, 239, 286, 298, 353, 395, 403, 420, 428, 453, 464, 467, 529, 555, 578):
     a. Z40.03 Encounter for prophylactic removal of fallopian tube(s)
  2) Add the following CPT code to multiple surgical OB/GYN lines (1, 25, 63, 133, 239, 286, 298, 353, 395, 403, 420, 453, 464, 467, 555):
     a. 58700 Salpingectomy, complete or partial, unilateral or bilateral (separate procedure)
  2) Add CPT code 58262 (Vaginal hysterectomy, for uterus 250 g or less with removal of tubes(s), and/or ovary(s)) to surgical OB/GYN lines 37, 133, 239, 286 and 555, where it does not appear, but which do include 58260 (Vaginal hysterectomy, for uterus 250 g or less)
  3) Add CPT code 58291 (Vaginal hysterectomy, for uterus greater than 250 g with removal of tube(s) and/or ovary(s)) to surgical OB/GYN lines 286, where it does not appear, but which do include 58290 (Vaginal hysterectomy, for uterus greater than 250 g)
  4) Modify GN 176 as shown in Appendix A

  MOTION: To recommend the code and guideline note changes as presented. CARRIES 5-0.

- **Topic:** Surgical treatments and islet cell autotransplantation after pancreatectomy for chronic pancreatitis

  Discussion: Smits reviewed the summary document. Olson suggested considering rescoring the surgical chronic pancreatitis line during the next biennial review; this topic will be placed on the list of topics for the 2022 Biennial Review. Gibson requested that a criteria be added to the proposed new guideline to require abstinence from alcohol prior to surgery; this change was accepted.

  Recommended Actions:
  1) Add HCPCS S2102 (Islet cell tissue transplant from pancreas; allogeneic) to line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
  2) Add entry for HCPCS S2102 to GN173 as shown in Appendix A
  3) Add partial and total pancreatectomy CPT codes to line 596 CHRONIC PANCREATITIS Treatment: SURGICAL TREATMENT
     a. CPT 48150-48154 (Subtotal pancreatectomy)
     b. CPT 48155 (Pancreatectomy, total)
  4) Add CPT 48160 and HCPCS G0341-G0343 to line 596 CHRONIC PANCREATITIS Treatment: SURGICAL TREATMENT
     a. 48160 Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells

b. G0341 Percutaneous islet cell transplant, includes portal vein catheterization and infusion
c. G0342 Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion
d. G0343 Laparotomy for islet cell transplant, includes portal vein catheterization and infusion

5) Remove CPT 48160 from line 84 DIABETES MELLITUS WITH END STAGE RENAL DISEASE Treatment: SIMULTANEOUS PANCREAS/KIDNEY (SPK) TRANSPLANT, PANCREAS AFTER KIDNEY (PAK) TRANSPLANT
6) Add a new guideline to line 596 as shown in Appendix B

MOTION: To recommend the code and guideline note changes as modified. CARRIES 5-0.

- **Topic:** Biologic matrix for breast reconstruction

Discussion: Smits reviewed the evidence summary.

Dr. Allen Gabriel, a plastic surgeon from the Portland area *(Note: he works as a consultant for several companies which manufacture acellular dermal matrix/ADM materials)* testified on behalf of the National Academy of Plastic Surgeons. He noted that ADM has been used for 2 decades and is the standard of care. ADM has multiple benefits, primarily the ability to have a one-stage reconstructive procedure. ADM limits inflammation, decreasing risk of long-term complications. The FDA has not approved ADM for breast surgery but does permit off-label use of products. US law mandates breast reconstruction after mastectomy for breast cancer. Dr. Gabriel noted that ADM is used 74% of the time for breast reconstruction surgeries. Lack of coverage of ADM would limit access to breast reconstruction for OHP patients and would limit access for other patients if other insurers follow suit. Some plastic surgeons refuse to provide care without ADMs, which limits access.

Irwin noted her concern with the lack of access to breast reconstruction in more rural areas if ADM is not covered and younger surgeons not trained in other techniques refuse to care for OHP patients.

Olson asked why, if ADM is so effective, are trials not able to demonstrate the superiority of ADM for reconstruction.

Gabriel agreed that the data does not support the use of ADMs, but argued that the data was flawed due to different underlying mastectomy techniques, etc. He noted a huge learning curve in use of ADMs. He also noted that younger surgeons do not know many techniques to reconstruct breasts without ADMs.

It was noted that CCOs can cover ADMs if they choose to, particularly if it helps them contract with reconstructive surgeons.

Gibson was concerned about lack of FDA approval of ADM for use in breasts. He recommended non-coverage until new evidence emerges.

Gabriel argued that nipple sparing mastectomies used to be experimental, but now are standard of care. There was a learning curve there as well. He agreed with the lack of good RCTs—they would be difficult to do now as ADM is standard of care in the reconstructive communities. He agreed that the data was not there, but this is best practice. Without ADM, breast reconstruction is generally a two-stage procedure, with an extra surgery.

Irwin noted that the most recent studies in the staff review show increased complications, so the negative literature may not be due to a problem with older surgical techniques or a surgeon learning curve with ADMs.

The VbBS decided to not cover ADM and accept the staff recommendations as presented.

Recommended Actions:

1) Move CPT 15777 (acellular dermal matrix) from line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS to line 500 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS
2) Modify GN172 as shown in Appendix A
3) Modify GN173 as shown in Appendix A

MOTION: To recommend the code and guideline note changes as presented. CARRIES 5-0.

- **Topic: Coverage Guidance—** Temporary percutaneous mechanical circulatory support devices (Impella)

Discussion: Livingston reviewed the issue summary and draft revisions of the coverage guidance language based on EbGS discussion. Obley reviewed the GRADE table. Gibson asked for clarity about where the evidence demonstrated benefit for the use of Impella devices. Obley confirmed that evidence that was reviewed did not show a benefit. He spoke about an ongoing trial out of Denmark which may be helpful in providing further information. There is a great deal of uncertainty about benefit in patients with cardiogenic shock. Members discussed that it is surprising that the studies evaluating cardiogenic shock did not impact mortality. So either Impella doesn't work or the studies weren't able to tease this out because of how sick the patients are.

The subcommittee then took public comment.

Erik Schulwolf, an attorney representing Abiomed, spoke about coverage by other payers, including the fact that payers cover Impella for elective high-risk PCI and recommendations of clinical society guidelines include the use of Impella. He expressed concern that OHP would be an outlier. He also raised concern about the procedural validity of the EbGS coverage guidance review. He quoted rules and stated that because Dr. Crispin Davies was designated as an ad hoc expert and did not attend the April EbGS meeting, the draft coverage guidance was not properly approved and argued it could not be considered by VbBS and the full HERC.

Stacey Bunk, Director of Reimbursement at Abiomed, referred the subcommittee to the submitted letters. She stated only 25 Impella devices were used in Oregon Medicaid patients in 2018. She also stated that there were previous EbGS discussions around payment with regard to these devices

which are misinformed, and because they are built into the DRG, no additional payment would be made. She also mentioned that the FDA letter, which was included in the packet, addressed a right heart device (Impella RP), and was not in the scope of the review. Also, salvage patients were not excluded from the post-approval study (which could explain the lack of a difference in mortality rates).

Erin Hanussak, a patient with no affiliation with Abiomed, shared her story. She became sick in Roseberg, had her gallbladder removed, and woke up 1 week later, learning that an Impella had been implanted at St. Vincent. They were exploring a potential heart transplant, which in the end she did not need. She is now healthy.

Carolyn Bonnin, a retired nurse, shared her story. She described an extensive family history of heart disease. In 2014 she was admitted with chronic cardiomyopathy, scheduled to be transferred to Stanford, then her blood pressure dropped and she required an Impella.

Kurt Klinger, a patient, shared his story. He started feeling indigestion 4 years ago and went into cardiac arrest with a massive blockage of a coronary artery. He needed an Impella to allow his heart to rest and recover.

Rocky Dallum, from Tonkon Torp, represented the Oregon Bioscience Association. He described challenges in the process and expressed general concerns about different data points used, reliance on experts, and the timing of the coverage guidance development. He stated a concern about how Impella is the standard of care and widely covered, yet Oregon Medicaid can come up with a different coverage recommendation. He shared it was challenging to digest recommendations within the time frame they were given and recommended slowing down the process.

Jason Wollmuth, an interventional cardiologist at Providence, testified about his experience providing Impella. He specializes in complex revascularation and complex coronary artery disease and has used 32 Impella devices out of 350 interventions. He shared he may be an outlier in his low rate of utilization. He described three things that have changed his practice in a major way, with Impella being one of those for high-risk PCI. He described two patient cases.

Coffman addressed the earlier public comment about experts and following protocol. Dr. Davies completed his assignment through the review of the EbGS. He attended the January HERC meeting as well. In January is when HERC asked EbGS to consider some of the concerns raised in the issue summary, discussed earlier this meeting by Livingston. Dr. Davies schedule did not allow him to attend the April EbGS meeting and the current one. He discussed the certain rules that are followed for the coverage guidance process and the explicit role of experts as it relates to the process, which was followed for this topic.

Gingerich further clarified that the regulations state we may solicit experts but not that they be appointed or attend all meetings.

Subcommittee members clarified that if HERC wanted to, they could have pushed through those issues on their own; it was up to them to offer to give it back to EbGS to weigh in on those points one additional time. Olson discussed that the HERC wanted the follow up given the vulnerability of the survivors and wanted to ensure the language was clear in cases that seemed compelling. It is a challenge given the vulnerability of the population and the evidence of lack of benefit. EbGS has

created a path to coverage for this vulnerable group. The elective PCI group, though, does not elicit these same concerns.

Gingerich clarified some of the payment issues. There is a specific DRG that could be triggered with the use of the Impella. Also, if a patient does not receive an elective high-risk PCI because of a lack of Impella coverage, then the difference would be the cost of the Impella-associated PCI versus medical care. In the evidence review the focus has been on effectiveness, rather than cost per se. If not effective, it cannot be cost-effective.

Gibson said that increasing costs associated with these hospitalizations will be incorporated into the next round of capitation rates, and therefore does not just impact hospitals.

Irwin raised the question about the requirement of an ejection fraction of <25%. Wollmuth shared that this is leaving a number of patients out; those with unstable angina, those with acute heart failure,and those with STEMI. He said that rather than have it be based on an ejection fraction alone, that there are a number of considerations, including hemodynamics and other comorbidities. He states he has been using less and less Impella. Wollmuth did agree with some of the proposed requirements including the need for a heart team discussion and requirement of complex left main or last remaining conduit disease. He also suggested that, particularly in rural areas, it may be hard to get two cardiothoracic surgeons to consult, as there may only be one available on call. Wollmuth also stated that acute decompensated congestive heart failure needed to be incorporated.

Livingston asked about the disconnect between the usage of these devices and the evidence demonstrating a lack of benefit. Wollmuth spoke about the evidence being terrible, that there just haven't been enough good studies. He also clarified that may of the patients who were involved in the studies (Protect II) were not high-risk enough. Cardiologists use Impella and see immediate benefits and make it hard to do a trial. Lots of providers would feel it is unethical. A study is possible, but there would be challenges in recruitment and providers would be fearful of withholding this life altering intervention. He also spoke about the 90-day data which did show a benefit. Obley addressed the reported 90-day benefit and stated that if one uses an intention-to-treat model it did not achieve statistical significance. If using a per-protocol approach, it does, but driven mainly by two components, including repeat vascularization. Epidemiologically, a one needs to be cautious about including an outcome that is affected by an unblinded anlysis.

Wollmuth discussed challenges of interpreting data about stenting people with stable angina, in which one would not expect to see a mortality benefit. Revascularization in stable angina is about symptomatic treatment.

Coffman discussed that the VbBS role is to recommend Prioritized List changes. HERC decides about the coverage guidance language. The options include tabling it, accepting it or accepting it with modifications. Subcommittee members discussed hearing veiled threat of legal action with regard to the actions of EbGS. Two things could be done, HERC could refer the coverage guidance back to EbGS with another doctor in the room, or the process could move forward as an expert who uses the device (Wollmuth) was present today and clarified things. Agreement was made that EbGS doesn't need to come up with revised language; HERC had asked them to wordsmith some things and they did.

Irwin noted a discrepancy between some policies about ejection fraction (25% versus 30%). Obley said that in PROTECT II it was <35%.

Olson addressed the concern raised that OHP may have different coverage than other health plans. Since the inception of the health plan, the argument that we aren't doing what everybody else does doesn't jibe; what everyone else was doing was unsustainable.

Gingerich spoke about a data query of the OHP population and that the minority of Impella use was in the angina population.

Recommended Actions:

1) Add 33990, 33991, 33992, and 33993 to Line 69 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION
2) Remove 33990 and 33991 from Lines 82,98,264
3) Do NOT add 33990 to Line 189 CHRONIC ISCHEMIC HEART DISEASE as this would be for elective high-risk percutaneous coronary intervention (PCI) for patients with stable coronary artery disease
4) Add a new guideline as shown in Appendix B (*Note: The Guideline Note was changed at the August 8, 2019 HERC meeting. See minutes of that meeting for final approved language).*

MOTION: To recommended the changes to the Prioritized List as modified, based on the draft coverage guidance scheduled for review by HERC at their August 8, 2019 meeting. CARRIES 4-0. *(Abstained: Irwin)*

- **Public Comment:**

  No additional public comment was received.

- **Issues for next meeting:**

  - Chronic lower extremity venous disease
  - Telephone and email consult guidelines
  - Vestibular rehabilitation

- **Next meeting:**

  The next meeting is tentatively scheduled for October 3, 2019 at Clackamas Community College, Wilsonville Training Center, Wilsonville Oregon, Rooms 111-112. At the conclusion of today's HERC meeting a decision will be made on the need for that meeting. If it is not necessary, the next meeting would be on November 14, 2019 at the same location.

- **Adjournment:**

The meeting adjourned at 1:20 PM.

Appendix A
Revised Guideline Notes

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

Lines 346,527

Spine surgery is included on Line 346 only in the following circumstances:

A) Decompressive surgery is included on Line 346 to treat debilitating symptoms due to central or foraminal spinal stenosis, and only when the patient meets the following criteria:
   1) Has MRI evidence of moderate or severe central or foraminal spinal stenosis AND
   2) Has neurogenic claudication OR
   3) Has objective neurologic impairment consistent with the 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

   Foraminal or central spinal stenosis causing only radiating pain (e.g. radiculopathic pain) is included only on Line 527.

B) Spinal fusion procedures are included on Line 346 for patients with MRI evidence of moderate or severe central spinal stenosis only when one of the following conditions are met:
   1) spinal stenosis in the cervical spine (with or without spondylolisthesis) which results in objective neurologic impairment as defined above OR
   2) 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
   3) 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 527.

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 (including ozone therapy injections)
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation

- percutaneous laser disc decompression
- radiofrequency denervation
- corticosteroid injections for cervical pain

Corticosteroid injections for low back pain with or without radiculopathy are only included on Line 527.

The development of this guideline note was informed by HERC coverage guidances on Percutaneous Interventions for Low Back Pain, Percutaneous Interventions for Cervical Spine Pain, Low Back Pain: Corticosteroid Injections and Low Back Pain: Minimally Invasive and Non-Cordicosteroid Percutaneous Interventions. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx.

GUIDELINE NOTE 43, LYMPHEDEMA

[Note: Final guideline language shown here. A redundant link to the LANA website was deleted from numbered item 2 in an errata subsequent to the meeting.]

Line 421

Lymphedema treatments are included on this line when medically appropriate. These services are to be provided by a licensed practitioner who is:

1) Certified by Lymphology Association of North America (LANA, http://www.clt-lana.org), OR
2) CLT-LANA eligible (graduates from a minimum 135-hour lymphedema program that meet the LANA eligibility requirements).

Services should be provided by a LANA certified therapist if available.
~~certified by one of the accepted lymphedema training certifying organizations or a graduate of one of the National Lymphedema Network accepted training courses within the past two years. The only accepted certifying organization at this time is LANA (Lymphology Association of North America; http://www.clt-lana.org).~~ Treatments for lymphedema are not subject to the visit number restrictions found in Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES.

It is the intent of the HERC that compression dressings/garments and other medical equipment needed for the treatment of lymphedema be covered even in the absence of ulcers or other complications.

GUIDELINE NOTE 129, FECAL INCONTINENCE

Lines 71,526

ICD-10-CM R15.9 (Full incontinence of feces) is included on Line 71 only for supportive equipment (e.g. diapers, gloves). Surgical treatment for fecal incontinence is included on Line 526 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS.

Sacral nerve stimulation is included on line 526 only for fecal incontinence and only when all of the following criteria are met:

Appendix A
Revised Guideline Notes

1) Documented failure or intolerance to conventional therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment); AND
2) A successful percutaneous test stimulation, defined as at least 50% sustained (more than one week) improvement in symptoms; AND
3) Condition is not related to anorectal malformation and/or chronic inflammatory bowel disease; AND
4) Incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.

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

Line 500

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

Procedure Code	Intervention Description	Rationale	Last Review
15777	Acellular dermal matrix for soft tissue reinforcement (eg, breast, trunk)	Unclear benefits versus other effective therapies; increased risk of adverse events	August, 2019
51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck surgical; with thermally-induced capsulorrhaphy	More effective treatments are available	August, 2019

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

Line 660

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

~~15777~~	~~Acellular dermal matrix for soft tissue reinforcement (eg, breast, trunk)~~	~~Greater harms than other effective therapies~~	~~March 2015~~
81225~~-81227~~, 81226, 81230-81231	Cytochrome P450 gene analysis	Insufficient evidence of effectiveness	December, 2011 November, 2017
M0076	Prolotherapy	Insufficient evidence of effectiveness	August, 2019
S2102	Islet cell tissue transplant from pancreas; allogeneic	Insufficient evidence of effectiveness	August, 2019

Appendix A
Revised Guideline Notes

GUIDELINE NOTE 176, OPPORTUNISTIC SALPINGECTOMY

Lines 1, 6, 25, 37, 51, 61, 63, 133, 239, 286, 298, 353, 395, 403, 420, 428, 453, 464, 467, 529, 555, 578

~~Opportunistic salpingectomy during gynecologic procedures is included on Line 6, when it does not involve an increased payment (i.e., using a form of reference-based pricing) or require a change in the setting in which the procedure would be performed (e.g. necessitate a hospital setting instead of an ambulatory surgical center.)~~

Opportunistic salpingectomy is defined as the prophylactic removal of the fallopian tubes for the primary prevention of ovarian cancer when a woman is undergoing pelvic surgery for another indication, or instead of a bilateral tubal ligation (BTL) for the purpose of sterilization. It is included on these lines when used for these purposes, however, no additional payment is intended beyond the cost of the indicated pelvic surgery (e.g. using reference-based pricing) or the cost of the BTL and as long as the addition of the opportunistic salpingectomy does not result in a change in setting (for example requiring a hospital setting versus ambulatory surgery center).

Opportunistic salpingectomy should be paired with Z40.03 *Encounter for prophylactic removal of fallopian tube(s) or Z30.2 Encounter for sterilization.*

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

Appendix B
New Guideline Notes

GUIDELINE NOTE 191, REPAIR OF VARICOCELES IN CHILDREN AND ADOLESCENTS

Lines 327,545

Varicocele repair is only included on line 327 for children and adolescents (up through age 18) with:

1) Pain affecting activities of daily living from the varicocele; OR
2) Objective evidence of reduced ipsilateral testicular size of 20% of more compared to the contralateral testicle; OR
3) Varicocele in a patient with a solitary testicle.

All other varicocele repair is included on line 545

GUIDELINE NOTE 192, SACRAL NERVE STIMULATION FOR URINARY CONDITIONS

[Note: Final guideline language shown here. An "and" changed to "or" in item 4 to reflect intent of having any one of the three conditions, not all, to meet the coverage criteria. This change appears in an errata subsequent to the meeting.]

Lines 327, 453

Sacral nerve stimulation is included on these lines only for urinary incontinence, non-obstructive urinary retention, and overactive bladder AND only when all of the following criteria are met:

1) The patient has had symptoms for at least 12 months and the condition has resulted in significant disability (the frequency and/or severity of symptoms are limiting the member's ability to participate in daily activities); AND
2) Documented failure or intolerance to pharmacotherapies and behavioral treatments (e.g., pelvic floor exercise, biofeedback, timed voids, and fluid management) and, for non-obstructive urinary retention, intermittent catheterization; AND
3) The patient must be an appropriate surgical candidate such that implantation with anesthesia can occur; AND
4) The patient does not have stress incontinence, urinary obstruction, or specific neurologic diseases (e.g., diabetes with peripheral nerve involvement, spinal cord injury, or multiple sclerosis); AND
5) Patient must have had a successful test stimulation, defined as a 50% or greater improvement in symptoms.

GUIDELINE NOTE 193, ARTIFICIAL URINARY SPHINCTERS

Line 453

Artificial urinary sphincters are included on this line only for patients with intrinsic sphincter deficiency with any of the following indications:

1) Children with intractable urinary incontinence due to intrinsic sphincter deficiency who are refractory to behavioral or pharmacological therapies and are unsuitable candidates for other types of surgical procedures for correction of urinary incontinence; OR
2) Patients who are 6 or more months post-prostatectomy who have had no improvement in the severity of urinary incontinence despite trials of behavioral and pharmacological therapies; OR
3) Men with epispadias-exstrophy in whom bladder neck reconstruction has failed; OR

4) Women with intractable urinary incontinence who have failed behavioral, pharmacological, and other surgical treatments.

GUIDELINE NOTE 194, TOTAL PANCREATECTOMY WITH ISLET CELL AUTOTRANSPLANT

[Note: Final guideline language shown here. Item number 9 was reworded for clarity to match intent. This change appears in an errata subsequent to the meeting.]

Line 596

Total pancreatectomy with islet cell autotransplant (TP IAT) is only included on this line when the patient meets all of the following criteria:

1) Has acquired intractable chronic pancreatitis
2) Has intractable abdominal pain despite optimal medical therapy
3) Has not responded to more conservative surgery including endoscopic pancreatic decompression or in whom such surgery is not clinically indicated
4) Has not responded to nerve block procedures or in whom these interventions are not clinically indicated
5) Has been assessed by the multidisciplinary team and determined to have pain of an organic nature and are thought likely to achieve significant pain reduction from TP IAT
6) Is an appropriate candidate for major surgery
7) Is able to adhere to the complex medical management required following TP IAT
8) Does not have type 1 diabetes, known pancreatic cancer or any other condition that would prevent isolation of islet cells for autotransplant
9) Does not have a condition (e.g., PVT or significant parenchymal liver disease such as cirrhosis of the liver) which increases the risks associated with islet cell transplant
10) Does not have any other contraindications such as active alcohol abuse

GUIDELINE NOTE 195 , TEMPORARY PERCUTANEOUS MECHANICAL CIRCULATORY SUPPORT WITH IMPELLA DEVICES

[Note: The guideline note was modified at the HERC August 8, 2019 meeting. See the minutes of that meeting for the final approved language.]

Line 69

Temporary percutaneous mechanical circulatory support with Impella devices is included on Line 69 only in the two following circumstances:

1) During percutaneous coronary intervention (PCI) in patients with acute myocardial infarction when all of the following conditions are met:
   - NSTEMI without cardiogenic shock
   - A heart team discussion determines the patient needs revascularization with coronary artery bypass graft (CABG) or PCI
   - Two cardiothoracic surgeons are consulted and agree the patient is inoperable (i.e., are not willing to perform CABG but agree revascularization is indicated)

- Patient has complex left main or last remaining conduit disease
- Ejection fraction (EF) < 30%

2) In patients with cardiogenic shock in patients who may be candidates for Left Ventricular Assist Device (LVAD) (destination therapy) or transplant (bridge to transplant), AND an advanced heart failure and transplant cardiologist agrees that Impella should be used as a bridge to decision for LVAD or transplant. Appropriate effort should be made to consult with a heart failure and transplant cardiologist, but coverage is recommended in circumstances where consultation cannot reasonably be obtained without endangering the patient's life and the treating physician believes the patient meets the criteria above.

Temporary percutaneous mechanical circulatory support with Impella devices is not included on this or any other line for elective high-risk PCI for patients with stable coronary artery disease.

2019 - NEW DIAGNOSIS CODES		
ICD10 Code	**Description**	**Recommended Placement**
D75.A	Glucose-6-phosphate dehydrogenase (G6PD) deficiency without anemia	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN
D81.30	Adenosine deaminase deficiency, unspecified	Dysfunction lines (71,292,345,377) 95 HEREDITARY IMMUNE DEFICIENCIES Tx Bone marrow transplant 313 DISORDERS INVOLVING THE IMMUNE SYSTEM
D81.31	Severe combined immunodeficiency due to adenosine deaminase deficiency	71,95,292,313,345,377
D81.32	Adenosine deaminase 2 deficiency	71,95,292,313,345,377
D81.39	Other adenosine deaminase deficiency	71,95,292,313,345,377
H81.4	Vertigo of central origin	510 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM
I26.93	Single subsegmental pulmonary embolism without acute cor pulmonale	214 ACUTE PULMONARY HEART DISEASE AND PULMONARY EMBOLI
I26.94	Multiple subsegmental pulmonary emboli without acute cor pulmonale	214 ACUTE PULMONARY HEART DISEASE AND PULMONARY EMBOLI
I48.11	Longstanding persistent atrial fibrillation	347 CARDIAC ARRHYTHMIAS
I48.19	Other persistent atrial fibrillation	347 CARDIAC ARRHYTHMIAS
I48.20	Chronic atrial fibrillation, unspecified	347 CARDIAC ARRHYTHMIAS
I48.21	Permanent atrial fibrillation	347 CARDIAC ARRHYTHMIAS
I80.241	Phlebitis and thrombophlebitis of right peroneal vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I80.242	Phlebitis and thrombophlebitis of left peroneal vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I80.243	Phlebitis and thrombophlebitis of peroneal vein, bilateral	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I80.249	Phlebitis and thrombophlebitis of unspecified peroneal vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I80.251	Phlebitis and thrombophlebitis of right calf muscular vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I80.252	Phlebitis and thrombophlebitis of left calf muscular vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I80.253	Phlebitis and thrombophlebitis of calf muscular vein, bilateral	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I80.259	Phlebitis and thrombophlebitis of unspecified calf muscular vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I82.451	Acute embolism and thrombosis of right peroneal vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I82.452	Acute embolism and thrombosis of left peroneal vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP

ICD10 Code	Description	Recommended Placement
I82.453	Acute embolism and thrombosis of peroneal vein, bilateral	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I82.459	Acute embolism and thrombosis of unspecified peroneal vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I82.461	Acute embolism and thrombosis of right calf muscular vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I82.462	Acute embolism and thrombosis of left calf muscular vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I82.463	Acute embolism and thrombosis of calf muscular vein, bilateral	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I82.469	Acute embolism and thrombosis of unspecified calf muscular vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I82.551	Chronic embolism and thrombosis of right peroneal vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I82.552	Chronic embolism and thrombosis of left peroneal vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I82.553	Chronic embolism and thrombosis of peroneal vein, bilateral	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I82.559	Chronic embolism and thrombosis of unspecified peroneal vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I82.561	Chronic embolism and thrombosis of right calf muscular vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I82.562	Chronic embolism and thrombosis of left calf muscular vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I82.563	Chronic embolism and thrombosis of calf muscular vein, bilateral	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
I82.569	Chronic embolism and thrombosis of unspecified calf muscular vein	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP
L89.006	Pressure-induced deep tissue damage of unspecified elbow	379 CHRONIC ULCER OF SKIN
L89.016	Pressure-induced deep tissue damage of right elbow	379 CHRONIC ULCER OF SKIN
L89.026	Pressure-induced deep tissue damage of left elbow	379 CHRONIC ULCER OF SKIN
L89.106	Pressure-induced deep tissue damage of unspecified part of back	379 CHRONIC ULCER OF SKIN
L89.116	Pressure-induced deep tissue damage of right upper back	379 CHRONIC ULCER OF SKIN
L89.126	Pressure-induced deep tissue damage of left upper back	379 CHRONIC ULCER OF SKIN
L89.136	Pressure-induced deep tissue damage of right lower back	379 CHRONIC ULCER OF SKIN
L89.146	Pressure-induced deep tissue damage of left lower back	379 CHRONIC ULCER OF SKIN
L89.156	Pressure-induced deep tissue damage of sacral region	379 CHRONIC ULCER OF SKIN
L89.206	Pressure-induced deep tissue damage of unspecified hip	379 CHRONIC ULCER OF SKIN
L89.216	Pressure-induced deep tissue damage of right hip	379 CHRONIC ULCER OF SKIN
L89.226	Pressure-induced deep tissue damage of left hip	379 CHRONIC ULCER OF SKIN

ICD10 Code	Description	Recommended Placement
L89.306	Pressure-induced deep tissue damage of unspecified buttock	379 CHRONIC ULCER OF SKIN
L89.316	Pressure-induced deep tissue damage of right buttock	379 CHRONIC ULCER OF SKIN
L89.326	Pressure-induced deep tissue damage of left buttock	379 CHRONIC ULCER OF SKIN
L89.46	Pressure-induced deep tissue damage of contiguous site of back, buttock and hip	379 CHRONIC ULCER OF SKIN
L89.506	Pressure-induced deep tissue damage of unspecified ankle	379 CHRONIC ULCER OF SKIN
L89.516	Pressure-induced deep tissue damage of right ankle	379 CHRONIC ULCER OF SKIN
L89.526	Pressure-induced deep tissue damage of left ankle	379 CHRONIC ULCER OF SKIN
L89.606	Pressure-induced deep tissue damage of unspecified heel	379 CHRONIC ULCER OF SKIN
L89.616	Pressure-induced deep tissue damage of right heel	379 CHRONIC ULCER OF SKIN
L89.626	Pressure-induced deep tissue damage of left heel	379 CHRONIC ULCER OF SKIN
L89.816	Pressure-induced deep tissue damage of head	379 CHRONIC ULCER OF SKIN
L89.896	Pressure-induced deep tissue damage of other site	379 CHRONIC ULCER OF SKIN
L89.96	Pressure-induced deep tissue damage of unspecified site	379 CHRONIC ULCER OF SKIN
N63.15	Unspecified lump in the right breast, overlapping quadrants	Diagnostic Workup File (DWF)
N63.25	Unspecified lump in the left breast, overlapping quadrants	Diagnostic Workup File (DWF)
N99.85	Post endometrial ablation syndrome	529 CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME, DYSPAREUNIA
Q66.00	Congenital talipes equinovarus, unspecified foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.01	Congenital talipes equinovarus, right foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.02	Congenital talipes equinovarus, left foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.10	Congenital talipes calcaneovarus, unspecified foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.11	Congenital talipes calcaneovarus, right foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.12	Congenital talipes calcaneovarus, left foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.211	Congenital metatarsus primus varus, right foot	540 DEFORMITIES OF FOOT
Q66.212	Congenital metatarsus primus varus, left foot	540 DEFORMITIES OF FOOT

ICD10 Code	Description	Recommended Placement
Q66.219	Congenital metatarsus primus varus, unspecified foot	540 DEFORMITIES OF FOOT
Q66.221	Congenital metatarsus adductus, right foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.222	Congenital metatarsus adductus, left foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.229	Congenital metatarsus adductus, unspecified foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.30	Other congenital varus deformities of feet, unspecified foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.31	Other congenital varus deformities of feet, right foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.32	Other congenital varus deformities of feet, left foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.40	Congenital talipes calcaneovalgus, unspecified foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.41	Congenital talipes calcaneovalgus, right foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.42	Congenital talipes calcaneovalgus, left foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.70	Congenital pes cavus, unspecified foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.71	Congenital pes cavus, right foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.72	Congenital pes cavus, left foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.90	Congenital deformity of feet, unspecified, unspecified foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.91	Congenital deformity of feet, unspecified, right foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q66.92	Congenital deformity of feet, unspecified, left foot	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
Q79.60	Ehlers-Danlos syndrome, unspecified	525 DEFORMITIES OF UPPER BODY AND ALL LIMBS

ICD10 Code	Description	Recommended Placement
Q79.61	Classical Ehlers-Danlos syndrome	525 DEFORMITIES OF UPPER BODY AND ALL LIMBS
Q79.62	Hypermobile Ehlers-Danlos syndrome	525 DEFORMITIES OF UPPER BODY AND ALL LIMBS
Q79.63	Vascular Ehlers-Danlos syndrome	525 DEFORMITIES OF UPPER BODY AND ALL LIMBS
Q79.69	Other Ehlers-Danlos syndromes	525 DEFORMITIES OF UPPER BODY AND ALL LIMBS
Q87.11	Prader-Willi syndrome	Dysfunction lines: 71,292,345,377
Q87.19	Other congenital malformation syndromes predominantly associated with short stature	Dysfunction lines: 71,292,345,377
R11.15	Cyclical vomiting syndrome unrelated to migraine	526 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS
R82.81	Pyuria	Diagnostic Workup File (DWF)
R82.89	Other abnormal findings on cytological and histological examination of urine	Diagnostic Workup File (DWF)
S02.121A	Fracture of orbital roof, right side, initial encounter for closed fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.121B	Fracture of orbital roof, right side, initial encounter for open fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.121D	Fracture of orbital roof, right side, subsequent encounter for fracture with routine healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.121G	Fracture of orbital roof, right side, subsequent encounter for fracture with delayed healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.121K	Fracture of orbital roof, right side, subsequent encounter for fracture with nonunion	441 MALUNION AND NONUNION OF FRACTURE
S02.121S	Fracture of orbital roof, right side, sequela	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.122A	Fracture of orbital roof, left side, initial encounter for closed fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.122B	Fracture of orbital roof, left side, initial encounter for open fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.122D	Fracture of orbital roof, left side, subsequent encounter for fracture with routine healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES

ICD10 Code	Description	Recommended Placement
S02.122G	Fracture of orbital roof, left side, subsequent encounter for fracture with delayed healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.122K	Fracture of orbital roof, left side, subsequent encounter for fracture with nonunion	441 MALUNION AND NONUNION OF FRACTURE
S02.122S	Fracture of orbital roof, left side, sequela	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.129A	Fracture of orbital roof, unspecified side, initial encounter for closed fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.129B	Fracture of orbital roof, unspecified side, initial encounter for open fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.129D	Fracture of orbital roof, unspecified side, subsequent encounter for fracture with routine healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.129G	Fracture of orbital roof, unspecified side, subsequent encounter for fracture with delayed healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.129K	Fracture of orbital roof, unspecified side, subsequent encounter for fracture with nonunion	441 MALUNION AND NONUNION OF FRACTURE
S02.129S	Fracture of orbital roof, unspecified side, sequela	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.831A	Fracture of medial orbital wall, right side, initial encounter for closed fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.831B	Fracture of medial orbital wall, right side, initial encounter for open fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.831D	Fracture of medial orbital wall, right side, subsequent encounter for fracture with routine healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.831G	Fracture of medial orbital wall, right side, subsequent encounter for fracture with delayed healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.831K	Fracture of medial orbital wall, right side, subsequent encounter for fracture with nonunion	441 MALUNION AND NONUNION OF FRACTURE
S02.831S	Fracture of medial orbital wall, right side, sequela	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES

ICD10 Code	Description	Recommended Placement
S02.832A	Fracture of medial orbital wall, left side, initial encounter for closed fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.832B	Fracture of medial orbital wall, left side, initial encounter for open fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.832D	Fracture of medial orbital wall, left side, subsequent encounter for fracture with routine healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.832G	Fracture of medial orbital wall, left side, subsequent encounter for fracture with delayed healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.832K	Fracture of medial orbital wall, left side, subsequent encounter for fracture with nonunion	441 MALUNION AND NONUNION OF FRACTURE
S02.832S	Fracture of medial orbital wall, left side, sequela	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.839A	Fracture of medial orbital wall, unspecified side, initial encounter for closed fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.839B	Fracture of medial orbital wall, unspecified side, initial encounter for open fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.839D	Fracture of medial orbital wall, unspecified side, subsequent encounter for fracture with routine healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.839G	Fracture of medial orbital wall, unspecified side, subsequent encounter for fracture with delayed healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.839K	Fracture of medial orbital wall, unspecified side, subsequent encounter for fracture with nonunion	441 MALUNION AND NONUNION OF FRACTURE
S02.839S	Fracture of medial orbital wall, unspecified side, sequela	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.841A	Fracture of lateral orbital wall, right side, initial encounter for closed fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.841B	Fracture of lateral orbital wall, right side, initial encounter for open fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.841D	Fracture of lateral orbital wall, right side, subsequent encounter for fracture with routine healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.841G	Fracture of lateral orbital wall, right side, subsequent encounter for fracture with delayed healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES

ICD10 Code	Description	Recommended Placement
S02.841K	Fracture of lateral orbital wall, right side, subsequent encounter for fracture with nonunion	441 MALUNION AND NONUNION OF FRACTURE
S02.841S	Fracture of lateral orbital wall, right side, sequela	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.842A	Fracture of lateral orbital wall, left side, initial encounter for closed fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.842B	Fracture of lateral orbital wall, left side, initial encounter for open fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.842D	Fracture of lateral orbital wall, left side, subsequent encounter for fracture with routine healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.842G	Fracture of lateral orbital wall, left side, subsequent encounter for fracture with delayed healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.842K	Fracture of lateral orbital wall, left side, subsequent encounter for fracture with nonunion	441 MALUNION AND NONUNION OF FRACTURE
S02.842S	Fracture of lateral orbital wall, left side, sequela	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.849A	Fracture of lateral orbital wall, unspecified side, initial encounter for closed fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.849B	Fracture of lateral orbital wall, unspecified side, initial encounter for open fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.849D	Fracture of lateral orbital wall, unspecified side, subsequent encounter for fracture with routine healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.849G	Fracture of lateral orbital wall, unspecified side, subsequent encounter for fracture with delayed healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.849K	Fracture of lateral orbital wall, unspecified side, subsequent encounter for fracture with nonunion	441 MALUNION AND NONUNION OF FRACTURE
S02.849S	Fracture of lateral orbital wall, unspecified side, sequela	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.85XA	Fracture of orbit, unspecified, initial encounter for closed fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.85XB	Fracture of orbit, unspecified, initial encounter for open fracture	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES

ICD10 Code	Description	Recommended Placement
S02.85XD	Fracture of orbit, unspecified, subsequent encounter for fracture with routine healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.85XG	Fracture of orbit, unspecified, subsequent encounter for fracture with delayed healing	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.85XK	Fracture of orbit, unspecified, subsequent encounter for fracture with nonunion	441 MALUNION AND NONUNION OF FRACTURE
S02.85XS	Fracture of orbit, unspecified, sequela	229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
T50.911A	Poisoning by multiple unspecified drugs, medicaments and biological substances, accidental (unintentional), initial encounter	103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T50.911D	Poisoning by multiple unspecified drugs, medicaments and biological substances, accidental (unintentional), subsequent encounter	103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T50.911S	Poisoning by multiple unspecified drugs, medicaments and biological substances, accidental (unintentional), sequela	103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T50.912A	Poisoning by multiple unspecified drugs, medicaments and biological substances, intentional self-harm, initial encounter	103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T50.912D	Poisoning by multiple unspecified drugs, medicaments and biological substances, intentional self-harm, subsequent encounter	103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T50.912S	Poisoning by multiple unspecified drugs, medicaments and biological substances, intentional self-harm, sequela	103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T50.913A	Poisoning by multiple unspecified drugs, medicaments and biological substances, assault, initial encounter	103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T50.913D	Poisoning by multiple unspecified drugs, medicaments and biological substances, assault, subsequent encounter	103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T50.913S	Poisoning by multiple unspecified drugs, medicaments and biological substances, assault, sequela	103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T50.914A	Poisoning by multiple unspecified drugs, medicaments and biological substances, undetermined, initial encounter	103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS

ICD10 Code	Description	Recommended Placement
T50.914D	Poisoning by multiple unspecified drugs, medicaments and biological substances, undetermined, subsequent encounter	103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T50.914S	Poisoning by multiple unspecified drugs, medicaments and biological substances, undetermined, sequela	103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T50.915A	Adverse effect of multiple unspecified drugs, medicaments and biological substances, initial encounter	103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T50.915D	Adverse effect of multiple unspecified drugs, medicaments and biological substances, subsequent encounter	103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T50.915S	Adverse effect of multiple unspecified drugs, medicaments and biological substances, sequela	103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
T50.916A	Underdosing of multiple unspecified drugs, medicaments and biological substances, initial encounter	Diagnostic Workup File (DWF)
T50.916D	Underdosing of multiple unspecified drugs, medicaments and biological substances, subsequent encounter	Diagnostic Workup File (DWF)
T50.916S	Underdosing of multiple unspecified drugs, medicaments and biological substances, sequela	Diagnostic Workup File (DWF)
T67.01XA	Heatstroke and sunstroke, initial encounter	181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)
T67.01XD	Heatstroke and sunstroke, subsequent encounter	181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)
T67.01XS	Heatstroke and sunstroke, sequela	181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)
T67.02XA	Exertional heatstroke, initial encounter	181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)
T67.02XD	Exertional heatstroke, subsequent encounter	181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)
T67.02XS	Exertional heatstroke, sequela	181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)
T67.09XA	Other heatstroke and sunstroke, initial encounter	181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)
T67.09XD	Other heatstroke and sunstroke, subsequent encounter	181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)

ICD10 Code	Description	Recommended Placement
T67.09XS	Other heatstroke and sunstroke, sequela	181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)
Y35.009A	Legal intervention involving unspecified firearm discharge, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.009D	Legal intervention involving unspecified firearm discharge, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.009S	Legal intervention involving unspecified firearm discharge, unspecified person injured, sequela	Informational Diagnosis File
Y35.019A	Legal intervention involving injury by machine gun, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.019D	Legal intervention involving injury by machine gun, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.019S	Legal intervention involving injury by machine gun, unspecified person injured, sequela	Informational Diagnosis File
Y35.029A	Legal intervention involving injury by handgun, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.029D	Legal intervention involving injury by handgun, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.029S	Legal intervention involving injury by handgun, unspecified person injured, sequela	Informational Diagnosis File
Y35.039A	Legal intervention involving injury by rifle pellet, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.039D	Legal intervention involving injury by rifle pellet, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.039S	Legal intervention involving injury by rifle pellet, unspecified person injured, sequela	Informational Diagnosis File
Y35.049A	Legal intervention involving injury by rubber bullet, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.049D	Legal intervention involving injury by rubber bullet, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.049S	Legal intervention involving injury by rubber bullet, unspecified person injured, sequela	Informational Diagnosis File

ICD10 Code	Description	Recommended Placement
Y35.099A	Legal intervention involving other firearm discharge, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.099D	Legal intervention involving other firearm discharge, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.099S	Legal intervention involving other firearm discharge, unspecified person injured, sequela	Informational Diagnosis File
Y35.109A	Legal intervention involving unspecified explosives, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.109D	Legal intervention involving unspecified explosives, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.109S	Legal intervention involving unspecified explosives, unspecified person injured, sequela	Informational Diagnosis File
Y35.119A	Legal intervention involving injury by dynamite, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.119D	Legal intervention involving injury by dynamite, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.119S	Legal intervention involving injury by dynamite, unspecified person injured, sequela	Informational Diagnosis File
Y35.129A	Legal intervention involving injury by explosive shell, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.129D	Legal intervention involving injury by explosive shell, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.129S	Legal intervention involving injury by explosive shell, unspecified person injured, sequela	Informational Diagnosis File
Y35.199A	Legal intervention involving other explosives, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.199D	Legal intervention involving other explosives, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.199S	Legal intervention involving other explosives, unspecified person injured, sequela	Informational Diagnosis File
Y35.209A	Legal intervention involving unspecified gas, unspecified person injured, initial encounter	Informational Diagnosis File

ICD10 Code	Description	Recommended Placement
Y35.209D	Legal intervention involving unspecified gas, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.209S	Legal intervention involving unspecified gas, unspecified person injured, sequela	Informational Diagnosis File
Y35.219A	Legal intervention involving injury by tear gas, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.219D	Legal intervention involving injury by tear gas, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.219S	Legal intervention involving injury by tear gas, unspecified person injured, sequela	Informational Diagnosis File
Y35.299A	Legal intervention involving other gas, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.299D	Legal intervention involving other gas, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.299S	Legal intervention involving other gas, unspecified person injured, sequela	Informational Diagnosis File
Y35.309A	Legal intervention involving unspecified blunt objects, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.309D	Legal intervention involving unspecified blunt objects, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.309S	Legal intervention involving unspecified blunt objects, unspecified person injured, sequela	Informational Diagnosis File
Y35.319A	Legal intervention involving baton, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.319D	Legal intervention involving baton, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.319S	Legal intervention involving baton, unspecified person injured, sequela	Informational Diagnosis File
Y35.399A	Legal intervention involving other blunt objects, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.399D	Legal intervention involving other blunt objects, unspecified person injured, subsequent encounter	Informational Diagnosis File

ICD10 Code	Description	Recommended Placement
Y35.399S	Legal intervention involving other blunt objects, unspecified person injured, sequela	Informational Diagnosis File
Y35.409A	Legal intervention involving unspecified sharp objects, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.409D	Legal intervention involving unspecified sharp objects, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.409S	Legal intervention involving unspecified sharp objects, unspecified person injured, sequela	Informational Diagnosis File
Y35.419A	Legal intervention involving bayonet, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.419D	Legal intervention involving bayonet, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.419S	Legal intervention involving bayonet, unspecified person injured, sequela	Informational Diagnosis File
Y35.499A	Legal intervention involving other sharp objects, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.499D	Legal intervention involving other sharp objects, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.499S	Legal intervention involving other sharp objects, unspecified person injured, sequela	Informational Diagnosis File
Y35.819A	Legal intervention involving manhandling, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.819D	Legal intervention involving manhandling, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.819S	Legal intervention involving manhandling, unspecified person injured, sequela	Informational Diagnosis File
Y35.831A	Legal intervention involving a conducted energy device, law enforcement official injured, initial encounter	Informational Diagnosis File
Y35.831D	Legal intervention involving a conducted energy device, law enforcement official injured, subsequent encounter	Informational Diagnosis File
Y35.831S	Legal intervention involving a conducted energy device, law enforcement official injured, sequela	Informational Diagnosis File

ICD10 Code	Description	Recommended Placement
Y35.832A	Legal intervention involving a conducted energy device, bystander injured, initial encounter	Informational Diagnosis File
Y35.832D	Legal intervention involving a conducted energy device, bystander injured, subsequent encounter	Informational Diagnosis File
Y35.832S	Legal intervention involving a conducted energy device, bystander injured, sequela	Informational Diagnosis File
Y35.833A	Legal intervention involving a conducted energy device, suspect injured, initial encounter	Informational Diagnosis File
Y35.833D	Legal intervention involving a conducted energy device, suspect injured, subsequent encounter	Informational Diagnosis File
Y35.833S	Legal intervention involving a conducted energy device, suspect injured, sequela	Informational Diagnosis File
Y35.839A	Legal intervention involving a conducted energy device, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.839D	Legal intervention involving a conducted energy device, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.839S	Legal intervention involving a conducted energy device, unspecified person injured, sequela	Informational Diagnosis File
Y35.99XA	Legal intervention, means unspecified, unspecified person injured, initial encounter	Informational Diagnosis File
Y35.99XD	Legal intervention, means unspecified, unspecified person injured, subsequent encounter	Informational Diagnosis File
Y35.99XS	Legal intervention, means unspecified, unspecified person injured, sequela	Informational Diagnosis File
Z01.020	Encounter for examination of eyes and vision following failed vision screening without abnormal findings	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
Z01.021	Encounter for examination of eyes and vision following failed vision screening with abnormal findings	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
Z11.7	Encounter for testing for latent tuberculosis infection	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
Z22.7	Latent tuberculosis	50 PULMONARY TUBERCULOSIS
Z71.84	Encounter for health counseling related to travel	Diagnoses not covered

ICD10 Code	Description	Recommended Placement
Z86.002	Personal history of in-situ neoplasm of other and unspecified genital organs	Informational Diagnosis File
Z86.003	Personal history of in-situ neoplasm of oral cavity, esophagus and stomach	314 CANCER OF ESOPHAGUS; BARRETT'S ESOPHAGUS WITH DYSPLASIA
Z86.004	Personal history of in-situ neoplasm of other and unspecified digestive organs	166 ANAL, RECTAL AND COLONIC POLYP
Z86.005	Personal history of in-situ neoplasm of middle ear and respiratory system	Informational Diagnosis File
Z86.006	Personal history of melanoma in-situ	Informational Diagnosis File
Z86.007	Personal history of in-situ neoplasm of skin	Informational Diagnosis File
Z86.15	Personal history of latent tuberculosis infection	Informational Diagnosis File
Z96.82	Presence of neurostimulator	Informational Diagnosis File

Section 2.0

Staff Report

Errata & Revisions to the October 1, 2019 and January 1 Prioritized Lists

Revisions to the October 1, 2019 Prioritized List

1) Several minor changes were made to the wording of guidelines approved at the August meeting prior to the initial posting of the October 1, 2019 prioritized list. The following changes were made by staff to clarify the guideline intent or remove redundant wording.
    a. In revised **GUIDELINE NOTE 43, LYMPHEDEMA**, the link to the LANA website (http://www.clt-lana.org) appeared twice; the second appearance was deleted.
    b. The entry in **GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS** had one corrected entry:

E0650-E0673, E0676	Pneumatic compressors and associated appliances, including intermittent limb compression devices. ~~Segmental pneumatic appliance for use with pneumatic compressor~~	Insufficient evidence of effectiveness	May, 2019

    c. The entry regarding neurological disease exclusions for sacral nerve stimulation in the new **GUIDELINE NOTE 192, SACRAL NERVE STIMULATION FOR URINARY CONDITIONS** was edited to change "and" to "or" which was the intent of the clause
        i. The patient does not have stress incontinence, urinary obstruction, ~~and~~ or specific neurologic diseases (e.g., diabetes with peripheral nerve involvement, spinal cord injury, or multiple sclerosis); AND
    d. The clause regarding liver disease exclusions for islet cell transplantation in the new **GUIDELINE NOTE 194, TOTAL PANCREATECTOMY WITH ISLET CELL AUTOTRANSPLANT** was edited to clarify the language
        i. ~~Does not have a high risk of islet cell transplant including portal vein thrombosis, and significant parenchymal liver disease (e.g. cirrhosis of the liver)~~
        ii. Does not have a condition (e.g. PVT or significant parenchymal liver disease such as cirrhosis of the liver) which increases the risks associated with islet cell transplant
    e. Guideline Note 195 was published as shown below, including revisions made for clinical consistency after the meeting:

        GUIDELINE NOTE 195, TEMPORARY PERCUTANEOUS MECHANICAL CIRCULATORY SUPPORT WITH IMPELLA DEVICES

        Line 69

        Temporary percutaneous mechanical circulatory support with Impella devices is included on Line 69 only in the two following circumstances:

        1. During percutaneous coronary intervention (PCI) in patients with acute coronary syndrome (ACS) when all of the following conditions are met:
            - ~~NSTE~~ACS without cardiogenic shock (STEMI, NSTEMI, or unstable angina ~~or acute ischemic systolic congestive heart failure~~)
            - A heart team discussion determines the patient needs revascularization with coronary artery bypass graft (CABG) or PCI

- A cardiothoracic surgeon is consulted and agrees the patient is inoperable (i.e., are not willing to perform CABG but agree revascularization is indicated)
- Patient has complex left main or last remaining conduit disease
- Ejection fraction (EF) < 30% or at high risk for hemodynamic collapse during intervention

2. In patients with cardiogenic shock who may be candidates for Left Ventricular Assist Device (LVAD) (destination therapy) or transplant (bridge to transplant), AND an advanced heart failure and transplant cardiologist agrees that Impella should be used as a bridge to decision for LVAD or transplant. Appropriate effort should be made to consult with a heart failure and transplant cardiologist, but coverage is recommended in circumstances where consultation cannot reasonably be obtained without endangering the patient's life and the treating physician believes the patient meets the criteria above.

Temporary percutaneous mechanical circulatory support with Impella devices is not included on this or any other line for elective high-risk PCI for patients with stable coronary artery disease.

Revisions to the January 1, 2019 Prioritized List

2) On the January 1, 2019 list, there was a CPT code error DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE. The correct entry is:
    a. CPT ~~81221~~ 81332, SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (eg, alpha-1-antitrypsin deficiency), gene analysis, common variants (eg, *S and *Z): The alpha-1-antitrypsin protein level should be the first line test for a suspected diagnosis of AAT deficiency in symptomatic individuals with unexplained liver disease or obstructive lung disease that is not asthma or in a middle age individual with unexplained dyspnea. Genetic testing of the anpha-1 phenotype test is appropriate if the protein test is abnormal or borderline. The genetic test is appropriate for siblings of people with AAT deficiency regardless of the AAT protein test results.
3) A number of sequela ICD-10-CM codes (codes ending in S) were deleted which had been inadvertently included on lines 103,121 and 285 (October 1 2019 line numbers).
4) A typo was corrected in DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING to reflect the correct CPT code for spinal muscular atrophy testing
    a. N. Screening for spinal muscular atrophy (CPT 81329 ~~81239~~) once in a lifetime

Section 3.0

Consent Agenda-

Straightforward Items

Consent Agenda Issues—November 2019

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
F17.210	Nicotine dependence, cigarettes, uncomplicated	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	CMS requires ICD-10 F17.210 to be included in the billing for low dose CT for lung cancer screening. F17.210 is currently found on line 5 TOBACCO DEPENDENCE	Add F17.210 to line 3
81507 81420	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy Fetal chromosomal aneuploidy (eg, trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21	1 PREGNANCY	Both 81507 and 91420 appear in the prenatal diagnostic guideline and also on line 1. They are meant to be diagnostic. If left on line 1, the diagnostic guideline will not apply.	Remove 81507 and 81420 from line 1 and add to diagnostic procedure file.

Abnormal Pap Smear Coding Clean Up

Issue: Several ICD-10 codes for abnormal pap smears do not appear on line 25 DYSPLASIA OF CERVIX AND CERVICAL CARCINOMA IN SITU, CERVICAL CONDYLOMA which contains the colposcopy CPT codes required for further evaluation of the cervix. There are also several other abnormal pap codes that only appear on line 286 CANCER OF VAGINA, VULVA, AND OTHER FEMALE GENITAL ORGANS, but would be more appropriate on line 25. The colposcopy CPT codes only appear on line 25, except for the vaginal colposcopy CPT codes which appear on both lines 25 and 286.

Unsatisfactory pap smears or pap smears without transformation zone may require a repeat pap, but not a colposcopy or similar testing. Tests positive for low risk HPV do not need any further work up as this type of HPV is not associated with cervical cancer; in fact, low risk HPV should not be routinely tested for. Vaginal pap smears after hysterectomy should only be done for women who had the hysterectomy for cancer. The CPT codes for vaginal paps were placed on line 286 to reflect this.

HERC staff recommendations:

1) Make the code placement changes shown in the table below
2) Change the name of line 25 to ABNORMAL PAP SMEARS; DYSPLASIA OF CERVIX AND CERVICAL CARCINOMA IN SITU, CERVICAL CONDYLOMA

ICD-10 Code	Code Description	Current Placement	Recommended Placement
R87.610	Atypical squamous cells of undetermined significance on cytologic smear of cervix (ASC-US)	25	No change
R87.611	Atypical squamous cells cannot exclude high grade squamous intraepithelial lesion on cytologic smear of cervix (ASC-H)	25	No change
R87.612	Low grade squamous intraepithelial lesion on cytologic smear of cervix (LGSIL)	25	No change
R87.613	High grade squamous intraepithelial lesion on cytologic smear of cervix (HGSIL)	25	No change
R87.614	Cytologic evidence of malignancy on smear of cervix	25	No change
R87.615	Unsatisfactory cytologic smear of cervix	25	DWF
R87.616	Satisfactory cervical smear but lacking transformation zone	25	DWF
R87.618	Other abnormal cytological findings on specimens from cervix uteri	DIAGNOSTIC WORKUP FILE (DWF)	25
R87.619	Unspecified abnormal cytological findings in specimens from cervix uteri	DIAGNOSTIC WORKUP FILE (DWF)	25
R87.620	Atypical squamous cells of undetermined significance on cytologic smear of vagina (ASC-US)	286	No change
R87.621	Atypical squamous cells cannot exclude high grade squamous intraepithelial lesion on cytologic smear of vagina (ASC-H)	286	No change
R87.622	Low grade squamous intraepithelial lesion on cytologic smear of vagina (LGSIL)	286	No change

Abnormal Pap Smear Coding Clean Up

ICD-10 Code	Code Description	Current Placement	Recommended Placement
R87.623	High grade squamous intraepithelial lesion on cytologic smear of vagina (HGSIL)	286	No change
R87.624	Cytologic evidence of malignancy on smear of vagina	286	No change
R87.625	Unsatisfactory cytologic smear of vagina	286	DWF
R87.628	Other abnormal cytological findings on specimens from vagina	286	No change
R87.629	Unspecified abnormal cytological findings in specimens from vagina	286	No change
R87.810	Cervical high risk human papillomavirus (HPV) DNA test positive	25	No change
R87.811	Vaginal high risk human papillomavirus (HPV) DNA test positive	DWF	286
R87.820	Cervical low risk human papillomavirus (HPV) DNA test positive	25	Informational
R87.821	Vaginal low risk human papillomavirus (HPV) DNA test positive	DWF	Informational

3D Rendering of Imaging Studies

Question: Should non-mammographic rendering of 3D imaging studies be removed from line 662/GN173 and added to the Diagnostic Procedures File?

Question source: Holly Jo Hodges, CCO medical director

Issue: 3D rendering is the 3D computer graphics manipulating 3-D images on an imaging device or computer. 3D rendering (CPT 76376-76377) was last reviewed in 2006 as a new code. At that time, it was placed on the "Excluded File" due to concern for overutilization and lack of necessity for 3D rendering in most clinical situations. CPT 76376-76377 is currently on line 662/GN173 without a rationale. Dr. Hodges reports multiple complaints from providers regarding neurological imaging, such as imaging for aneurysms, which providers state must be done in 3D.

3D mammograms (tomosynthesis) are represented by CPT 77061-77063 and are on line 662/GN173.

Similar code HCPCS G0288 (Reconstruction, computed tomographic angiography of aorta for surgical planning for vascular surgery) is on the Diagnostic Procedure File.

HOSC minutes January 2006

> 76378/76377, 3D rendering of imaging studies – Sohl stated that the professional component is very low, while the technical component is fairly high. Often 3D is unnecessary, but occasionally it is very important, but these occasions are rare, and the potential for overutilization is high. Saha suggested not adding it, allowing the provider to perform the 3D, but not receive additional reimbursement. Walsh was concerned that there did not seem to be an effect on outcome. [Note: the CPT codes cited above were correct in 2006; they have since changed]
>
> Approval to act as follows:
> Do not add 76378 and 76377 to diagnostic file.

From Dr. Hodges

> We really need a full review of these 3D rendering codes as I am getting significant push-back and threatening language from neurologists and neurosurgeons that they cannot care for OHP members if they cannot use 3D rendering on aneurysms and such. There is no reasoning for why these are on line 660.

Evidence review:
No specific reviews of 3D vs 2D imaging for non-mammographic studies were found.
Searches for 3D imaging of cerebral aneurysms found that most reviews consider 3D CT to be standard for cases with need for rapid diagnosis

Other payer policies:

1) *Cigna 2019*: covers 3D imaging in multiple clinical situations
2) *Anthem BCBS 2019*

   a. Anthem considers 3D rendering of imaging studies to be included in the reimbursement for the imaging study performed. Anthem considers 3D rendering of imaging studies to be a technology and technique improvement, enabling computer generated real-time interaction with the image volume dataset. Therefore, separate visual enhancements reported with CPT codes 76376 and 76377 are not eligible for separate or additional reimbursement even when billed with modifier -59.

3) *Aetna 2019*:
   a. Does not cover 3D rendering for OB ultrasound

HERC staff summary:

3D image rendering does not appear to have been rigorously studied compared to 2D imaging. Some private insurers cover these procedures, while other consider 3D rendering to be included in the base imaging study.

HERC staff recommendation:

1) Continue the current policy of lack of coverage for 3D rendering separately from base imaging studies
   a. Edit the line 662/GN173 entry as shown below

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

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
76376-76377	3D rendering of imaging studies	No additional proven benefit beyond the standard study, therefore not reimbursed separately	November 2019

Section 4.0

Advisory Panel Reports

Procedure	Nomenclature	Comments	Recommended placement
D0419	Assessment of salivary flow by measurement	This procedure is for identification of low salivary flow in patients at risk for hyposalivation and xerostomia, as well as effectiveness of pharmacological agents used to stimulate saliva production. Similar to D0418 (Analysis of saliva sample) which is Excluded	EXCLUDED FILE
D1551	Re-cement or re-bond bilateral space maintainer – maxillary	Similar to D1550 Re-cement or re-bond space maintainer which is on line 53	53 PREVENTIVE DENTAL SERVICES
D1552	Re-cement or re-bond bilateral space maintainer – mandibular	Similar to D1550 Re-cement or re-bond space maintainer which is on line 53	53 PREVENTIVE DENTAL SERVICES
D1553	Re-cement or re-bond unilateral space maintainer – per quadrant	Similar to D1550 Re-cement or re-bond space maintainer which is on line 53	53 PREVENTIVE DENTAL SERVICES
D1556	Removal of fixed unilateral space maintainer – per quadrant	Similar to D1550 Re-cement or re-bond space maintainer which is on line 53	53 PREVENTIVE DENTAL SERVICES
D1557	Removal of fixed bilateral space maintainer – maxillary	Procedure performed by dentist or practice that did not originally place the appliance. Similar to D1555 Removal of fixed space maintainer which is on line 53	53 PREVENTIVE DENTAL SERVICES
D1558	Removal of fixed bilateral space maintainer – mandibular	Procedure performed by dentist or practice that did not originally place the appliance. Similar to D1555	53 PREVENTIVE DENTAL SERVICES
D2753	Crown - porcelain fused to titanium or titanium alloy	Similar to D2750 Crown-porcelain fused to high noble metal which is on 591	591 ADVANCED RESTORATIVE-ELECTIVE
D5284	Removable unilateral partial denture – one piece flexible base (including clasps and teeth)- per quadrant	Similar to D5282 Removable unilateral partial denture – one-piece cast metal (including clasps and teeth), maxillary which is on 591	591 ADVANCED RESTORATIVE-ELECTIVE
D5286	Removable unilateral partial denture – one piece resin (including clasps and teeth) - per quadrant	Similar to D5282	591 ADVANCED RESTORATIVE-ELECTIVE
D6082	Implant supported crown - porcelain fused to predominantly base alloys	A single metal-ceramic crown restoration that is retained, supported and stabilized by an implant. Similar to D6066 Implant supported porcelain fused to metal crown (titanium, titanium alloy, high noble metal) which is on line 619 IMPLANTS	619 IMPLANTS

Procedure	Nomenclature	Comments	Recommended placement
D6083	Implant supported crown - porcelain fused to noble alloys	A single noble metal-ceramic crown restoration that is retained, supported and stabilized by an implant. Similar to D6066 Implant supported porcelain fused to metal crown (titanium, titanium alloy, high noble metal) which is on 619	619 IMPLANTS
D6084	Implant supported crown - porcelain fused to titanium or titanium alloy	A single noble metal-ceramic crown restoration that is retained, supported and stabilized by an implant. Similar to D6066 Implant supported porcelain fused to metal crown (titanium, titanium alloy, high noble metal) which is on 619	619 IMPLANTS
D6086	Implant supported crown - predominantly base alloys	Similar to D6067 Implant supported metal crown (titanium, titanium alloy, high noble metal) which is on 619	619 IMPLANTS
D6087	Implant supported crown - noble alloys	Similar to D6067 Implant supported metal crown (titanium, titanium alloy, high noble metal) which is on 619	619 IMPLANTS
D6088	Implant supported crown - titanium/titanium alloys	Similar to D6067 Implant supported metal crown (titanium, titanium alloy, high noble metal) which is on 619	619 IMPLANTS
D6097	Abutment supported crown - porcelain fused to titanium or titanium alloys	Similar to D6094 Abutment supported crown - (titanium) which is on 619	619 IMPLANTS
D6098	Implant supported retainer for metal FPD - porcelain fused to predominantly base alloys	Similar to D6076 Implant supported retainer for porcelain fused to metal fpd (titanium, titanium alloy, or high noble metal) which is on 619	619 IMPLANTS
D6099	Implant supported retainer for metal FPD - porcelain fused to noble alloys	Similar to D6076 Implant supported retainer for porcelain fused to metal fpd (titanium, titanium alloy, or high noble metal) which is on 619	619 IMPLANTS
D6120	Implant supported retainer - porcelain fused to titanium or titanium alloy	Similar to D6076 Implant supported retainer for porcelain fused to metal fpd (titanium, titanium alloy, or high noble metal) which is on 619	619 IMPLANTS
D6121	Implant supported retainer for metal FPD - predominantly base alloys	Similar to D6076 Implant supported retainer for porcelain fused to metal fpd (titanium, titanium alloy, or high noble metal) which is on 619	619 IMPLANTS
D6122	Implant supported retainer for metal FPD - noble alloys	Similar to D6076 Implant supported retainer for porcelain fused to metal fpd (titanium, titanium alloy, or high noble metal) which is on 616	616 IMPLANTS
D6123	Implant supported retainer for metal FPD- titanium or titanium alloy	Similar to D6076 Implant supported retainer for porcelain fused to metal fpd (titanium, titanium alloy, or high noble metal) which is on 619	619 IMPLANTS
D6195	Abutment supported retainer - porcelain fused to titanium or titanium alloy	Similar to D6072 Abutment supported retainer for cast metal fpd (high noble metal) which is on 619	619 IMPLANTS

Procedure	Nomenclature	Comments	Recommended placement
D6243	Pontic - porcelain fused to titanium or titanium alloys	Similar to D6240 Pontic-porcelain fused to high noble metal which is on 619	619 IMPLANTS
D6753	Retainer crown - porcelain fused to titanium or titanium alloys		619 IMPLANTS
D6784	Retainer crown ¾ - titanium and titanium alloys	Similar to D6780 Retainer crown - 3/4 cast high noble metal which is on 591	591 ADVANCED RESORATIVE-ELECTIVE
D7922	Placement of intra-socket biological dressing to aid in hemostasis or clot stabilization, per site	This procedure can be performed at time and/or after extraction to aid in hemostasis. The socket is packed with hemostatic agent to aid in hemostasis and or clot stabilization. Similar to D7921 Collection and application of autologous blood concentrate product which is Excluded	EXCLUDED FILE
D8696	Repair of orthodontic appliance – maxillary	Does not include bracket and standard fixed orthodontic appliances. It does include functional appliances and palatal expanders. Replaces D8691 Repair of orthodontic appliance which was on 42, 257, 300, and 615	42 CLEFT PALATE WITH AIRWAY OBSTRUCTION 257 DEFORMATIES OF HEAD 300 CLEFT PALATE AND/OR CLEFT LIP 615 ORTHODONTIA
D8697	Repair of orthodontic appliance – mandibular	Does not include bracket and standard fixed orthodontic appliances. It does include functional appliances and palatal expanders.	42 CLEFT PALATE WITH AIRWAY OBSTRUCTION 256 DEFORMATIES OF HEAD 300 CLEFT PALATE AND/OR CLEFT LIP 618 ORTHODONTIA
D8698	Re-cement or re-bond fixed retainer – maxillary	Replaces D8693 Re-cement or re-bond fixed retainer, which was on 42, 256, 300, and 618	42 CLEFT PALATE WITH AIRWAY OBSTRUCTION 256 DEFORMATIES OF HEAD 300 CLEFT PALATE AND/OR CLEFT LIP 618 ORTHODONTIA
D8699	Re-cement or re-bond fixed retainer – mandibular	Replaces D8693 Re-cement or re-bond fixed retainer, which was on 42, 256, 300, and 618	42 CLEFT PALATE WITH AIRWAY OBSTRUCTION 256 DEFORMATIES OF HEAD 300 CLEFT PALATE AND/OR CLEFT LIP 618 ORTHODONTIA
D8701	Repair of fixed retainer, includes reattachment – maxillary		42 CLEFT PALATE WITH AIRWAY OBSTRUCTION 257 DEFORMATIES OF HEAD 300 CLEFT PALATE AND/OR CLEFT LIP 615 ORTHODONTIA
D8702	Repair of fixed retainer, includes reattachment – mandibular		42 CLEFT PALATE WITH AIRWAY OBSTRUCTION 256 DEFORMATIES OF HEAD 300 CLEFT PALATE AND/OR CLEFT LIP 618 ORTHODONTIA

Procedure	Nomenclature	Comments	Recommended placement
D8703	Replacement of lost or broken retainer – maxillary	Does not include bracket and standard fixed orthodontic appliances. It does include functional appliances and palatal expanders. Repaces D8692 Replacement of lost or broken retainer on these lines	42 CLEFT PALATE WITH AIRWAY OBSTRUCTION 256 DEFORMATIES OF HEAD 300 CLEFT PALATE AND/OR CLEFT LIP 618 ORTHODONTIA
D8704	Replacement of lost or broken retainer – mandibular	Does not include bracket and standard fixed orthodontic appliances. It does include functional appliances and palatal expanders	42 CLEFT PALATE WITH AIRWAY OBSTRUCTION 256 DEFORMATIES OF HEAD 300 CLEFT PALATE AND/OR CLEFT LIP 618 ORTHODONTIA
D9997	Dental case management – patients with special health care needs	Special treatment considerations for patients/individuals with physical, medical, developmental or cognitive conditions resulting in substantial functional limitations, which require that modifications be made to delivery of treatment to provide comprehensive oral health care services. Similar to D9992 Dental case management - care coordination which is Ancillary	ANCILLARY

MINUTES

Behavioral Health Advisory Panel
Clackamas Community College
Wilsonville Training Center, Room 111
Wilsonville, OR
October 7, 2019
1:00 pm--3:00 pm

Members Present: Lynnea Lindsey, PhD Chair; Kathy Savicki, LCSW

Members Absent: Gary Cobb; Eric Davis, MSW, CADC III, PSS; MSCP; Sheldon Levy, PhD; Nimisha Gokaldas MD.

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Jason Gingerich

Also Attending: Laurie Theodorou, LCSW, Donny Jardine, and Nat Jacobs (OHA); Kevin Mintz (Multnomah County); Keith Cheng, MD (CareOregon); Tracy Zent and Morgan Pitchford (Oregon Recovery); Lorne Bulling (COHO); Rita Bierek (OMA); Doreen Crail (Central City Concern).

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1. CALL TO ORDER

Lynnea Lindsey called the meeting to order at 1:05 PM. Note that this advisory body to the Medical Director of the Health Evidence Review Commission on issues to take forward to the Value-based Benefits Subcommittee does not require a quorum to meet.

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2. PRIORITIZED LIST ISSUES

1) 2020 Health and behavior assessment CPT codes: The members agreed with the HERC staff recommended placements for the new CPT codes. Lindsey noted that the new health and behavior assessment codes include a longer, 30-minute initial time interval, as CMS has noted that most previous billings were for two 15-minute visits. Also, the new CPT codes are planned to have a higher RVU. 97129 was briefly discussed. Savicki suggested considering adding this code to the schizophrenia line; Lindsey disagreed, noting that this would open the code up quite a bit. The recommendation is to place 97129 on the lines with current code 97127 as suggested by HERC staff and readdress if and when a provider requests a review.

2) Straightforward behavioral health coding changes: Staff presented behavioral health line standardization, including categorizing each line as inpatient or outpatient. The BHAP members discussed the need for inpatient consults for some conditions when a patient is hospitalized for a physical health condition. Lindsey will provide the CPT codes that her group uses for inpatient consults, and staff will draft up a proposal to add these CPT codes to the appropriate lines. Keith Cheng from Legacy testified that autism should have ER codes added, otherwise, patients will be seen in the ER and the billings will be made under different diagnoses, which will be a problem. The BHAP members felt that several lines should be considered for possible addition of inpatient

code or inpatient consults, including the lines for PSYCHOLOGICAL FACTORS AGGRAVATING PHYSICAL CONDITION (line 252), mild depression (line 203) and anxiety (line 414).

a. Action item: Lindsey will work with her team to determine CPT codes for inpatient consults and provide them to HERC staff. These codes will be considered for addition to the three lines identified above

3) Autism wraparound services: there was a robust discussion on this topic. Savicki felt that adding wraparound services to the autism line would be complicated. These services are used only for the highest complexity of children, and are only cost effective for complex kids when it keeps them out of higher levels of care. Opening these services to children with milder forms of autism would not be as cost effective and would put a strain on the delivery system.

Nat Jacobs, from the OHA Child and Family Behavioral Health group, testified that she oversees the wraparound program. The request for pairing autism with wraparound services was brought to her by several communities. Autism is the only serious condition affecting children not currently covered by the wraparound program. Not covering wraparound services can lead to non-coordinated care. Only children who are involved in two different child systems (e.g. foster care and medically fragile) qualify for wraparound services. Many kids with autism are already getting these services under other diagnoses; therefore, Jacobs does not anticipate a large number of new children qualifying for these services. Jacobs also testified that there are specific rules around which clients qualify for wraparound services, meaning that low needs children with autism will not qualify. She did not feel that adding wraparound services to the autism line would strain the delivery system.

Lindsey raised concerns about the cost of wraparound services, and how such costs should be distributed amongst the various systems (education, medical, mental health, etc.).

Keith Cheng from Legacy testified that children can get more appropriate services earlier with the wraparound program, which will prevent downstream costs from having these children require higher levels of care, get involved with corrections, etc.

Theodorou testified that adding wraparound services for autism will break down silos in the system, and possibly save costs across the system.

Jacobs noted that in addition to the two HCPCS codes identified by staff for wraparound services, HCPCS H2014, H0038 and T1016 should be added to the autism line as these codes are also used for wraparound services provision.

BHAP recommended adding wraparound services (using all 5 identified HCPCS codes) to the autism line. HERC staff will draft a more robust summary for the November VbBS/HERC meetings.

4) Neuropsychological status exam/Neuropsychological testing evaluation services: the BHAP members felt that both neuropsychological status exam CPT codes and neuropsychologist testing evaluation service CPT codes should be covered as diagnostic. Lindsey noted that such testing would still need to be medical necessary. The members discussed limiting these services with a guideline that would include only covering when “there is a lack of diagnostic clarity,” “when symptoms are not explained by an alternative diagnosis,” and/or “when the intended use of the

testing results is to develop a care plan." Theodorou felt that a guideline would be very helpful, in addition to making these codes diagnostic.

The BHAP recommendation is to recommend that both neuropsychological status exams and neuropsychological testing evaluation services be added to the Diagnsotic Procedures File with a new diagnostic guideline.

a) Action item: BHAP members and HERC staff will reach out to experts and the CCOs for assistance in writing the requested new guideline and will circulate this guideline via email to BHAP members prior to the November VbBS/HERC meetings.

5) Yoga and acupuncture for PTSD and anxiety disorders: Smits reviewed the summary document. Laura Ocker, LAc testified that she has treated many patients with these conditions and finds acpuncture to be beneficial for a variety of anxiety conditions. Ocker noted that acupuncture is hard to study, as acupuncture services involve a variety of treatments, such as lifestyle advice and motivational interviewing, as well as acupuncture needle placement.

Lindsey noted that Medicare does not cover acupuncture or yoga for mental health issues. She expressed concern with coverage of yoga for these conditions, given the lack of licensure and oversight for yoga providers. Savicki commented that yoga and/or acupuncture might help divert patietns from psychiatric services and need for psychiatric medication. She noted that the evidence that medication helps PTSD is poor. Savicki also felt that adding these services would add tools for OHP patients dealing with these conditions.

The BHAP felt that they did not have the expertise to fully analyze the evidence for acupuncture and yoga for PTSD/anxiety and deferred further discussion to the VbBS.

6) Counseling to prevent peripartum mood disorders: Smits reviewed the summary document. Lindsey noted that the health and behavior assessment codes are intended for just this circumstance—counseling when there is a physical health issue but no diagnosed mental health issue. The BHAP members strongly felt that psychotherapy codes should not be added to line 1 PREGNANCY. The public members present also felt that psychotherapy codes should not be paired with pregnancy or postpartum diagnoses. Lindsey remarked that the health and behavior assessment codes are already present on line 1 and 3. The BHAP members felt that a modification of the proposed guideline would be useful.

a) Action item: HERC staff to revise the proposed guideline for counseling to prevent peripartum mood disorders and circulate to BHAP members via email prior to taking to VbBS/HERC.

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3. PUBLIC COMMENT

No additional public comment was received.

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4. ADJOURNMENT

The meeting was adjourned at 2:45 pm.

Wraparound Services for Autism

Question: Should several HCPCS codes for community-based wraparound services be added to the autism line?

Question source: HSD mental health division; BHAP

Issue: The HCPCS codes for community-based wraparound services are currently on 26 lines, but not line 193 AUTISM SPECTRUM DISORDERS. The wraparound process is an intensive, individualized care management process for youths with serious or complex needs. The wraparound plan typically includes formal services and interventions, together with community services and interpersonal support and assistance provided by friends, kin, and other people drawn from the family's social networks.

The addition of wraparound services for autism was discussed at the October BHAP meeting. A large amount of public testimony was heard on this topic. BHAP was initially concerned about adding wraparound services to the autism line, as it would greatly increase the number of children with access to these services, which would increase costs and strain the delivery system. Testimony was heard from the staff of the OHA Child and Family Behavioral Health group, indicating that many children with autism are already getting wraparound services, but with other comorbid diagnoses. To qualify for wraparound services, a child must be involved in two or more child systems (e.g. foster care and medically fragile), and that OHA has rules regarding the level of severity a child must have before qualifying for these services. Not covering wraparound services can lead to non-coordinated care. OHA staff did not feel that a large number of new children would qualify for these services, and felt that adding the pairing with autism would not strain the delivery system. Keith Cheng, MD, a psychiatrist with Legacy, testified that treating children with appropriate wraparound services can prevent downstream costs by avoiding later requirements for higher levels of care for these kids. Laurie Theodorou from OHA testified that adding wraparound services for autism will break down silos in the system, and possibly save costs across the system.

HCPCS Code	**Code Description**	**Current Placement**
H0038	Self-help/peer services, per 15 minutes	40+ lines, incl. 193
H2014	Skills training and development, per 15 minutes	40+ lines, incl. 193
H2021	Community-based wrap-around services, per 15 minutes	35 lines
H2022	Community-based wrap-around services, per diem	35 lines
T1016	Case management, each 15 minutes	Ancillary

HERC staff/BHAP recommendation:

1) Add wraparound services to line 193 AUTISM SPECTRUM DISORDERS
    a. HCPCS H2021 (Community-based wrap-around services, per 15 minutes)
    b. HCPCS H2022 (Community-based wrap-around services, per diem)

Neuropsychological Status Exams and Neuropsychological Testing

Questions:

1) Should neuropsychological status exam procedure codes be removed from line 662 and added to the Diagnostic Procedures File?
2) Should neuropsychological testing procedure codes be removed from existing lines and added to the Diagnostic Procedures File?

Question sources: BHAP, multiple CCOs

Issue:

1) The CCOs have been getting requests for coverage for neuropsychological status exams, which are currently on line 662/Guideline Note 173. Similar codes (e.g. CPT 96132-96133 Neuropsychological testing evaluation) are diagnostic. CPT 96121 was reviewed by BHAP and by VbBS/HERC in 2018 as a new 2019 CPT code, and as part of that review, placement of CPT 96116 was reviewed. During those reviews, the placement of CPT 96116 on line 662 was affirmed and CPT 96121 was added to line 662 as an extension of this code; there was no discussion.
2) Neuropsychological testing is currently on 3 lines when done by a psychologist or physician, and on line 662 when done by computer or technician. These codes were recently added to the epilepsy surgery line to allow pre-surgical testing to evaluate for any issues with language or other major functions with ablation of the epilepsy focus. The CCOs are requesting that these codes be re-reviewed to see if they are appropriate for any additional lines. These codes were last reviewed at the 2018 BHAP and HERC meetings, as new 2019 CPT codes. They were placed where the cross-walked previous codes had been prioritized.

BHAP discussed adding the neuropsychological status exam and neuropsychological testing CPT codes to the diagnostic list at their October, 2019 meeting. The BHAP members and the public testimony heard at the BHAP meeting supported moving these codes to the diagnostic list with a new guideline regarding when they are covered. HERC staff were directed to work with experts to devise such a guideline.

Current Prioritized List status:

CPT	Code Description	Current Line(s)/List
96116	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; first hour	**662** CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
96121	each additional hour	**662**
96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive	**91** SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS **173** POSTTRAUMATIC STRESS DISORDER **174** GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION

	feedback to the patient, family member(s) or caregiver(s), when performed; first hour	OF IMPAIRMENT OF CONSCIOUSNESS Treatment SINGLE FOCAL SURGERY **193** AUTISM SPECTRUM DISORDERS **201** CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS
96133	each additional hour	**91,173,174,193,201**

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

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	**Intervention Description**	**Rationale**	**Last Review**
96116 96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities)		November, 2018

HERC staff/BHAP recommendations:

1) Remove the following codes from all current lines on the Prioritized List and advise HSD to add these codes to the Diagnostic Procedures File
    a. CPT 96116 Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; first hour
    b. CPT 96121 each additional hour
    c. CPT 96132 Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
    d. CPT 96133 each additional hour
2) Delete the GN173 entry for CPT 96116 and 96121

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

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
~~96116~~ ~~96121~~	~~Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities)~~		~~November, 2018~~

3) Adopt a new Diagnostic Guideline as shown below

DIAGNOSTIC GUIDELINE DXX, NEUROBEHAVIORAL STATUS EXAMS AND NEUROPSYCHOLOGICAL TESTING

Neurobehavioral status exams (CPT 96116 and 96121) and neuropsychological testing services (CPT 96116 and 96121) are only covered when all of the following are met:

1) Symptoms are not explained by an existing diagnosis; AND
2) When the results of such testing will be used to develop a care plan.

Counseling to Prevent Peripartum Mood Disorders

Question: How should coverage for counseling to prevent peripartum mood disorders be clarified on the Prioritized List?

Question source: HERC staff, BHAP

Issue: The USPSTF just came out with a new recommendation in February 2019. https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/perinatal-depression-preventive-interventions

The USPSTF recommends that clinicians provide or refer pregnant and postpartum persons who are at increased risk of perinatal depression to counseling interventions. GRADE B.

- Includes pregnant persons and persons who are less than 1 year postpartum
- No current depression diagnosis, but at increased risk
- Risk factors include:
    - personal or family history of depression
    - history of physical or sexual abuse
    - having an unplanned or unwanted pregnancy
    - current stressful life events
    - pregestational or gestational diabetes
    - complications during pregnancy (eg, preterm delivery or pregnancy loss)
    - low socioeconomic status
    - lack of social or financial support
    - adolescent parenthood has also been shown to increase the risk of developing *However, there is no accurate screening tool for identifying women at risk of perinatal depression and who might benefit from preventive interventions.*
- Counseling – CBT or Interpersonal therapy:
    - Ranged from 4 to 20 meetings (median, 8 meetings) lasting for 4 to 70 weeks
    - Group and individual, mostly in person
    - Intervention staff included psychologists, midwives, nurses, and other mental health professionals

A pragmatic approach, based on the populations included in the systematic evidence review, would be to provide counseling interventions to women with 1 or more of the following: a history of depression, current depressive symptoms (that do not reach a diagnostic threshold), certain socioeconomic risk factors such as low income or adolescent or single parenthood, recent intimate partner violence, or mental health–related factors such as elevated anxiety symptoms or a history of significant negative life events.

USPSTF found limited or mixed evidence that other studied interventions such as physical activity, education, pharmacotherapy, dietary supplements, and health system interventions were effective in preventing perinatal depression.

Current Prioritized List Status

Line: **1**

Condition: PREGNANCY (See Guideline Notes 2,4,22,33,39,64,65,85,92,99,147,150,153,175)

Treatment: MATERNITY CARE

ICD-10: N88.3,O02.81-O02.89,O09.00-O09.A3,O09.211-O09.93,O10.011-O10.93,O11.1-O11.9,O12.00-O12.25,O13.1-O13.9,O14.00-O14.95,O15.00-O15.9,O16.1-O16.9,O20.0-O20.9,O21.0-O21.9,O22.00-O22.53,O22.8X1-O22.93,O23.00-O23.43,O23.511-O23.93,O24.011-O24.93,O25.10-O25.3,O26.00-O26.53,O26.611-O26.93,O29.011-O29.93,O30.001-O30.93,O31.00X0-O31.8X99,O32.0XX0-O32.9XX9,O33.0-O33.2,O33.3XX0-O33.9,O34.00-O34.13,O34.211-O34.93,O35.0XX0-O35.9XX9,O36.0110-O36.93X9,O40.1XX0-O40.9XX9,O41.00X0-O41.93X9,O42.00,O42.011-O42.92,O43.011-O43.93,O44.00-O44.53,O45.001-O45.93,O46.001-O46.93,O47.00-O47.9,O48.0-O48.1,O60.00-O60.03,O60.10X0-O60.23X9,O61.0-O61.9,O62.0-O62.9,O63.0-O63.9,O64.0XX0-O64.9XX9,O65.0-O65.9,O66.0-O66.3,O66.40-O66.9,O67.0-O67.9,O68,O69.0XX0-O69.9XX9,O70.0-O70.1,O70.20-O70.9,O71.00-O71.9,O72.0-O72.3,O73.0-O73.1,O74.0-O74.9,O75.0-O75.5,O75.81-O75.9,O76,O77.0-O77.9,O80-O85,O86.11-O86.89,O87.0-O87.9,O88.011-O88.83,O89.01-O89.9,O90.1-O90.6,O90.81-O90.9,O91.011-O91.03,O91.211-O91.23,O92.011-O92.79,O98.011-O98.93,O99.011-O99.89,O9A.111-O9A.53,Q92.61,Q95.0-Q95.1,Z03.71-Z03.79,Z22.330,Z29.13,Z31.82,Z32.00-Z32.02,Z34.00-Z34.93,Z36.0-Z36.5,Z36.81-Z36.9,Z39.0-Z39.2,Z86.32,Z87.51-Z87.59

CPT: 01958-01963,01967-01969,10140,12021,12041,12042,13131-13133,37191-37193,57022,58150,58180,58260,58262,58290,58291,58541-58544,58550-58554,58559-58573,59000-59100,59160-59622,59866,59871,74712,74713,76801-76828,76945,76946,80081,81420,81507-81512,84163,84704,88235,88267,88269,93792,93793,96150-96155,97802-97814,98960-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99449,99451,99452,99468-99480,99487-99491,99495-99498,99605-99607

HCPCS: C1880,G0068,G0071,G0108,G0109,G0248-G0250,G0270,G0271,G0396,G0397,G0406-G0408,G0425-G0427,G0463-G0467,G0490,G0508-G0511,G0513,G0514,G2010-G2012,H0045,S2401-S2403,S2405,S2411,S8055,S9140,S9141,S9208-S9214

Line: 3

Condition: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS (See Coding Specification Below) (See Guideline Notes 1,17,64,65,106,122,140,179,181)

Treatment: MEDICAL THERAPY

ICD-10: R73.03,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,Z13.31-Z13.39,Z13.41-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,Z68.53-Z68.54,Z71.41,Z71.7,Z76.1-Z76.2,Z80.0,Z80.41,Z86.32,Z87.891,Z91.81

CPT: 0403T,0488T,44392,44394,45333,45338,45384,45385,76706,77067,90378,90460-90472,90620,90621,90630-90689,90696-90716,90723-90736,90739-90748,90750,90756,92002-92014,92551,93792,93793,96110,96127,96150-96161,98962-98969,99051,99060,99070,99078,99173,99188,99201-99215,99281-99285,99341-99378,99381-99404,99408-99449,99451,99452,99487-99491,99495-99498,99605-99607

HCPCS: D0191,D1206,G0008-G0010,G0068,G0071,G0104,G0105,G0121,G0248-G0250,G0296,G0297,G0396,G0397,G0438-G0445,G0463-G0468,G0490,G0511,G0513,G0514,G2010-G2012,G9873-G9891,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.

GUIDELINE NOTE 181, POSTPARTUM DEPRESSION SCREENING

Line 3

Postpartum depression screening using a validated instrument (e.g. Edinburgh Postpartum Severity Score, PHQ-9) is included on this line during the child's visit (CPT 96161) or during the mother's visit (CPT 96160, 96127) when there is a plan in place to address positive depression screens.

Line: 7

Condition: MAJOR DEPRESSION, RECURRENT; MAJOR DEPRESSION, SINGLE EPISODE, SEVERE (See Guideline Notes 64,65,69,102)

Treatment: MEDICAL/PSYCHOTHERAPY

ICD-10: F32.2-F32.5,F32.9,F33.0-F33.3,F33.40-F33.42,F33.9,F53.0

CPT: 90785,90832-90840,90846-90853,90867-90870,90882,90887,93792,93793,98966-98969,99051,99060,99201-99239,99281-99285,99304-99357,99366,99415,99416,99441-99449,99451,99452,99487-99491,99495-99498,99605-99607

HCPCS: G0068,G0071,G0176,G0177,G0248-G0250,G0406-G0408,G0410,G0411,G0425-G0427,G0459,G0463-G0467,G0469,G0470,G0508-G0511,G0513,G0514,G2012,H0004,H0017-H0019,H0023,H0032-H0039,H0045,H2010,H2012-H2014,H2021-H2023,H2027,H2032,S5151,S9125,S9480,S9484,T1005

Codes

Code	Code Description	Current Prioritized List Placement
Z13.32	Encounter for screening for maternal depression	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
Z13.39	Encounter for screening examination for other mental health and behavioral disorders	3
Z39.2	Encounter for routine postpartum follow-up	1 PREGNANCY 6 REPRODUCTIVE SERVICES

Code	Code Description	Current Prioritized List Placement
90832	Psychotherapy, 30 minutes with patient	4,7,22,26,62,65,97,121 and 36 other lines.
90833	Psychotherapy, 30 minutes with patient when performed with an evaluation and management service (List separately in addition to the code for primary procedure)	4,7,22,26,62,65,97,121 and 36 other lines.
90834	Psychotherapy, 45 minutes with patient	4,7,22,26,62,65,97,121 and 36 other lines.
90836	Psychotherapy, 45 minutes with patient when performed with an evaluation and management service (List separately in addition to the code for primary procedure)	4,7,22,26,62,65,97,121 and 36 other lines.
90837	Psychotherapy, 60 minutes with patient	4,7,22,26,62,65,97,121 and 36 other lines.
90838	Psychotherapy, 60 minutes with patient when performed with an evaluation and management service (List separately in addition to the code for primary procedure)	4,7,22,26,62,65,97,121 and 36 other lines.
90839	Psychotherapy for crisis; first 60 minutes	4,7,22,26,62,65,97,121 and 36 other lines.
90840	Psychotherapy for crisis; each additional 30 minutes (List separately in addition to code for primary service)	4,7,22,26,62,65,97,121 and 36 other lines.
90846	Family psychotherapy (without the patient present), 50 minutes	4,7,22,26,62,97,121,122 and 35 other lines.
90847	Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes	4,7,22,26,62,97,121,122 and 34 other lines.
90849	Multiple-family group psychotherapy	4,7,22,26,62,121,122,149 and 34 other lines.
90853	Group psychotherapy (other than of a multiple-family group)	4,7,22,26,62,97,121,122 and 35 other lines.

Code	Code Description	Prioritized List Placement

Code	Code Description	Prioritized List Placement
96127	Brief emotional/behavioral assessment (eg, depression inventory, attention-deficit/hyperactivity disorder [ADHD] scale), with scoring and documentation, per standardized instrument	Diagnostic and 3
96150	Health and behavior assessment (eg, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; initial assessment	1,3,4,5,8,9,10,12 and 184 other lines.
96151	Health and behavior assessment (eg, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; re-assessment	1,3,4,5,8,9,10,12 and 184 other lines.
96152	Health and behavior intervention, each 15 minutes, face-to-face; individual	1,3,4,5,8,9,10,12 and 184 other lines.
96153	Health and behavior intervention, each 15 minutes, face-to-face; group (2 or more patients)	1,3,4,5,8,9,10,12 and 184 other lines.
96154	Health and behavior intervention, each 15 minutes, face-to-face; family (with the patient present)	1,3,4,5,8,9,10,11 and 194 other lines.
96155	Health and behavior intervention, each 15 minutes, face-to-face; family (without the patient present)	1,3,4,5,8,9,10,11 and 194 other lines.

Code	Code Description	Current Prioritized List Placement
99401	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 15 minutes	1,2,3,4,5,6,7,8 and 630 other lines.
99402	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 30 minutes	1,2,3,4,5,6,7,8 and 630 other lines.
99403	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 45 minutes	1,2,3,4,5,6,7,8 and 630 other lines.
99404	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to an individual (separate procedure); approximately 60 minutes	1,2,3,4,5,6,7,8 and 630 other lines.
99411	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to individuals in a group setting (separate procedure); approximately 30 minutes	1,2,3,4,5,6,7,8 and 630 other lines.
99412	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to individuals in a group setting (separate procedure); approximately 60 minutes	1,2,3,4,5,6,7,8 and 630 other lines.

Code	Code Description	Prioritized List Placement
H0004	Behavioral health counseling and therapy, per 15 minutes	4,7,22,26,62,97,122,149 and 33 other lines.

BHAP input

BHAP discussed this issue at their October 2019 meeting. The members were strongly against adding psychotherapy CPT codes to line 1 PREGNANCY. Members noted that the health and behavior assessment codes are intended to be used for counseling for patients with a physical health condition, such as pregnancy, without a diagnosed mental health condition. They noted that the health and behavior assessment codes have been updated for 2020 and will have a higher RVU associated with them. The BHAP members felt that the staff proposed guideline reviewed at the meeting was useful, but required edits and gave some initial suggestions for editing. Specifically, BHAP members felt that defining postpartum to mean up to 1 year after birth was helpful. Public testimony indicated that the coding information in the guideline was useful.

HERC Staff Summary

The new USPSTF recommendation would apply to all OHP pregnant and postpartum women (up to 1 year). The health behavior assessment codes already present on lines 1 and 3 should be sufficient for the counseling required under the USPSTF recommendation.

HERC Staff Recommendations:

1. Add a new guideline to lines 1 PREGNANCY and 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

    - **GUIDELINE NOTE XXX, COUNSELING FOR PREGNANT AND POSTPARTUM WOMEN**

        Lines 1, 3

        Counseling for the prevention of peripartum mood disorders for pregnant and postpartum women (including up to 1 year after birth) are included on these lines according to USPSTF recommendations https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/perinatal-depression-preventive-interventions and should be coded with health behavior assessment and intervention procedure codes.

        Supervision of pregnancy codes (ICD-10 O09.X, Z34.X), encounter for screening for maternal depression (ICD-10 Z13.32), and encounter for routine postpartum follow-up (ICD-10 Z39.2) are appropriate to pair with health behavior assessment and interventions for these purposes.

2. Considering adding *H0004 Behavioral health counseling and therapy*, per 15 minutes to Line 1

Highlights

Genetic Advisory Panel
Conference Call hosted at:
Five Oak Building
Transformation Center Conference Room, Suite 775
421 SW Oak, Portland, Oregon
October 23, 2019
9:00-11:00 am

Members Present: Karen Kovak; Sue Richards, PhD; Cary Harding, MD; Jaellah Thalberg; Carl Stevens, MD; Nicoleta Voian; Supriya Raina-Hukku

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

Also Attending: Devki Saraya, Myriad

The meeting was called to order at 9 AM. Roll was called. This is an advisory panel to the HERC Medical Director in preparing meeting materials for deliberation by the Value-based Benefits Subcommittee at their 11/14/19 meeting and a quorum is not necessary as no votes are taken. The highlights from the 2018 GAP meeting were reviewed and no changes were suggested.

Staff report

Smits reported to the Panel regarding topics requested for follow up at the 2018 meeting that are not on the current agenda. Both cell free fetal DNA (NIPS) for non-high-risk women and whole exome sequencing are the topics of Washington HTA reports due to be completed soon. HERC staff plan on addressing these topics at the 2020 GAP meeting, informed by these HTA reports. GAP members were comfortable with this approach, but requested that HERC staff send them the HTA reports when they become available.

Prioritized List issues

1. 2020 CPT codes related to cancer oncology: Smits reviewed the summary document. There was minimal discussion, and no changes were suggested to the staff recommendations.

2. Non-prenatal, non-cancer genetic testing guideline: Smits reviewed the summary document for both cytochrome P450 testing and for the other suggested changes to the guideline. There was minimal discussion regarding the suggested changes around cytochrome P450 testing. Stevens requested that HERC staff draft up wording for GN173 regarding non-coverage for genetic testing for antidepressant therapy. On further evaluation, HERC staff members felt that this topic should be re-reviewed and brought to the 2020 GAP meeting for discussion.

   The GAP members discussed the question regarding microarray testing. Diagnostic Guideline D1 places more restrictions on CPT 81229, but this test has become the standard for microarray testing, and 81228 is only rarely used. GAP members recommended that the section in D1 regarding CPT 81228 and 81229 have the additional restrictions for 81229 removed. As the entries for 81228 and 81229 with then be the same, the GAP recommended merging these sections.

   GAP members discussed the request for clarification on trio testing (of the affected individual and both parents) for whole exome sequencing. The members indicated that trio testing is preferred if both parents are available, as it is only slightly more costly but has a much better diagnostic rate.

   GAP members identified the CALR testing issue as actually relating to the non-prental, non-cancer genetic testing guideline. The staff proposal to add the CPT code for CALR testing (CPT 81219) to the Diagnostic List was not recommended. The members noted that this test should not be done as a separate test, but rather as part of a panel. Several gene panels include CALR, and testing for this gene alone should be added to line 662/GN173.

   a. Actions:
      i. HERC staff will re-review genetic testing for antidepressant therapy and draft a proposed guideline for the 2020 GAP meeting.
      ii. Staff will make the proposed changes to Diagnostic Guideline D1 for review at the November 2019 VbBS/HERC meeting
      iii. Staff will revise the CALR testing topic to reflect the recommendation to add to Line 662/GN173.
         1. Note: staff on later review recommended line 502/GN172 as a better placement. This will not change the GAP recommendation for non-covage

3. Prenatal genetic testing guideline: Smits first introduced the cystic fibrosis testing issue. The GAP members felt that prenatal genetic testing guideline should have all the CPT codes for possible CF testing (CPT 81220-81224) included, and HERC staff should review the ACOG guidelines on this testing and consider putting in a reference to ACOG in Guideline D17. The additional CPT codes allow for variant testing if a relative has a known CF mutation. Additionally, other types of CF testing might be recommended based on certain ultrasound findings.

The GAP then discussed CF testing in Diagnosotic Guideline D1. They recommended adding a mention of CPT 81221 to the first entry under CF diagnostic testing for completeness. They also recommended adding CPT 81221-81224 to the second entry regarding carrier testing, to allow for testing for family members of persons with known mutations or if the partner with whom pregnancy is contemplated is a carrier with a known mutation. HERC staff was directed to work on wording for D1 to reflect this discussion and send to the GAP for further possible input. On review of the ACOG guideline, HERC staff determined that no further changes were required to Diagnostic Guideline D1.

The only other preposed change to diagnostic Guideline D17 was to remove wording regarding screening for thrombophilia for recurrent pregnancy loss, as this was not a prenatal test.

a. Action:
    i. HERC staff will edit Diagnostic Guideline D1 CF carrier testing to allow broader types of testing in certain clinical circumstances and send to the GAP for further possible input

4. Hereditary cancer genetic testing guideline: Smits reviewed the summary document. The NCCN reference updates were noted without discussion. There was discussion about the entry for hereditary breast cancer panel testing. The GAP felt that the CCO question was based on confusion regarding the guideline wording. Revised wording was suggested that clarifies that the patient has to meet NCCN guidelines as eligible for testing, rather than the testing had to meet NCCN guidelines.

    a. Action: HERC staff will edit Diagnostic Guideline D25 as suggested by GAP for consideration at the VBBS/HERC in November 2019

Other issues: Members brought up an issue not on the agenda that needs correction: two CPT codes for generic genetic tests are being used quite a bit for panels of various genes. These are both appropriate codes in certain clinical situations but currently are on line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS, and need to be moved to the Diagnostic Procedures List with a recommendation for manual review. These codes are CPT 81479 (Unlisted molecular pathology procedure) and 81599 (Unlisted multianalyte assay with algorithmic analysis). HERC staff looked into this issue further after the meeting and determined that both of these codes had been on the "Suspend for Review" file at some point. Subsequently, CPT 81479 was mentioned in DIAGNOSTIC GUIDELINE D25, HEREDITARY CANCER GENETIC TESTING with the entry "Hereditary breast cancer-related disorders genomic sequence analysis panels (CPT 81432, 81433, 81479) are only included for patients meeting the criteria for hereditary cancer syndrome testing per NCCN guidelines." The entry in GN173 lists these codes are on line 662 only for certain tumor testing, not for all indications. HERC staff will need to look into this issue further prior to recommending a solution.

Public comment: A typo was pointed out in the prenatal genetic testing guideline. The correct CPT code for spinal muscular atrophy testing is CPT 81329. HERC staff will correct this error in the errata.

There was also a question raised about re-review of expanded carrier screening. This topic was reviewed by GAP at their 2018 meeting and recommended for coverage. However, VbBS did not approve this recommendation, due mainly to concerns about how the additional information would be interpreted or used. The public member asked how to go about getting this topic re-reviewed, and Smits recommended sending any new literature, guidelines, or other new material to HERC staff for review and consideration for placement on a future VbBS agenda.

The meeting was adjourned at 10:30 AM.

Non-Prenatal, Non-Cancer Genetic Testing Guideline

Issue: Several changes were recommended at the October 2019 GAP meeting for the Diagnostic Guideline D1.

1) Changes based on the cytochrome P450 review
    a. Add an entry for CPT 81226-81230 specifying only covered when FDA required
2) Remove additional restrictions on CPT 81229 and merge this entry with the entry for 81228.
3) Add additional CPT codes for cystic fibrosis carrier screening to match the prenatal genetic testing guideline; this will allow for other testing if clinically indicated

DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE

A) Genetic tests are covered as diagnostic, unless they are listed below in section E1 as excluded or have other restrictions listed in this guideline. To be covered, initial screening (e.g. physical exam, medical history, family history, laboratory studies, imaging studies) must indicate that the chance of genetic abnormality is > 10% and results would do at least one of the following:
    1) Change treatment,
    2) Change health monitoring,
    3) Provide prognosis, or
    4) Provide information needed for genetic counseling for patient; or patient's parents, siblings, or children

B) Pretest and posttest genetic counseling is required for presymptomatic and predisposition genetic testing. Pretest and posttest genetic evaluation (which includes genetic counseling) is covered when provided by a suitable trained health professional with expertise and experience in genetics.
    1) "Suitably trained" is defined as board certified or active candidate status from the American Board of Medical Genetics, American Board of Genetic Counseling, or Genetic Nursing Credentialing Commission.

C) A more expensive genetic test (generally one with a wider scope or more detailed testing) is not covered if a cheaper (smaller scope) test is available and has, in this clinical context, a substantially similar sensitivity. For example, do not cover CFTR gene sequencing as the first test in a person of Northern European Caucasian ancestry because the gene panels are less expensive and provide substantially similar sensitivity in that context Related to diagnostic evaluation of individuals with intellectual disability (defined as a full scale or verbal IQ < 70 in an individual > age 5), developmental delay (defined as a cognitive index <70 on a standardized test appropriate for children < 5 years of age), Autism Spectrum Disorder, or multiple congenital anomalies:
    1) CPT 81228 and 81229, Cytogenomic constitutional microarray analysis ~~for copy number variants for chromosomal abnormalities~~: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder.
    ~~2) CPT 81229, Cytogenomic constitutional microarray analysis for copy number variants for chromosomal abnormalities; plus cytogenetic constitutional microarray analysis for single nucleotide polymorphism (SNP) variants for chromosomal abnormalities: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay;~~

~~multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder; only if (a) consanguinity and recessive disease is suspected, or (b) uniparental disomy is suspected, or (c) another mechanism is suspected that is not detected by the copy number variant test alone. (~~combine with 81228 entry)

3) CPT 81243, 81244, 81171,81172 Fragile X genetic testing is covered for individuals with intellectual disability/developmental delay. Although the yield of Fragile X is 3.5-10%, this is included because of additional reproductive implications.
4) A visit with the appropriate specialist (often genetics, developmental pediatrics, or child neurology), including physical exam, medical history, and family history is covered. Physical exam, medical history, and family history by the appropriate specialist, prior to any genetic testing is often the most cost-effective strategy and is encouraged.

D) Related to other tests with specific CPT codes:
1) Certain genetic tests have not been found to have proven clinical benefit. These tests are listed in Guideline Note 173, INTERVENTIONS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS; UNPROVEN INTERVENTIONS
2) The following tests are covered only if they meet the criteria in section A above AND the specified situations:
a) CPT 81205, BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, Maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X): Cover only when the newborn screening test is abnormal and serum amino acids are normal
b) Diagnostic testing for cystic fibrosis (CF)
i) CFTR, cystic fibrosis transmembrane conductance regulator tests. CPT 81220, 81221, 81222, 81223: For infants with a positive newborn screen for cystic fibrosis or who are symptomatic for cystic fibrosis, or for clients that have previously been diagnosed with cystic fibrosis but have not had genetic testing, CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered. If two mutations are not identified, CFTR full gene sequencing (CPT 81223) is covered. If two mutations are still not identified, duplication/deletion testing (CPT 81222) is covered. These tests may be ordered as reflex testing on the same specimen.
c) Carrier testing for cystic fibrosis
i) CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220-81224) is covered once in a lifetime.
d) CPT 81224, CFTR (cystic fibrosis transmembrane conductance regulator) (eg. cystic fibrosis) gene analysis; introm 8 poly-T analysis (eg. male infertility): Covered only after genetic counseling.
e) CPT 81226-81231 (cytochrome P450). Covered only for determining eligibility for medication therapy if required or recommended in the FDA labelling for that medication. These tests have unproven clinical utility for decisions regarding psychiatric medications and are not covered for testing prior to psychiatric medication therapy, except when required in the FDA labelling for the medication

f) CPT 81240. F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant: Factor 2 20210G>A testing should not be covered for adults with idiopathic venous thromoboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.

g) CPT 81241. F5 (coagulation Factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant: Factor V Leiden testing should not be covered for: adults with idiopathic venous thromoboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.

h) CPT 81247. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; common variant(s) (eg, A, A-) should only be covered
   i) After G6PD enzyme activity testing is done and found to be normal; AND either
      (a) There is an urgent clinical reason to know if a deficiency is present, e.g. in a case of acute hemolysis; OR
      (b) In situations where the enzyme activity could be unreliable, e.g. female carrier with extreme Lyonization.

i) CPT 81248. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; known familial variant(s) is only covered when the information is required for genetic counseling.

j) CPT 81249. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; full gene sequence is only covered
   i) after G6PD enzyme activity has been tested, and
   ii) the requirements under CPT 81247 above have been met, and
   iii) common variants (CPT 81247) have been tested for and not found.

k) CPT 81256, HFE (hemochromatosis) (eg, hereditary hemochromatosis) gene analysis, common variants (eg, C282Y, H63D): Covered for diagnostic testing of patients with elevated transferrin saturation or ferritin levels. Covered for predictive testing ONLY when a first degree family member has treatable iron overload from HFE.

l) CPT 81332, SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (eg, alpha-1-antitrypsin deficiency), gene analysis, common variants (eg, *S and *Z): The alpha-1-antitrypsin protein level should be the first line test for a suspected diagnosis of AAT deficiency in symptomatic individuals with unexplained liver disease or obstructive lung disease that is not asthma or in a middle age individual with unexplained dyspnea. Genetic testing of the anpha-1 phenotype test is appropriate if the protein test is abnormal or borderline. The genetic test is appropriate for siblings of people with AAT deficiency regardless of the AAT protein test results.

m) CPT 81329, Screening for spinal muscular atrophy: is covered once in a lifetime for preconception testing or testing of the male partner of a pregnant female carrier

n) CPT 81415-81416, exome testing: A genetic counseling/geneticist consultation is required prior to ordering test

o) CPT 81430-81431, Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel: Testing for mutations in GJB2 and GJB6 need to be done first and be negative in non-syndromic patients prior to panel testing.

p) CPT 81440, 81460, 81465, mitochondrial genome testing: A genetic counseling/geneticist or metabolic consultation is required prior to ordering test.
q) CPT 81412 Ashkenazi Jewish carrier testing panel: panel testing is only covered when the panel would replace and would be similar or lower cost than individual gene testing including CF carrier testing.

* American College of Medical Genetics Standards and Guidelines for Clinical Genetics Laboratories. 2008 Edition, Revised 7/2018 and found at http://www.acmg.net/PDFLibrary/Cystic-Fibrosis-Population-Based-Carrier-Screening-Standards.pdf.

Cytochrome P450 Genetic Testing Indications

Questions:

1) Should CYP2C9 genetic testing be paired with any diagnoses other than multiple sclerosis?
2) Should any other cytochrome P450 genetic tests be covered for any diagnosis?

Question source: HERC; HERC staff; GAP; Pharmacy and Therapeutics Committee

Issues: Recently, the FDA approved siponimod (brand name Mayzent) as a new medication for multiple sclerosis (MS), but required CYP2C9*3/*3 genetic testing prior to prescribing. If a patient is positive for the CYP2C9*3/*3 genetic variant, the drug is contraindicated. Testing is billed with CPT 81227 (CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)), which is currently on line 660/GN173. CPT 81227 was placed on line 660 as a new 2012 CPT code. At the time of the 2011 Genetics Advisory Panel review, this code was being used for testing for determining anticoagulant therapy, for which there is no evidence of effectiveness. At the August, 2019 HERC meeting, CPT 81227 was added to the MS line and deleted from Line 660 to allow testing prior to siponimod therapy. The HERC requested that the GAP provide input into any additional indications/diagnoses that should be paired with CPT 81227.

Review of commercial payer coverage policies found no other indications for CPT 81227 that are currently covered.

Additionally, there are multiple other cytochrome P450 genetic tests for drug metabolism which are all currently non-covered. These were reviewed as new CPT codes in 2011 and 2017, and found to have no evidence of effectiveness.

1) CPT 81225 (CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)) is covered by some private insurers for testing prior to initiation of clopidogrel
2) CPT 81226 (CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *9, *10, *17, *19, *29, *35, *41, *1XN, *2XN, *4XN)) is covered by some private insurers for testing prior to tetrabenazine or eliglustat therapy. We have received a request from the Pharmacy and Therapeutics Committee to add coverage for this test for patients being considered for eliglustat therapy due to the drug being contraindicated in patients with certain mutations. P&T staff also recommend adding coverage for patients being considered for tetrabenazine therapy for Huntington's disease, as the FDA labeling recommends testing for mutations prior to giving doses greater than 50mg
3) CPT 81230 (CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (eg, drug metabolism), gene analysis, common variant(s) (eg, *2, *22)) does not appear to be covered by private insurers
4) CPT 81231 (CYP3A5 (cytochrome P450 family 3 subfamily A member 5) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *7)) does not appear to be covered by private insurers

This topic was discussed at the October 2019 GAP meeting. The GAP members recommended adding CPT 81227 to the Diagnostic List and removing from the MS line, with an addition to the non-prenatal non-hereditary cancer guideline limiting use to patients being considered for siponimod therapy. GAP also recommended adding CPT 81226 to the Diagnostic List with a guideline entry limiting coverage to "determining eligibility for eliglustat or tetrabenazine therapy."

After the GAP meeting, HERC staff met with P&T staff. P&T staff informed HERC staff that there are additional drugs in the approval process that will have FDA required or recommended testing in the drug labeling. P&T staff requested that all cytochrome P450 codes be added to the Diagnostic Procedures File and that the genetics guideline entry be made more generic to allow coverage for any drug with FDA labelling testing requirements. P&T staff was concerned that the GAP recommendation would require further changes once these drugs area approved and would provide barriers to access to these drugs until the Prioritized List could be updated.

HERC staff discussed this P&T requested change with QHOC medical directors. The medical directors expressed significant concern with the cytochrome P450 codes being used for testing prior to psychiatric medication prescribing, which is not an FDA required or recommended use, and which GAP has previously recommended against covering. Data review found that the 4 cytochrome P450 codes had over 10,000 claims in the past year that were denied. The CCOs would need to prior authorize all of these codes if the intent is only to cover for FDA approved or recommended indications. The CCO medical directors requested wording in the genetics guideline specifically calling out that these tests are not covered prior to psychiatric drug prescribing, unless FDA required.

HERC staff recommendations:

1) Advise HSD to add cytochrome P450 testing to the Diagnostic Procedure File:
    a. CPT 81227 (CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6))
        i. Remove from the MS line
    b. CPT 81226 (CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *9, *10, *17, *19, *29, *35, *41, *1XN, *2XN, *4XN))
        i. Remove from line 660/GN173
    c. CPT 81230 (CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (eg, drug metabolism), gene analysis, common variant(s) (eg, *2, *22)) does not appear to be covered by private insurers
    d. CPT 81231 (CYP3A5 (cytochrome P450 family 3 subfamily A member 5) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *7)) does not appear to be covered by private insurers
2) Add the following entry to section D of DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE
    a. CPT 81226-81231 (cytochrome P450). Covered only for determining eligibility for medication therapy if required or recommended in the FDA labelling for that medication. These tests have unproven clinical utility for decisions regarding psychiatric medications and are not covered for testing prior to psychiatric medication therapy, except when required in the FDA labelling for the medication.
3) Revise GN173 as shown below

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

Line 660

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

Procedure Code	Intervention Description	Rationale	Last Review
~~81225,81226, 81230-81231~~	~~Cytochrome P450 gene analysis~~	~~Insufficient evidence of effectiveness~~	~~December, 2011~~ ~~November, 2017~~

CALR Genetic Testing for Myeloproliferative Disease
VBBS November 2019

Question: Should testing for CALR (calreticulin) be covered for patients with myeloproliferative disorders?

Question source: Holly Jo Hodges, CCO medical director

Issue: CPT 81219 (CALR (calreticulin) (eg, myeloproliferative disorders), gene analysis, common variants in exon 9) was reviewed as a new CPT code in 2015 and placed in the Services Recommended for Non-Coverage Table, as at that time it was not recommended by NCCN for work up of myeloproliferative disease. It is currently listed in the Excluded File.

Newer NCCN guidelines now recommend that patients with suspicion of myeloproliferative disease who are JAK2 V617F negative are either 1) tested for both CALR and MPL or 2) provided a multigene testing panel that includes JAK2, CALR and MPL. Testing for JAK2 (CPT 81270, JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, p.Val617Phe (V617F) variant) is currently on the Diagnostic Procedures File.

This issue was discussed at the October 2019 GAP meeting. The GAP members discussed that CALR is not appropriate to test for alone. There are several panels that include this test that should be used instead. The GAP recommended adding this code to line 662/GN173. On further review, HERC staff recommend adding this code to line 50~~0~~2 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS, which is for placement of less cost-effective procedures.

GAP/HERC staff recommendation:

1) Add CPT 81219 (CALR (calreticulin) (eg, myeloproliferative disorders), gene analysis, common variants in exon 9) to line 502/GN172 as shown below

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

Line 502

The following interventions are prioritized on Line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS:

Procedure Code	Intervention Description	Rationale	Last Review
81219	CALR (calreticulin) (eg, myeloproliferative disorders), gene analysis, common variants in exon 9	Individual test not cost-effective; should only be done as part of a gene panel	November 2019

Prenatal Genetic Testing Guideline

Issue: One change to the Prenatal Genetic Testing Guideline was recommended by the GAP at their October, 2019 meeting

1) Delete screening for thrombophilia from the guideline
    a. Does not refer to a prenatal test
    b. CPT codes related to this testing are discussed in Diagnostic Guideline D1

DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

The following types of prenatal genetic testing and genetic counseling are covered for pregnant women:

A) Genetic counseling (CPT 96040, HPCPS S0265) for high-risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect.
B) Genetic counseling (CPT 96040, HPCPS S0265) prior to consideration of chorionic villus sampling (CVS), amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening
C) Validated questionnaire to assess genetic risk in all pregnant women
D) Screening high-risk ethnic groups for hemoglobinopathies (CPT 83020, 83021)
E) Screening for aneuploidy with any of five screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, and contingency] (CPT 76813, 76814, 81508-81511,81512,82105,82677)
F) Cell free fetal DNA testing (CPT 81420, 81507) for evaluation of aneuploidy in women who have an elevated risk of a fetus with aneuploidy (maternal age >34, family history or elevated risk based on screening).
G) Ultrasound for structural anomalies between 18 and 20 weeks gestation (CPT 76811, 76812)
H) CVS or amniocentesis (CPT 59000, 59015, 76945,76946, 82106, 88235, 88261-88264, 88267, 88269, 88280, 88283, 88285, 88289,88291) for a positive aneuploidy screen, maternal age >34, fetal structural anomalies, family history of inheritable chromosomal disorder or elevated risk of neural tube defect.
I) Array CGH (CPT 81228, 81229) when major fetal congenital anomalies are apparent on imaging, or with normal imaging when array CGH would replace karyotyping performed with CVS or amniocentesis in #8 above.
J) FISH testing (CPT 88271, 88272, 88274, 88275, 81171, 81172) only if karyotyping is not possible due a need for rapid turnaround for reasons of reproductive decision-making (i.e. at 22w4d gestation or beyond)
K) Screening for Tay-Sachs carrier status (CPT 81255) in high-risk populations. First step is hex A, and then additional DNA analysis in individuals with ambiguous Hex A test results, suspected variant form of TSD or suspected pseudodeficiency of Hex A
L) Screening for cystic fibrosis carrier status once in a lifetime (CPT 81220-81224)
M) Screening for fragile X status (CPT 81243, 81244, 81171. 81172) in patients with a personal or family history of
    a. fragile X tremor/ataxia syndrome
    b. premature ovarian failure
    c. unexplained early onset intellectual disability
    d. fragile X intellectual disability

    e. unexplained autism through the pregnant woman's maternal line

N) Screening for spinal muscular atrophy (CPT 81329) once in a lifetime
O) Screening those with Ashkenazi Jewish heritage for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255). Ashkenazi Jewish carrier panel testing (CPT 81412) is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing.
P) Expanded carrier screening only for those genetic conditions identified above

The following genetic screening tests are not covered:

A) Serum triple screen
B) ~~Screening for thrombophilia in the general population or for recurrent pregnancy loss~~
C) Expanded carrier screening which includes results for conditions not explicitly recommended for coverage

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

Hereditary Cancer Genetic Testing Guideline 2019

VBBS November 2019

Issue: Several changes are recommended by the GAP for the Hereditary Cancer Genetic Testing Guideline:

1) Update NCCN references as shown below
2) Revise the section on breast cancer panel testing to clarify the intent of the GAP

DIAGNOSTIC GUIDELINE D25, HEREDITARY CANCER GENETIC TESTING

Related to genetic testing for patients with breast/ovarian and colon/endometrial cancer or other related cancers suspected to be hereditary, or patients at increased risk to due to family history, services are provided according to the Comprehensive Cancer Network Guidelines.

A) Lynch syndrome (hereditary colorectal, endometrial and other cancers associated with Lynch syndrome) services (CPT 81288, 81292-81300, 81317-81319, 81435, 81436) and familial adenomatous polyposis (FAP) services (CPT 81201-81203) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Colorectal V2.2019 (8/8/19) ~~V1.2018 (7/12/18~~). www.nccn.org.

B) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81212, 81215-81217) for patients without a personal history of breast, ovarian and other associated cancers should be provided to high-risk patients as defined by the US Preventive Services Task Force or according to the NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast and Ovarian. V3.2019 (1/18/19) ~~V2.2019 (7/30/18).~~ www.nccn.org.

C) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81212, 81215-81217)) for women with a personal history of breast, ovarian, or other associated cancers and for men with breast or other associated cancers should be provided according to the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovarian. V3.2019 (1/18/19) ~~V2.2019 (7/30/18).~~ www.nccn.org.

D) PTEN (Cowden syndrome) services (CPT 81321-81323) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovarian. V3.2019 (1/18/19) ~~V2.2019 (7/30/18)~~ or Genetic/Familial High-Risk Assessment: Colorectal V2.2019 (8/8/19) ~~V1.2018 (7/12/18).~~ www.nccn.org.

Genetic counseling should precede genetic testing for hereditary cancer whenever possible.

A) Pre and post-test genetic counseling should be covered when provided by a suitable trained health professional with expertise and experience in cancer genetics. Genetic counseling is recommended for cancer survivors when test results would affect cancer screening.
   1) "Suitably trained" is defined as board certified or active candidate status from the American Board of Medical Genetics, American Board of Genetic Counseling, or Genetic Nursing Credentialing Commission.

B) If timely pre-test genetic counseling is not possible for time-sensitive cases, appropriate genetic testing accompanied by pre- and post- test informed consent and post-test disclosure performed by a board-certified physician with experience in cancer genetics should be covered.
   1) Post-test genetic counseling should be performed as soon as is practical.

If the mutation in the family is known, only the test for that mutation is covered. For example, if a mutation for BRCA 1 has been identified in a family, a single site mutation analysis for that mutation is covered (CPT 81215), while a full sequence BRCA 1 and 2 (CPT 81163) analyses is not. There is one

exception, for individuals of Ashkenazi Jewish ancestry with a known mutation in the family, the panel for Ashkenazi Jewish BRCA mutations is covered (CPT 81212).

Costs for rush genetic testing for hereditary breast/ovarian and colon/endometrial cancer is not covered.

Hereditary breast cancer-related disorders genomic sequence analysis panels (CPT 81432, 81433, 81479) are only included ~~for~~ if the patient~~s~~ meets~~ing the~~ NCCN guideline criteria for hereditary cancer syndrome testing ~~per NCCN guidelines~~.

Section 5.0

New Codes

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
15769	Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)	Replacing CPT 20926 (Tissue grafts, other (eg, paratenon, fat, dermis)) which was ancillary	Ancillary Procedure File	
21601	Excision of chest wall tumor including rib(s)	Replacing 19260 (Excision of chest wall tumor including ribs)	200 CANCER OF BONES 262 CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS 372 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS	
21602	Excision of chest wall tumor involving rib(s), with plastic reconstruction; without mediastinal lymphadenectomy	Replacing 19271 (Excision of chest wall tumor involving ribs, with plastic reconstruction; without mediastinal lymphadenectomy)	200, 262, 372	
21603	Excision of chest wall tumor involving rib(s), with plastic reconstruction; with mediastinal lymphadenectomy	Replacing 19272 (Excision of chest wall tumor involving ribs, with plastic reconstruction; with mediastinal lymphadenectomy)	200, 262, 372	
33016	Pericardiocentesis, including imaging guidance, when performed	Replacing 33010 (Pericardiocentesis; initial) and 33011 (Pericardiocentesis; subsequent)	81 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS	
33017	Pericardial drainage with insertion of indwelling catheter, percutaneous, including fluoroscopy and/or ultrasound guidance, when performed; 6 years and older without congenital cardiac anomaly	Used for persistent pericardiac effusions. ICD10 I31.3 (Pericardial effusion (noninflammatory)) is on line 81	81 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS	

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
33018	Pericardial drainage with insertion of indwelling catheter, percutaneous, including fluoroscopy and/or ultrasound guidance, when performed; birth through 5 years of age or any age with congenital cardiac anomaly	See above	81 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS	
33019	Pericardial drainage with insertion of indwelling catheter, percutaneous, including CT guidance	See above	81 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS	
33858	Ascending aorta graft, with cardiopulmonary bypass, includes valve suspension, when performed; for aortic dissection	Replacing 33860 (Ascending aorta graft, with cardiopulmonary bypass, includes valve suspension, when performed) which was on lines 284 and 325. Now dissection is split out from non-dissection	284 DISSECTING OR RUPTURED AORTIC ANEURYSM	
33859	Ascending aorta graft, with cardiopulmonary bypass, includes valve suspension, when performed; for aortic disease other than dissection (eg, aneurysm)	See above	325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE	
33871	Transverse aortic arch graft, with cardiopulmonary bypass, with profound hypothermia, total circulatory arrest and isolated cerebral perfusion with reimplantation of arch vessel(s) (eg, island pedicle or individual arch vessel reimplantation)	Replacing 33870 (Transverse arch graft, with cardiopulmonary bypass)	134 INTERRUPTED AORTIC ARCH 284 DISSECTING OR RUPTURED AORTIC ANEURYSM 325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE	

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
34717	Endovascular repair of iliac artery at the time of aorto-iliac artery endograft placement by deployment of an iliac branched endograft including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone angioplasty/stenting, when performed, for rupture or other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer, traumatic disruption), unilateral (List separately in addition to code for primary procedure)	Similar code 34703-34706 (Endovascular repair of infrarenal aorta and/or iliac artery(ies) by deployment of an aorto-uni-iliac endograft…) are on lines 284,325	284 DISSECTING OR RUPTURED AORTIC ANEURYSM 325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE	

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
34718	Endovascular repair of iliac artery, not associated with placement of an aorto-iliac artery endograft at the same session, by deployment of an iliac branched endograft, including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone angioplasty/stenting, when performed, for other than rupture (eg, for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer), unilateral	See above	284 DISSECTING OR RUPTURED AORTIC ANEURYSM 325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE	
35702	Exploration not followed by surgical repair, artery; upper extremity (eg, axillary, brachial, radial, ulnar)	Similar codes (deleted for 2020) 35721, 35741 and 35761 (Exploration (not followed by surgical repair), with or without lysis of artery, various arteries) on lines 235,349	235 LIMB THREATENING VASCULAR DISEASE, INFECTIONS, AND VASCULAR COMPLICATIONS 349 NON-LIMB THREATENING PERIPHERAL VASCULAR DISEASE	

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
35703	Exploration not followed by surgical repair, artery; lower extremity (eg, common femoral, deep femoral, superficial femoral, popliteal, tibial, peroneal)	Replacing 35721 (Exploration (not followed by surgical repair), with or without lysis of artery; femoral artery) which was on lines 235,349; and 35741 (Exploration (not followed by surgical repair), with or without lysis of artery; popliteal artery) which was on lines 235,254,349	235 LIMB THREATENING VASCULAR DISEASE, INFECTIONS, AND VASCULAR COMPLICATIONS 349 NON-LIMB THREATENING PERIPHERAL VASCULAR DISEASE	
46948	Hemorrhoidectomy, internal, by transanal hemorrhoidal dearterialization, 2 or more hemorrhoid columns/groups, including ultrasound guidance, with mucopexy, when performed	Similar ehmorrhoidectomy codes 46260-46262 (Hemorrhoidectomy, internal and external, 2 or more columns/groups;) are on lines 474,621	474 THROMBOSED AND COMPLICATED HEMORRHOIDS 621 UNCOMPLICATED HEMORRHOIDS	
62328	Spinal puncture, lumbar, diagnostic; with fluoroscopic or CT guidance	Similar code 62270 (Spinal puncture, lumbar, diagnostic) is diagnostic	Diagnostic Procedures File	
62329	Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter); with fluoroscopic or CT guidance	Similar code 62272 (Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter)) is on lines 19,125,196,285,294,371	19 HYDROCEPHALUS AND BENIGN INTRACRANIAL HYPERTENSION 125 BENIGN NEOPLASM OF THE BRAIN AND SPINAL CORD 196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN 285COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 294 CANCER OF BRAIN AND NERVOUS SYSTEM 371 ENCEPHALOCELE	

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
66987	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation	CPT 66984 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification)) is on lines 139,296,370,393	139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE 296 CATARACT 370 AMBLYOPIA 393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN	
66988	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation	See above	139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE 296 CATARACT 370 AMBLYOPIA 393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN	
74221	Radiologic examination, esophagus, including scout chest radiograph(s) and delayed image(s), when performed; double-contrast (eg, high-density barium and effervescent agent) study	CPT 74230 (Barium swallow) is on the Diagnsotic Procedures File	Diagnostic Procedures File	

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
74248	Radiologic small intestine follow-through study, including multiple serial images (List separately in addition to code for primary procedure for upper GI radiologic examination)	See above	Diagnostic Procedures File	
78830	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, single area (eg, head, neck, chest, pelvis), single day imaging	Similar code 78803 (Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); tomographic (SPECT)) is diagnostic. This code is also replacing CPT 78205, 78206, 78320, 78607, 78647, 78710, and 78805-78807, which were SPECT scans for particular organs or for inflammatory processes. These codes were all diagnostic. Note: this code does not include cardiac SPECT	Diagnostic Procedures File	Cardiac and neuroimaging SPECT have diagnostic guidelines regarding their utilization
78831	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), minimum 2 areas (eg, pelvis and knees, abdomen and pelvis), single day imaging, or single area imaging over 2 or more days	See above	Diagnostic Procedures File	

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
78832	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, minimum 2 areas (eg, pelvis and knees, abdomen and pelvis), single day imaging, or single area imaging over 2 or more days	See above	Diagnostic Procedures File	
78835	Radiopharmaceutical quantification measurement(s) single area (List separately in addition to code for primary procedure)	Secondary to SPECT codes	Diagnostic Procedures File	
80145	Adalimumab	Drug level	Diagnostic Procedures File	
80187	Posaconazole	Drug level	Diagnostic Procedures File	
80230	Infliximab	Drug level	Diagnostic Procedures File	
80235	Lacosamide	Drug level	Diagnostic Procedures File	
80280	Vedolizumab	Drug level	Diagnostic Procedures File	
80285	Voriconazole	Drug level	Diagnostic Procedures File	
87563	Infectious agent detection by nucleic acid (DNA or RNA); Mycoplasma genitalium, amplified probe technique	Similar code 87798 (Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism) is diagnostic	Diagnostic Procedures File	

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
90619	Meningococcal conjugate vaccine, serogroups A, C, W, Y, quadrivalent, tetanus toxoid carrier (MenACWY-TT), for intramuscular use	Similar code 90734 (Meningococcal conjugate vaccine, serogroups A, C, Y and W-135, quadrivalent (MCV4 or MenACWY), for intramuscular use) is on line 3	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	
90694	Influenza virus vaccine, quadrivalent (aIIV4), inactivated, adjuvanted, preservative free, 0.5 mL dosage, for intramuscular use	Other influenza vaccines on line 3	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	
90912	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient	Replacing 90911 (Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry) which was on line 455 URINARY INCONTINENCE	455 URINARY INCONTINENCE	
90913	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)	See above	455 URINARY INCONTINENCE	
92201	Ophthalmoscopy, extended; with retinal drawing and scleral depression of peripheral retinal disease (eg, for retinal tear, retinal detachment, retinal tumor) with interpretation and report, unilateral or bilateral	Replacing 92225 and 92226 (Ophthalmoscopy, extended, with retinal drawing) which were on 50+ lines	Any line with 92226	

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
92202	Ophthalmoscopy, extended; with drawing of optic nerve or macula (eg, for glaucoma, macular pathology, tumor) with interpretation and report, unilateral or bilateral	See above	Any line with 92226	
93985	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	Similar codes 93925-93926 (Duplex scan of lower extremity arteries or arterial bypass grafts) are diagnostic	Diagnostic Procedures File	
93986	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	See above	Diagnostic Procedures File	
95700	Electroencephalogram (EEG) continuous recording, with video when performed, setup, patient education, and takedown when performed, administered in person by EEG technologist, minimum of 8 channels	Current EEG codes (CPT 95812-95827) are being replaced; they were all on the Diagnostic Procedures File	Diagnostic Procedures File	
95705	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, 2-12 hours; unmonitored		Diagnostic Procedures File	
95706	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, 2-12 hours; with intermittent monitoring and maintenance		Diagnostic Procedures File	

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
95707	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, 2-12 hours; with continuous, real-time monitoring and maintenance		Diagnostic Procedures File	
95708	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, each increment of 12-26 hours; unmonitored		Diagnostic Procedures File	
95709	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, each increment of 12-26 hours; with intermittent monitoring and maintenance		Diagnostic Procedures File	
95710	Electroencephalogram (EEG), without video, review of data, technical description by EEG technologist, each increment of 12-26 hours; with continuous, real-time monitoring and maintenance		Diagnostic Procedures File	
95711	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2-12 hours; unmonitored		Diagnostic Procedures File	
95712	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2-12 hours; with intermittent monitoring and maintenance		Diagnostic Procedures File	

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
95713	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, 2-12 hours; with continuous, real-time monitoring and maintenance		Diagnostic Procedures File	
95714	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12-26 hours; unmonitored		Diagnostic Procedures File	
95715	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12-26 hours; with intermittent monitoring and maintenance		Diagnostic Procedures File	
95716	Electroencephalogram with video (VEEG), review of data, technical description by EEG technologist, each increment of 12-26 hours; with continuous, real-time monitoring and maintenance		Diagnostic Procedures File	
95717	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation and report, 2-12 hours of EEG recording; without video		Diagnostic Procedures File	

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
95718	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation and report, 2-12 hours of EEG recording; with video (VEEG)		Diagnostic Procedures File	
95719	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, each increment of greater than 12 hours, up to 26 hours of EEG recording, interpretation and report after each 24-hour period; without video		Diagnostic Procedures File	
95720	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, each increment of greater than 12 hours, up to 26 hours of EEG recording, interpretation and report after each 24-hour period; with video (VEEG)		Diagnostic Procedures File	

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
95721	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 36 hours, up to 60 hours of EEG recording, without video		Diagnostic Procedures File	
95722	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 36 hours, up to 60 hours of EEG recording, with video (VEEG)		Diagnostic Procedures File	
95723	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 60 hours, up to 84 hours of EEG recording, without video		Diagnostic Procedures File	Guidelines found for extended EEG monitoring, which may be required to diagnose epilepsy if events occur infrequently.

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
95724	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 60 hours, up to 84 hours of EEG recording, with video (VEEG)		Diagnostic Procedures File	
95725	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 84 hours of EEG recording, without video		Diagnostic Procedures File	
95726	Electroencephalogram (EEG), continuous recording, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and summary report, complete study; greater than 84 hours of EEG recording, with video (VEEG)		Diagnostic Procedures File	
96156	Health behavior assessment, or re-assessment (ie, health-focused clinical interview, behavioral observations, clinical decision making)	Replacing 96150-96155 (Health and behavior assessment and intervention codes) which were on 190+ lines (each including the entire range)	All lines with 96150	BHAP reviewed and agreed with placement
96158	Health behavior intervention, individual, face-to-face; initial 30 minutes		All lines with 96152	BHAP reviewed and agreed with placement

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
96159	Health behavior intervention, individual, face-to-face; each additional 15 minutes (List separately in addition to code for primary service)		All lines with 96152	BHAP reviewed and agreed with placement
96164	Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes		All lines with 96153	BHAP reviewed and agreed with placement
96165	Health behavior intervention, group (2 or more patients), face-to-face; each additional 15 minutes (List separately in addition to code for primary service)		All lines with 96153	BHAP reviewed and agreed with placement
96167	Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes		All lines with 96154	BHAP reviewed and agreed with placement
96168	Health behavior intervention, family (with the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service)		All lines with 96154	BHAP reviewed and agreed with placement
96170	Health behavior intervention, family (without the patient present), face-to-face; initial 30 minutes		All lines with 96155	BHAP reviewed and agreed with placement
96171	Health behavior intervention, family (without the patient present), face-to-face; each additional 15 minutes (List separately in addition to code for primary service)		All lines with 96155	BHAP reviewed and agreed with placement

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
97129	Therapeutic interventions that focus on cognitive function (eg, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (eg, managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; initial 15 minutes	Replaceing 97127 (Therapeutic interventions that focus on cognitive function (eg, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (eg, managing time or schedules, initiating, organizing and sequencing tasks), direct (one-on-one) patient contact)	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS 178 INTRACEREBRAL HEMORRHAGE 196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN 201 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 317 STROKE 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	BHAP reviewed and agreed with placement

New CPT Codes
Consent Agenda

Code	Code Description	Similar Code(s)	Placement Recommendation	Comments
97130	Therapeutic interventions that focus on cognitive function (eg, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (eg, managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; each additional 15 minutes (List separately in addition to code for primary procedure)	See above	91, 178, 196, 201, 285, 317, 345, 377	BHAP reviewed and agreed with placement

2020 CPT Code Review
Fat Grafting

Codes:

1) CPT 15771 Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
2) CPT 15772 Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
3) CPT 15773 Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate
4) CPT 15774 Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)

Description: The surgical process by which fat is transferred from one area of the body to another, with the goal of augmenting the area in which the fat is injected. The technique involves harvesting the fat by liposuction, processing the fat, and then injecting in the target area.

Indications: Fat grafting is used in breast reconstruction after breast cancer surgery, release of painful scar contractures, and treatment of burn scars and radiodermatitis. It is also used for cosmetic augmentation in the face, hands, buttocks, and hips (**Simonacci 2017**). According to Simonacci et al, fat grafting is helpful for patients with retractile and painful scars compromising the normal daily activity/mobility of the joint involved.

Similar codes: Most tissue graft CPT codes (skin graft, bone graft, tendon draft, etc.) are in the Ancillary File.

Evidence

1) **NICE 2012**, Breast reconstruction using lipomodelling after breast cancer treatment
    a. Efficacy
        i. N=4 studies
            1. 3 case series N=734, 820, 69
            2. 1 non-randomized comparative study (N=61)
        ii. Outcomes were subjective judgments of aesthetic outcomes or asymmetry
        iii. The nonrandomized study (n=20 lipomodelling, n=42 other treatment), significant improvement in aesthetic results at 3-month follow up with lipomodelling
    b. Safety
        i. N= 2 studies, both case series (N=734, 137)
        ii. No increased risk of local breast cancer recurrence
        iii. 1 intraoperative pneumothorax
        iv. Local infection in <1% of procedures
        v. 3% rate of fat necrosis
        vi. Other reported adverse events: oil cysts, hematoma, calcification, complete resorption of fat
2) **Borrelli 2019**, review of treatment of radionecrosis
    a. recent preclinical and clinical studies have suggested that fat grafting may be of therapeutic benefit, reversing detrimental changes to soft tissue following radiotherapy

b. Although fat grafting has shown incredible promise with treatment of radiation-induced soft tissue injury, there remain a number of challenges to address, particularly with grafting into hostile irradiated tissue. Fat retention is already variable even at nonirradiated recipient sites, and resorption rates may range between 40% and 60%....but irradiated tissue is hypovascular, inflamed, and fibrotic. This can lead to fat necrosis and stimulate an inflammatory reaction resulting in fibrosis, cyst formation, calcification, or local infection.

Expert guidelines

1) NICE 2012

a. Current evidence on the efficacy of breast reconstruction using lipomodelling after breast cancer treatment is adequate and the evidence raises no major safety concerns

1) American Society of Plastic Surgeons 2015

a. Recommendations limited to fat grafting to the breast
    i. An evaluation of available literature on autologous fat grafting following mastectomy with no remaining native breast tissue indicates that the body of evidence is comprised mostly of case series, and when combined, the studies provide consistent evidence, thus resulting in grade B recommendations. A grade B recommendation encourages clinicians to employ the available information while remaining cognizant of newer, evidence-based findings. The existing evidence suggests autologous fat grafting is an effective adjunct to breast reconstruction following mastectomy demonstrating moderate to significant aesthetic improvement. In addition, the available evidence also cites autologous fat grafting as a useful modality for alleviating post mastectomy pain syndrome. Furthermore, the evidence suggests autologous fat grafting as a viable option for improving the quality of irradiated skin present in the setting of breast reconstruction.
    ii. POLICY
        1. Autologous fat grafting should no longer be considered experimental but should be regarded as part of reconstructive surgery when it is performed to approximate a normal appearance of the breasts following mastectomy or lumpectomy or in patients with asymmetry or hypoplasia of other origins

Other payer policies:

1) Aetna 2019

a. Aetna considers harvesting (via of lipectomy or liposuction) and grafting of autologous fat as a replacement for implants for breast reconstruction, or to fill defects after breast conservation surgery or other reconstructive techniques medically necessary

2) Cigna and Wellmark

a. No policies found

Current breast reconstruction guideline

GUIDELINE NOTE 79, BREAST RECONSTRUCTION

Line 191

Breast reconstruction is only covered after mastectomy as a treatment for breast cancer or as prophylactic treatment for the prevention of breast cancer in a woman who qualifies under Guideline Note 3, and must be completed within 5 years of initial mastectomy. Revision of previous reconstruction is only covered in cases where the revision is required to address complications of the surgery (wound dehiscence, fistula, chronic pain directly related to the surgery, etc.). Revisions are not covered solely for cosmetic issues.

Breast reconstruction may include contralateral reduction mammoplasty (CPT 19318) or contralateral mastopexy (CPT 19316). Mastopexy is only to be covered when contralateral reduction mammaplasty is inappropriate for breast reconstruction and mastopexy will accomplish the desired reconstruction result.

2020 CPT Code Review
Fat Grafting

HERC staff summary

Fat grafting appears to only have a substantive research base for breast reconstruction, and is recommended by trusted sources and national societies for this indication. However, these recommendations are based on case series with aesthetics as the major outcome. Fat grafting appears to be used in treatment of scars and radiation skin damage; however, there is little literature in these areas. The majority of non-breast reconstruction use of fat grafting appears to be for elective aesthetic procedures.

HERC staff recommendations:

1) Add fat grafting by liposuction technique to the breast to line 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
    a. CPT 15771 Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
    b. CPT 15772 Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
2) Add fat grafting by liposuction technique to non-breast areas to line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS /GN173
    a. CPT 15773 Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate
    b. CPT 15774 Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)

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

Line 662

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

Procedure Code	Intervention Description	Rationale	Last Review
15773, 15774	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet	Insufficient evidence of effectiveness; utilization mainly for cosmetic purposes	November 2019

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Review

Procedure, applications, and outcomes of autologous fat grafting

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HIGHLIGHTS

- Fat grafts are used to correct post-surgery defects, release of scars contractures, radiodermatitis, and cosmetic surgery.
- Different fat harvesting, processing, and injecting procedures have been proposed by various authors.
- Fat grafts exhibit regenerative potential owing to the presence of adipose stem cells.
- Autologous fat grafting is a low-risk procedure with minimal discomfort for patients.

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ABSTRACT

Objective: To systematically review the procedure, applications, and outcomes of autologous fat grafting, a promising technique with various clinical applications.
Patients and methods: Literature review of publications concerning autologous fat grafting.
Results: Since its introduction, lipofilling has become increasingly popular; however, its results are variable and unpredictable. Several modifications have been made to the procedures of fat harvesting, processing, and injecting. Surgical excision and low negative-pressure aspiration with large-bore cannulas minimize adipocyte damage during fat harvesting. The "wet" method of fat harvesting involves fluid injection at the donor site and facilitates lipoaspiration while minimizing pain and ecchymosis. For fat processing, centrifugation at a low speed is preferable to high-speed centrifugation, gravity separation or filtration. Fat injection at the recipient site should be performed using small-gauge cannulas in a fanning out pattern over multiple sessions, rather than a single session. Fat grafts exhibit not only dermal filler properties but also regenerative potential owing to the presence of stem cells in fat tissue. Thus, the clinical applications of autologous fat grafting include correction of secondary contour defects after breast reconstruction, release of painful scar contractures, and treatment of burn scars and radiodermatitis. Lipofilling is also used in aesthetic surgery, such as facial and hand rejuvenation, augmentation rhinoplasty, and breast and gluteal augmentation. The complications of lipofilling are minimal and include bruising, swelling, pain, infection, necrosis, and calcification.
Conclusions: Lipofilling is a low-risk procedure that can be used to correct soft-tissue defects in the face, trunk, and extremities, with minimal discomfort for patients.

Contents

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NICE guidance

Breast reconstruction using lipomodelling after breast cancer treatment

Interventional procedures guidance
Published: 23 January 2012
nice.org.uk/guidance/ipg417

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

1.1 Current evidence on the efficacy of breast reconstruction using lipomodelling after breast cancer treatment is adequate and the evidence raises no major safety concerns. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 There is a theoretical concern about any possible influence of the procedure on recurrence of breast cancer in the long term, although there is no evidence of this in published reports. NICE therefore encourages long-term data collection on this procedure.

1.3 Patient selection should be carried out by a breast cancer multidisciplinary team.

1.4 Breast reconstruction using lipomodelling after breast cancer treatment should only be carried out by surgeons with specialist expertise and training in the procedure.

2 The procedure

2.1 Indications and current treatments

2.1.1 Breast reconstruction following surgery for breast cancer may be done during the same operation or at a later date, and may involve prosthetic material (implant) alone, or autologous tissue (tissue from elsewhere in the body, usually the abdomen, buttocks or back), or a combination of the two.

2.2 Outline of the procedure

2.2.1 Lipomodelling uses the patient's own fat cells to replace volume after breast reconstruction, or to fill defects in the breast following breast-conserving surgery. It can be used on its own or as an adjunct to other reconstruction techniques. The procedure aims to restore breast volume and contour without the morbidity of other reconstruction techniques. However, a degree of fat resorption is common in the first 6 months and there have been concerns that it may make future mammographic images more difficult to interpret.

2.2.2 With the patient under general or local anaesthesia, fat is harvested by aspiration with a syringe and cannula, commonly from the abdomen, outer thigh and/or flank. The fat is usually washed and centrifuged before being injected into the breast. Patients subsequently undergo repeat treatments (typically 2–4 sessions).

2.2.3 Commencement of lipomodelling treatment may be delayed for a variable period of time after treatment of breast cancer.

> Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3 Efficacy

2.3.1 In a case series of 734 procedures for breast reconstruction (880 procedures in total), the results of lipomodelling following conservative surgery were judged to be 'very good' in 50% of procedures, 'good' in 40% and 'moderately good' in 10% (based on clinical examination, photographs and patient opinion: absolute numbers not stated).

2.3.2 A case series of 820 patients, including 381 with asymmetry after mastectomy and breast reconstruction, reported that the majority of patients had a 'significant improvement in their breast size and/or shape postoperatively'. Long-term breast asymmetry was reported in 4% (34/820) of patients.

2.3.3 A case series of 69 patients (74 breasts) reported a 'good to very good' improvement in 87% (64/74) of breasts and a 'moderate' improvement in 14% (10/74) of breasts (assessment from photographs by 2 independent surgeons).

2.3.4 A non-randomised comparative study of 61 patients (62 breasts) treated by lipomodelling (n = 20) or standard treatment only (n = 42) (not described) reported improvement in mean aesthetic results from 2.7 at baseline to 4.3 and 3.1 points respectively at 3-month follow-up ($p \leq 0.032$) (evaluated using a 5-point scale: 5 = very good).

2.3.5 The Specialist Advisers listed key efficacy outcomes as volume change, aesthetic assessment of breast shape, quality of life and body image assessments.

2.4 Safety

2.4.1 The case series of 734 lipomodelling procedures for breast reconstruction reported that 10 years of oncological follow-up did not reveal any increased risk of local recurrence after mastectomy or after conservative treatment. In a case

series of 137 patients who had a modified radical mastectomy, 96% were free from recurrence and 98% were free from distant metastasis at 5-year follow-up (absolute figures not stated).

2.4.2 The case series of 880 procedures reported 1 intraoperative pneumothorax (probably caused by the transfer cannula piercing the pleura), which resolved with the insertion of a pleural drain.

2.4.3 The case series of 880 procedures reported local infection in less than 1% of procedures (6/880); all resolved with treatment and had no impact on the final result. There was also an infection at a harvesting site in 1 case, which resolved with antibiotics.

2.4.4 The case series of 880 procedures reported a 3% rate of fat necrosis (absolute figures not stated). Liponecrotic cysts were reported in 7% (5/74) of breasts at 3-month follow-up in the case series of 69 patients and in 5% (2/43) in a case series of 37 patients.

2.4.5 The Specialist Advisers listed adverse events known from reports or experience as oil cysts, haematoma, calcification, donor and breast site deformity, complete resorption of fat, and uncertain findings on clinical surveillance and mammography. They raised the theoretical possibility of an increased rate of breast cancer recurrence and fat embolism.

2.5 Other comments

2.5.1 The Committee noted that there have been concerns about possible interference as a result of the procedure with imaging of the breast for cancer surveillance. However, it was advised that this ought not to be an issue with current techniques for lipomodelling and with expert interpretation of subsequent images.

2.5.2 The Committee noted that the techniques used for lipomodelling continue to evolve.

2.5.3 The Committee noted that devices are being introduced which aim to concentrate adipose stem cells in the tissue that is being used for lipomodelling. Further information about the outcomes of this and other adaptations of the

technique of lipomodelling is desirable for guiding their future use in clinical management.

2.5.4 The Committee noted that joint guidelines on lipomodelling are in development and these include a dataset for a proposed national audit.

3 Further information

3.1 For related NICE guidance see the NICE website.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedures guidance process.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes after publication
May 2012: minor maintenance

Your responsibility
This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual

responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation

Radiation-Induced Skin Fibrosis

Pathogenesis, Current Treatment Options, and Emerging Therapeutics

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Abstract: Radiotherapy (RT) has become an indispensable part of oncologic treatment protocols for a range of malignancies. However, a serious adverse effect of RT is radiodermatitis; almost 95% of patients develop moderate to severe skin reactions following radiation treatment. In the acute setting, these can be erythema, desquamation, ulceration, and pain. Chronically, soft tissue atrophy, alopecia, and stiffness can be noted. Radiodermatitis can delay oncologic treatment protocols and significantly impair quality of life. There is currently a paucity of effective treatment options and prevention strategies for radiodermatitis. Importantly, recent preclinical and clinical studies have suggested that fat grafting may be of therapeutic benefit, reversing detrimental changes to soft tissue following RT. This review outlines the damaging effects of RT on the skin and soft tissue as well as discusses available treatment options for radiodermatitis. Emerging strategies to mitigate detrimental, chronic radiation-induced changes are also presented.

Key Words: fat grafting, fibrosis, radiation-induced fibrosis, radiodermatitis

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Radiation therapy or radiotherapy (RT) has become an essential part of curative as well as palliative oncologic treatment protocols for a range of malignancies; currently, RT is used as an adjunct therapy in more than 50% of cancer patients.[1,2] While delivery methods for RT have been developed to combat cancer more effectively, collateral damage to healthy tissue in the radiation field surrounding the area of malignancy remains a serious adverse outcome. Skin is particularly radiosensitive, and more than 95% of patients receiving RT develop moderate to severe skin reactions.[3,4] In the acute phase following radiation exposure, the skin typically becomes erythematous and may desquamate or ulcerate. On the molecular level, cytokine cascades and fibroinflammatory pathways are up-regulated because of radiation, which can progress for many years leading to substantial fibrosis, the hallmark of chronic RT damage.[5] Cutaneous fibrosis alters form, function, and aesthetic appearance of the skin, and the consequences can significantly impact quality of life. Although a number of treatment options have been described, none has proven to be effective in preventing or reversing radiation-induced fibrosis (RIF) of the skin. Recent clinical and preclinical studies have demonstrated the benefit of autologous fat grafting (AFG) in the treatment of RIF.[6,7] First used for reconstructive purposes, fat is increasingly recognized to exert regenerative effects upon the tissue into which it is transplanted.[8–10] In irradiated skin, fat grafts can attenuate acute inflammation and slow/reverse the progression of chronic RIF.[6] The mechanisms by which fat regenerates the overlying skin and soft tissue remain to be elucidated but are thought to be driven by adipose-derived stromal cells (ASCs) of the stromal vascular fraction (SVF) of adipose tissue. Adipose-derived stromal cells have potent paracrine signaling action and are also multipotent and able to differentiate into a number of mesenchymal cell lineages. In this review, we outline the current understanding of RIF, the current treatment options, and the benefit of AFG within this setting. We also delve into alternative emerging strategies to mitigate RIF.

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RADIATION-INDUCED CELL DEATH

Radiation therapy is the process of delivering lethal doses of radiation to areas of malignancy to kill cancer cells. Radiation therapy has evolved to allow for more specific targeting of cancer cells and reduction of the "bystander response" in neighboring healthy tissue.[11] There are 3 main ways to deliver RT: (1) external beam RT directs radiation beams from outside a patient's body in the direction of the tumor; (2) brachytherapy delivers radiation internally with the insertion of radioactive materials inside the body; and (3) radioisotope therapy systemically circulates radiation throughout the bloodstream via injection of a targeted radioisotope[12–14] Radiotherapy can utilized alone or can be combined with other treatment modalities—such as chemotherapy or surgery—to treat primary malignancies as well as metastatic disease.[15]

Radiation therapy is based on the concept that malignant cells are more sensitive to radiation and cannot repair damage as efficiently as healthy cells. The molecular mechanisms of radiation-induced cell death are not completely understood,[16] and several mechanisms may be at play. Within hours of radiation, a number of cytokine signaling and inflammatory cascades are initiated. Radiation therapy forms ions that pass through tissues, which can directly induce double-stranded breaks in genetic material.[17] Cell death ensues via apoptosis, mitotic cell death, necrosis, and/or senescence,[12] including the release of damage-associated molecule pattern molecules.[18,19] Release of damage-associated molecule patterns activates the innate and adaptive immune systems that allow for additional antitumor responses.[20,21] Energy from ionizing radiation also acts on other molecules within cells, such as water, to generate reactive oxygen species (ROS), such as superoxide, hydrogen peroxide, and hydroxyl radical, which indirectly cause further damage of the DNA and other cellular components (eg, proteins, lipids).[22,23] Generation of ROS is thought to account for more than 60% of the total radiation-induced damage.[24,25]

To improve targeting of malignant cells with RT, Begg and colleagues[26] have described several approaches to modulate cellular response to radiation. These include inhibiting additional DNA repair mechanisms, cell cycle checkpoints, and signal transduction pathways.[26] For example, breast cancer cells with *BRCA1* or *BRCA2* mutations already have an impaired ability to repair double-stranded breaks in DNA via homologous recombination and rely on other mechanisms of DNA repair, such as base excision repair and single-strand break repair,

ASPS RECOMMENDED INSURANCE COVERAGE CRITERIA

AUTOLOGOUS FAT GRAFTING TO THE BREAST

INTRODUCTION

Autologous fat grafting to the breast is defined as removal of fat tissue from other parts of the body, followed by placement of the non-vascularized fat into the subcutaneous chest tissue to rebuild or reconstruct the breast. Fat grafting may also be referred to as fat transfer, lipoinjection, lipofilling, lipomodelling, and fat injection. This procedure has emerged as a common plastic surgery technique. Current data, technical advances in fat grafting, and numerous scholarly publications encourage physicians to consider fat grafting for breast reconstruction. However, fat grafting is not limited to the breast; it is also progressing in other areas of the body. Before engaging in the practice of autologous fat grafts, experienced plastic surgeons should consider the safety, efficacy, and evidence of various applications and techniques.

In light of findings by the ASPS Fat Graft Subcommittee, recommendations herein are limited to fat graft in the breast.

BACKGROUND

Since the 1980s, there has been an increased interest in autologous fat transfer for breast reconstruction. Fat grafting uses the patient's own fat cells from thighs, buttocks, or trunk to replace volume, fill defects, and contour deformities after breast reconstruction. The fat is harvested by aspiration with a syringe or cannula. It then may be washed, filtered, strained, decanted, and/or centrifuged before being transferred to the breast.

These policy recommendations address proposed indications for fat grafting to correct deformities following oncologic surgery or to correct breast asymmetry or hypoplasia in the adult patient. These include correction of contour deformities (improvement of shape and volume), and restoration of irradiated skin to non-irradiated appearance and consistency.

DEFINITIONS

The following definitions of cosmetic and reconstructive surgery were adapted by the American Medical Association in 1989 and reaffirmed in 2003:

> *Cosmetic Surgery* is performed to reshape normal structures of the body in order to improve the patient's appearance and self-esteem.

Reconstructive Surgery is performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. It is generally performed to improve function, but may also be done to approximate a normal appearance.

SCIENTIFIC EVIDENCE

An evaluation of available literature on autologous fat grafting following mastectomy with no remaining native breast tissue indicates that the body of evidence is comprised mostly of case series, and when combined, the studies provide consistent evidence, thus resulting in grade B recommendations. A grade B recommendation encourages clinicians to employ the available information while remaining cognizant of newer, evidence-based findings. The existing evidence suggests autologous fat grafting is an effective adjunct to breast reconstruction following mastectomy demonstrating moderate to significant aesthetic improvement. In addition, the available evidence also cites autologous fat grafting as a useful modality for alleviating post mastectomy pain syndrome. Furthermore, the evidence suggests autologous fat grafting as a viable option for improving the quality of irradiated skin present in the setting of breast reconstruction.

INSURANCE COVERAGE SUMMARY

Insurance company	**Fat Grafting Coverage**	**Fat Grafting Coverage Criteria Explanation**
Aetna	Yes	Grafting of autologous fat as a replacement for implants for breast reconstruction, or to fill defects after breast conservation surgery or other reconstructive techniques is considered medically necessary, includes lipectomy and liposuction.
Anthem	No Information Available	N/A
Blue Cross Blue Shield	No	The use of autologous fat grafting to the breast, with or without adipose-derived stem cells, is considered investigational.
Cigna	No	Autologous fat transplanting (lipoinjection, lipolifting, lipomodelling, ADSCs) following breast reconstruction procedures is not covered because such treatment is considered experimental, investigational or unproven.
Coventry	No Information Available	N/A
Health Net	Yes	Autologous fat/graft transfer (e.g. lipoinjection, lipofilling, lipomodelling) post-mastectomy, when no native breast tissue is present, is considered medically necessary.
Humana	No	Humana members MAY NOT be eligible for autologous fat graft, fat transplant (lipoinjection, lipomodeling), suction lipectomy or liposuction in conjunction with breast reconstruction. These technologies are considered experimental/investigational.

United Health Group	No Information Available	N/A

As the above table indicates, most insurance companies continue to consider fat grafting not "medically necessary" and will not reimburse for any procedure related to fat grafting. As such, members should develop a "self-pay" package for this service outlining the cost of the procedure to include pre/post-operative care, surgeon and anesthesiologist fees, cost of drugs and supplies, etc. Members should also discuss the lack of coverage with their state Attorneys General (AG) office and solicit further investigation by their AG to ensure coverage for fat grafting under the federal mandate for breast cancer reconstruction services.

POLICY

Autologous fat grafting should no longer be considered experimental but should be regarded as part of reconstructive surgery when it is performed to approximate a normal appearance of the breasts following mastectomy or lumpectomy or in patients with asymmetry or hypoplasia of other origins. Breast reconstruction of the affected breast, as well as surgery on the contralateral breast to achieve symmetry, is considered reconstructive surgery and in accordance with the Women's Health and Cancer Rights Act must be a covered benefit and reimbursed by third-party payers.

Legislation: Women's Health and Cancer Rights Act of 1998.
In October 1998, federal legislation was signed into law requiring group health plans and health issuers that provide medical and surgical benefits with respect to mastectomy, to cover the cost of reconstructive breast surgery for women who have undergone a mastectomy. The law states:

- *The attending physician and patient are to be consulted in determining the appropriate type of surgery.*
- *Coverage must include all stages of reconstruction of the diseased breast, procedures to restore and achieve symmetry on the opposite breast and the cost of prostheses and complications of mastectomy, including lymphedema.*

*Group health plans and health insurance issuers offering group health coverage **may not**:*

- *Deny a patient eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan, solely for the purpose of avoiding the requirements of the statute.*
- *Penalize, reduce, or limit the reimbursement of an attending provider.*
- *Provide incentives to attending provider to induce such provider to provide care to an individual participant or beneficiary in a manner inconsistent with this section.*

CODING & BILLING

The following codes are provided as a guideline for the physician and are not meant to be exclusive of other possible codes.

Procedure	**CPT Code(s)**	**RVUs**
Tissue grafts, other (eg, paratenon, fat, dermis)	20926	Work RVU = 5.79
Breast reconstruction, other	19366	40.45. Work RVU=21.84

Revise breast reconstruction	19380	22.25. Work RVU=10.41
Diagnosis codes	**ICD-9 code**	**ICD-10 code**
Acquired absence of breast	V45.71	Z90.10 – Z90.13
Atrophy of breast	611.4	N64.2
Breast asymmetry/ disproportion of reconstructed breast	612.1	N65.1
Breast cancer	174.0 - 174.9	C50.011 – C50.929
Congenital malformation of breast	757.6	Q83.0 – Q83.9
Deformity of reconstructed breast	612.0	N65.0
Encounter for breast reconstruction following mastectomy	V51.0	Z42.1
Genetic susceptibility to malignant neoplasm	V84.01	Z15.01
History of breast cancer	V10.3	Z85.3
Hypoplasia of breast	611.82	N64.82
Late effects of medical/surgical care	909.3	T88.9xxs
Late effects of radiation	909.2	L59.9
Scar, fibrosis	709.2	L90.5

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Approved by the ASPS® Executive Committee: June, 2015.

2020 CPT Code Review
Dry Needling

Codes:

1) CPT 20560 Needle insertion(s) without injection(s); 1 or 2 muscle(s)
2) CPT 20561 Needle insertion(s) without injection(s); 3 or more muscles

Description: Dry needling refers to a procedure in which a fine needle is inserted into the skin and muscle at a site of myofascial pain. The needle may be moved in an up-and-down motion, rotated, and/or left in place for as long as 30 minutes. The intent is to stimulate underlying myofascial trigger points, muscles, and connective tissues to manage myofascial pain. Dry needling may be performed with acupuncture needles or standard hypodermic needles but is performed without the injection of medications (eg, anesthetics, corticosteroids). Dry needling is proposed to treat dysfunctions in skeletal muscle, fascia, and connective tissue; diminish persistent peripheral pain, and reduce impairments of body structure and function.

Evidence:

1) **CADTH 2016**, systematic review of dry needling for musculoskeletal and joint disorders
    a. N=15 systematic reviews and meta-analyses (Jan 2011-July 2016)
    b. The higher quality systematic reviews generally found that dry needling had similar or worse outcomes compared to comparator interventions.
    c. Conclusions: Despite the number of systematic reviews on dry needling, evidence to show that it is an effective intervention is still lacking. Most of the systematic reviews, even those with conclusions that favored dry needling, noted that current evidence is inadequate and better quality trials with standardized interventions are needed to determine whether there is value in this procedure
2) **Espejo-Antunez 2017**, systematic review of RCTs of dry needling for trigger points
    a. N=15 RCTs of dry needling vs a variety of other interventions
    b. The results suggest that dry needling is effective in the short term for pain relief, increase range of motion and improve quality of life when compared to no intervention/sham/placebo. There is insufficient evidence on its effect on disability, analgesic medication intake and sleep quality.
    c. Conclusions: Despite some evidence for a positive effect in the short term, further randomized clinical trials of high methodological quality, using standardized procedures for the application of dry needling are needed.
3) **Hall 2018**, systematic review and meta-analysis of dry needling for upper extremity pain
    a. N=11 RCTs (496 patients)
    b. There was very low evidence that trigger point dry needling (TDN) of the shoulder region is effective for reducing pain and improving function in the short term. There is some evidence that needling both active and latent trigger points is more effective than needling an active trigger point alone for pain immediately and 1-week after treatment (SMD = −0.74, 95%CI = −1.2 to −0.3; and SMD = −1.0, 95%CI = −1.52 to −0.59).
    c. Conclusion: There is very low evidence to support the use of TDN in the shoulder region for treating patients with upper extremity pain or dysfunction. Most common adverse effects included bruising, bleeding, and pain during or after treatment. Future studies are likely to change the estimates of the effectiveness of TDN for patients with upper extremity pain or dysfunction.
4) **Liu 2018,** systematic review and meta-analysis of dry needling on low back pain
    a. N=11 RCTs (802 patients)

   b. Results suggested that compared with other treatments, dry needling of myfacial trigger points was more effective in alleviating the intensity of LBP (standardized mean difference [SMD], -1.06; 95%confidence interval [CI], -1.77 to -0.36; P=.003) and functional disability (SMD, -0.76; 95% CI, -1.46 to -0.06; P=.03); however, the significant effects of dry needling plus other treatments on pain intensity could be superior to dry needling alone for LBP at postintervention (SMD, 0.83; 95% CI, 0.55-1.11; P<.00001).
   c. Conclusions: The low-to-moderate-quality evidence showed that compared with other treatments, dry needling resulted in significant reduction in pain intensity and functional disability at postintervention. However, dry needling plus other treatments for LBP was more effective than dry needling alone in pain intensity reduction at postintervention, but the quality of evidence was low. To date, data remain insufficient to draw conclusions regarding the follow-up effects of dry needling compared with other treatments in treating LBP.

5) **Machado 2018**, systematic review and meta-analysis of dry needling for treatment of TMJ
   a. N=18 studies
   b. Due to the heterogeneity of the primary studies it was not possible to perform a meta-analysis. The narrative analysis of the results showed that most of the studies had methodological limitations and biases that compromised the quality of the findings.
   c. Dry needling and local anesthetic injections seem promising, but there is a need to conduct further randomized clinical trials, with larger samples and longer follow-up times, to evaluate the real effectiveness of the technique and evaluated substances.
6) **Salvioli 2017,** systematic review and meta-analysis of non-pharmacologic therapy for plantar fasciitis
   a. N=20 studies
      i. 1 study of dry needling
   b. 1 study of dry needling (Cotchett 2014), N=84 patients.
      i. this study demonstrated a significant reduction in pain intensity in the treated group (MD −18.20 (−31.19; −51.21) P =0.006).
      ii. Moderate quality evidence resulted from this study, as there was a moderate risk of performance bias.
   c. The interventions: shock waves, laser therapy, orthoses, pulsed radiofrequency, dry-needling, and calcaneal taping resulted in being effective treatments for the outcome pain in patients with plantar heel pain when compared to the placebo. However, considering that the improvements were very small, and the quality of evidence was mostly low or moderate for many of the interventions, it was not possible to give definitive conclusions for clinical practice.

<u>Other payer policies</u>

1) Aetna 2019 considers dry needling investigational
2) Wellmark 2018 considers dry needling investigational

<u>HERC staff summary</u>

Multiple systematic reviews and meta-analyses of dry needling for a variety of musculoskeletal conditions have been published; however, these studies generally conclude that there is a lack of evidence of effectiveness for dry needling and a need for future high quality studies to be performed.

2020 CPT Code Review
Dry Needling

HERC staff recommendation

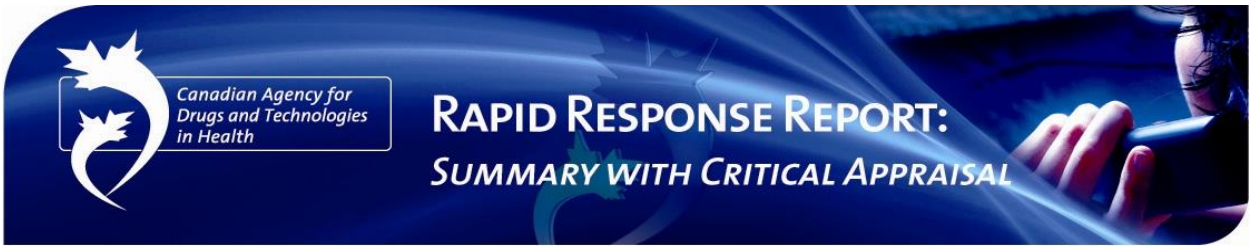
1) Add dry needling to line 662/Guideline note 173 due to lack of evidence of effectiveness
    a. CPT 20560 Needle insertion(s) without injection(s); 1 or 2 muscle(s)
    a. CPT 20561 Needle insertion(s) without injection(s); 3 or more muscles

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

Line 662

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

Procedure Code	Intervention Description	Rationale	Last Review
20560, 20561	Dry needling	Insufficient evidence of effectiveness	November 2019



TITLE: Dry Needling and Injection for Musculoskeletal and Joint Disorders: A Review of the Clinical Effectiveness, Cost-Effectiveness, and Guidelines

DATE: 22 August 2016

CONTEXT AND POLICY ISSUES

Musculoskeletal pain is a common reason for primary healthcare visits.[1,2] Dry needling is a procedure that appears to be increasingly used to treat this type of pain.[3] Dry needling involves the insertion of needles to treat "myofascial pain" or "myofascial trigger point" pain. Trigger points are palpable, hypersensitive areas (nodules or bands) within muscle tissue that may cause local or referred pain.[3-5] Dry needling may also be used in other parts of the body, not involving trigger points, such as ligaments and tendons.[6]

WorkSafe BC defines dry needling as *"a technique that uses needles to treat myofascial pain in any body part, including low back pain. Dry needling involves the insertion of a needle (it can be an acupuncture needle or any other injection needle without injecting any liquid) at the myofascial trigger pain points (not toward meridian points as it is practiced in acupuncture). The needles are removed once the trigger point is inactivated. The activation of the trigger point should be followed by exercises, for example, with the purpose of re-establishing a painless, full range of motion and avoid recurrences. At present, the mechanisms, underlying the action of dry needling is [sic] still unclear."*[7]

There is no widely accepted, standard definition of myofascial trigger points, but they have been associated with musculoskeletal pain, including joint and spinal disorders, tendonitis, pelvic pain, and neuralgia.[8] The trigger points may be "active" or "latent".[5,9] Active trigger points are localized areas that are painful with or without palpation, and that may also cause radiated pain elsewhere in the body. Latent trigger points are only painful when palpated or activated through some kind of stimulus.[8]

It is important to note that the validity of myofascial trigger point pain theories have been questioned.[10,11] A 2007 review identified 19 different descriptions of diagnostic criteria for myofascial trigger points and associated pain, but found a lack consensus or standard definition.[2]

A 2009 systematic review found physical examination (palpation) was unreliable in identifying trigger points.[1] The authors concluded that "*the diagnosis and treatment of TPs [trigger points] does not have a firm clinical basis. Until a reliable diagnostic test for TPs has been demonstrated it is recommended that this diagnosis should not be considered as a primary, or exclusive diagnosis for patients presenting a report of pain. If a treatment or management plan is to be implemented on the basis of a diagnosis of TPs, then patients should be informed of the ambiguity of this diagnosis so that they may make an informed choice about their treatment options…. Reliable methods of identifying TPs should be demonstrated before the implementation of further studies investigating the prevalence or treatment of trigger points.*"[1]

Other studies have found poor inter-examiner reliability in identifying trigger points.[6,10,11] Some of the studies included in the systematic reviews noted the importance of achieving the local twitch response (LTR) to determine the precise area for needling, and included this as part of their study protocols, while other studies either did not require or report this aspect of the procedure.[6,12]

Dry needling may also be called dry needle fenestration, intramuscular manual stimulation, intramuscular needling, intramuscular manual therapy, intra-muscular stimulation (IMS), ultrasound-guided needling, needle release, needling therapy or trigger point dry needling.[5,6] When used as a treatment for disorders of the tendons, dry needling may be performed with ultrasound guidance and called tendon fenestration or tenotomy.[13] Whether dry needling is actually another form of acupuncture,[3,9,14] is also controversial and it is sometimes referred to as "western acupuncture".[4]

Various theories or schools of dry needling, have been put forward, including the radiculopathy model or intramuscular stimulation, proposed by Canadian physician, Dr. Chan Gunn.[3,4,12,15] The umbrella term of dry needling includes different techniques, such as:[9]

- Deep dry needling - insertion of the needle deep into the muscle tissue of the trigger point
- Superficial dry needling - insertion of the needle into the tissue overlying the trigger point
- Paraspinal dry needling – needling of both the myofascial trigger points and the corresponding paraspinal muscles[4]
- Ultrasound-guided tendon fenestration.[13]

As well as differences in the depth of needle insertion, other techniques used in dry needling vary.[8] These variations include the type, size and number of needles used, whether the needle is manipulated after insertion (moved in and out, rotated, or left static), and the period of time the needle remains inserted.[3,5]

Unlike trigger point injections ("wet needling"), for musculoskeletal pain, dry needling does not involve the injection of fluids (such as, corticosteroids, sclerosants or anesthetics).[6] However, dry needling is seldom offered in isolation, and injections and other procedures, such as massage and exercise therapies, are usually included as part of the patient's overall treatment.[5,9,10] Dry needling may also be combined with plasma-rich platelet (PRP) injections formulated from the patient's blood and usually injected with ultrasound guidance.[16,17]

Depending on professional scopes of practice within their jurisdictions, dry needling may be administered by different healthcare practitioners -- including physiotherapists, acupuncturists, occupational therapists, naturopaths, osteopaths, chiropractors, dentists, and physicians -- who have received training in the procedure.[18]

Although the use of dry needling appears to be increasing,[3,11] it is not clear whether there is good evidence that this procedure is clinically effective. The purpose of this review is to appraise the evidence on dry needling to inform decisions on whether this procedure should be funded through the public healthcare system.

RESEARCH QUESTIONS

1. What is the clinical effectiveness of dry needling for patients with musculoskeletal and joint disorders?

2. What is the clinical effectiveness of dry needling plus injection vs. injection alone for patients with musculoskeletal and joint disorders?

3. What is the cost-effectiveness of dry needling for patients with musculoskeletal and joint disorders?

4. What is the cost-effectiveness of dry needling plus injection vs. injection alone for patients with musculoskeletal and joint disorders?

5. What are the evidence-based guidelines on the use of dry needling and injection to treat patients with musculoskeletal and joint disorders?

KEY FINDINGS

Evidence on the effectiveness of dry needling is mixed. Limited evidence suggests that wet needling (injection) is more effective than dry needling in the treatment of musculoskeletal or joint pain.

Our literature search found no information on the cost-effectiveness of dry needling for patients with musculoskeletal or joint disorders, or on the cost-effectiveness of dry needling plus injection vs. injection alone for patients with these conditions.

No evidence-based guidelines were identified on the use dry needling in the treatment of musculoskeletal or joint disorders. While there are some statements on this treatment issued by physiotherapy and other healthcare professional associations, these are practitioner guides outlining competencies and safe practices for providing this procedure.

METHODS

Literature Search Methods

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No methodological filters were applied to limit retrieval. Where possible, retrieval was limited to studies of the intervention in humans, and English language documents published between January 1, 2011 and July 19, 2016.

Rapid Response reports are organized so that the evidence for each research question is presented separately.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1. Systematic reviews and meta-analyses that included studies of dry needling (with or without injections) were included.

Table 1: Selection Criteria

Population	Adult patients with musculoskeletal pain, joint disorders, joint pain, derangement of joints, chronic tendinosis, tendinopathy, etc.
Intervention	Dry needling with or without injection, dry needling, ultrasound needling
Comparator	No comparator (or any treatment that is used to treat patients with above conditions)
Outcomes	Safety, effectiveness, cost-effectiveness, and clinical practice guidelines
Study Designs	Health technology assessment reports, systematic reviews, meta-analyses, economic evaluations or evidence-based guidelines

Exclusion Criteria

Publications were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, were not published in English, or were published prior to 2011. Guidelines that did not appear to be based on systematic reviews of the evidence were also excluded. Studies of dry needling in conditions other than those involving musculoskeletal or joint pain were also excluded (where possible). For example, the following conditions were not included: plantar fasciitis (heel pain), neuralgia, fibromyalgia, headache, and pelvic pain.

Critical Appraisal of Individual Studies

The systematic reviews were critically appraised using the AMSTAR checklist.[19] Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations of each included study were described narratively.

SUMMARY OF EVIDENCE

Quantity of Research Available

A total of 309 citations were identified in the literature search of bibliographic databases. Following screening of titles and abstracts, 292 citations were excluded, and 17 potentially relevant systematic reviews and meta-analyses identified by the electronic database search were retrieved for full-text review. No relevant publications were identified from the grey literature search. One additional systematic review (identified through the reference list of another study) met the inclusion criteria and was included in this report. Of the 18 articles selected for full-text screening, 15 met the selection criteria for this review. Appendix 1 describes the PRISMA flowchart of the study selection.

Summary of Study Characteristics

Details on study characteristics, critical appraisal and findings are shown in Appendices 2, 3, and 4.

Study Design
This rapid response report is based on 15 systematic reviews and meta-analyses that included primary studies (mainly randomized controlled trials of varying quality) with dry needling as either the main treatment intervention, or as the comparator or control. These reviews were published from 2012 to 2016. The literature searches covered the most recent few years to as far back as the databases covered. The end-search date of the most recent review was August 2015.

Country of Origin
None of the systematic reviews were from Canada, but they were from multiple countries: USA,[8,12,20,21] UK, Europe,[22-27] Australia,[17] New Zealand,[28] China,[29] and Korea.[30,31] Each of the systematic reviews included primary studies from multiple countries.

Patient Population
All of the systematic reviews included adult patients with various types of musculoskeletal pain and tendinopathies, in particular: upper and lower body myofascial pain,[8,21,24] neck,[12,21,24,26,28-30] shoulder,[12,17,20-24,27-29,31] elbow,[17,20,23,24] back,[12,21,24,31] thigh,[8] knee,[8,12,17,23,25] and Achilles heel.[8,12,17,20,25]

Interventions and Comparators
In most of the systematic reviews dry needling was the main intervention (or one of them),[8,12,20-22,24,26-31] but in some reviews it was used as the comparator or control treatment for interventions such as platelet-rich plasma injection (PRP).[17,23,25]

The techniques used in dry needling varied across the primary studies and it was often combined with other treatment interventions (such as exercise therapy or injections). Comparators to dry needling included: exercise or stretching,[8,12,21,24,26,28,30] physiotherapy,[29,30] compression,[26,29] injections (of saline, anesthetics (such as lidocaine),[12,21,24,26,28,29] corticosteroids,[24,27] botinulum toxin,[21] platelet-rich plasma (PRP)[17,23,25] or other types of autologous blood products),[20] various types of acupuncture,[8,21,25,26,29-31] extracorporeal shockwave therapy (ESWT),[17,27] transcutaneous electrical nerve stimulation (TENS),[8] percutaneous electrical nerve stimulation (PENS),[12] laser,[21,28,29] drug therapies,[12,30,31] sham or superficial needling,[8,21,26,29,30] placebo,[12,24,29] or "usual care".[30] One systematic review compared ultrasound-guided needling and extracorporeal shock wave therapy to arthroscopic surgery for rotator cuff tendinopathy.[22]

Outcomes
Reduction in pain (pain intensity) was the main outcome assessed in most of the systematic reviews.[8,12,17,20,21,23,24,26-31] Various pain scales were used, most commonly a Visual Analog Scale (VAS). Some reviews also included range of movement (ROM).[12,24,26,30] Information on other outcomes, such as quality-of-life[30] and function/disability[20,22,23,27,30] were included in some reviews – from a smaller sub-set of studies that included this information.

Summary of Critical Appraisal

The 15 systematic reviews and meta-analyses included in this rapid response were of variable quality. Most followed general principles for systematic reviews, but many had limitations that may have affected their conclusions. Using the AMSTAR checklist[19], the most common limitations identified in the reviews were:

- a limited literature search (for example, searching only a single database, poor search terms, or a brief date range for the search)[12,21,25,26]
- use of a single reviewer for data extraction and quality assessment of studies[8]
- no indication that the risk of publication bias had been assessed.[8,12,17,20,22,25-27]

Two studies did not report performing quality assessment of the included studies.[20,25] The PEDro scale and the Cochrane risk of bias were the most commonly tools for quality assessment, but some studies used others, including GRADE, the MacDermid Quality Checklist, and the Coleman Methodology Score.

Most of the systematic reviews noted the included studies were heterogeneous, particularly in terms of the different dry needling techniques used (both with and without other interventions), in some cases the conditions treated, the variety of comparators, and the length of patient follow-up.

With one exception (where the information was not reported),[24] none of the authors of the systematic reviews reported a conflict of interest. Several good quality systematic reviews were available.[23,24,27-31]

Summary of Findings

Clinical effectiveness of dry needling

The higher quality systematic reviews generally found that dry needling had similar or worse outcomes compared to comparator interventions.

One review found dry needling had a positive effect on pain relief for lower body (lower back, hip, and knee pain) in short-term follow-up (up to six months), compared to stretching, no intervention, or sham needling.[8] However, dry needling did not appear to have a positive effect on range of movement, function, or quality of life.[8]

Another review compared dry needling to numerous other interventions for all types of musculoskeletal pain (e.g., neck, upper body, back, and legs).[12] The authors considered most of studies in their review to be high quality and showed dry needling was more effective in reducing pain than stretching exercises or percutaneous electric nerve stimulation, and at least as effective as manual trigger point release or other types of needling (such as acupuncture).[12] However, a critique of this review found the conclusions were overstated, and that many of the included studies had one or more methodological flaws, including failure to demonstrate a statistically significant difference from sham treatments, failure to control for confounders (such as the natural history of the condition), and limited follow-up (immediate to short-term) of outcomes.[11]

An older review compared pain relief with intramuscular stimulation therapy, a form of dry needling, to sham acupuncture, intramuscular electrical stimulation, drug therapy, or trigger point dry needling, for various musculoskeletal conditions (e.g., shoulder, lower back).[31] The authors found the four included trials had positive findings, but their methodological flaws prevented drawing evidence-based conclusions on the effectiveness of intramuscular stimulation therapy.[31] In the one trial that used trigger point dry needling as the comparator, intramuscular stimulation provided greater neck pain relief than dry needling.[31]

One review of acupuncture (including dry needling) for whiplash found dry needling was no more effective for pain relief than sham dry needling or other interventions (such as physiotherapy, exercise, and sham acupuncture).[30]

Another review that assessed extracorporeal shockwave therapy, ultrasound-guided dry needling, and arthroscopic surgery for rotator cuff tendinopathy found significant improvement in functional outcomes with dry needling at one-year follow-up, but that similar results were achieved with all three treatments.[22]

Dry needling vs. wet needling

One systematic review, on platelet-rich plasma injection, that included four studies of dry needling as a control intervention in patients with various tendinopathies (shoulder, elbow, knee, heel) found no difference in pain reduction between the control interventions used - injections of either saline, local anesthetic, corticosteroids, or dry needling.[17]

For neck and shoulder pain relief, one review found that dry needling could be effective for short (immediate to three days) to medium term (nine to 28 days) pain relief, but that wet needling (with lidocaine injection) provided more effective pain relief than dry needling in the medium term.[29] However, a second review, also for neck and shoulder pain, found no difference between dry needling and lidocaine injection immediately after treatment or at up to six months follow-up.[28]

A third review of dry needling for upper body myofascial pain (neck, shoulder, back), concluded that for immediate post-treatment pain relief and at four weeks lidocaine injection was superior to dry needling.[21] Nevertheless, the results of their meta-analysis of three trials found that dry needling may be superior to sham or placebo treatment for immediate pain relief, but the difference at 4 weeks was not statistically significant.[21]

One review assessed ischemic compression (exercise therapy) and dry needling (with or without exercise or stretching) compared to several other interventions (including lidocaine injection) for patients with neck pain.[26] Although the authors concluded that there was good evidence that dry needling reduced pain, in the four studies that compared dry needling plus stretching exercises to lidocaine injection plus stretching exercises pain relief outcomes were similar.[26]

Another review found ultrasound-guided needling was not more effective than ultrasound-guided subacromial corticosteroid injection for rotator cuff injury.[27] However, this study found, based on one low quality study, that dry needling was better than no treatment at three month follow-up.

One review of dry needling for various types of myofascial pain (e.g., in the neck, upper back, shoulder, elbow) found dry needling was not more effective in decreasing pain in comparison to placebo but was less effective than other treatments (including injections [lidocaine, corticosteroids, botulinum toxin], ultrasound, laser, stretching exercises).[24] For improving range of movement, dry needling was more effective than placebo, but less effective than the other treatments.[24]

A review of platelet-rich plasma injection for patients with various tendinopathies included two studies that used dry needling as a control intervention.[23] The authors concluded that no difference in pain relief was seen between dry needling or placebo (saline or corticosteroid injections) and platelet-rich plasma. The only exception was a small clinical improvement with platelet-rich plasma in patients with rotator cuff tendinopathy.[23]

Another review of platelet-rich plasma injection for knee and heel tendinopathies included one study with dry needling as both the co-intervention and the comparator treatment for patients with knee tendinopathy.[25] Platelet-rich plasma injection plus dry needling achieved better clinical outcomes (not specified) than dry needling alone.[25]

One review of four studies that compared tendon needling (in one study needling with exercise) to needling plus injection of autologous blood products (including platelet-rich plasma) for tendinopathies (shoulder, elbow and heel), concluded that tendon needling reduced pain at six months.[20] However, two of the studies found a benefit to the addition of platelet-rich plasma injection, while two found no difference.[20]

Safety of dry needling

Most of the systematic reviews did not report on safety outcomes, Of the systematic reviews that did include information on adverse events, the following were noted:

- pain during and after dry needling[22]
- minor petechial hemorrhage (bleeding)[27]
- mild vagal reaction (fainting)[27]
- painful bursitis and frozen shoulder.[27]

Other details of adverse events associated with dry needling have been reported in the literature. A 2014 review of the literature on the safety of dry needling, by the Health Quality Council of Alberta, addressed this issue.[15] In addition, Physiotherapy Alberta further outlines the types of adverse events that may occur with dry needling. Serious adverse events from dry needling are rare, but include pneumothorax (collapsing the lung), puncturing other vital tissue, infection, and broken needles.[15,32] Less serious adverse events include bruising, bleeding, pain (during and after treatment), drowsiness, dizziness, nausea or vomiting, fainting, sweating, headache, and seizure.[32] The Physiotherapy Alberta association recommends that patients be informed of the possible risks associated with this procedure.[32] Mild, transient adverse events (bruising, bleeding and pain) are common with dry needling.[32] However, one commentary noted that the difference in frequency of adverse events between dry needling and the sham group found in one trial meant that one in three patients treated with dry needling would experience an adverse event.[11]

Cost-effectiveness of dry needling

No information on the cost-effectiveness of dry needling for patients with joint disorders was identified.

Cost-effectiveness of dry needling plus injection vs. injection alone

No information on the cost-effectiveness of dry needling plus injection vs. injection alone for patients with joint disorders was identified.

Evidence-based guidelines on the use of dry needling

We found no evidence-based guidelines on the use dry needling in the treatment of joint disorders.

Limitations

Because of the ambiguous terminology in this area, and the volume of literature on acupuncture, studies of dry needling that used some of the less common terms for the procedure, or did not refer to dry needling in the title or abstract may not have been captured by the literature search.

In studies of chronic pain treatments, measurement of multiple outcomes is recommended. The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) group recommends that, in addition to the measurement of pain intensity, additional measures such as physical functioning and psychological well-being should also be assessed.[33] Many of the primary studies included in the systematic reviews focused on pain reduction, and there is insufficient evidence on the effects of dry needling on other outcomes, such as range of movement or quality of life.

Although there is an abundance of studies on dry needling for various conditions, the systematic reviews found that most of the primary studies were methodologically flawed. For example, blinding of participants and assessors was often inadequate,[26,31] many studies were underpowered to accurately indicate treatment effects, patient populations were heterogeneous, outcome measures and length of follow-up varied, and most studies included various non-standardized treatment and comparator interventions that may have affected the outcomes.

The minimum clinically important difference (MCID) or "smallest worthwhile effect" is important when examining studies on chronic pain.[34] MCID is a patient-derived measure to determine what patients see as a *clinically significant* improvement or meaningful change – rather than a change in pain level, but one that does not make a difference to the patient. The IMMPACT group recommends:

- a 10% to 20% reduction in pain be considered the minimal clinically important difference
- a reduction in pain of more than 30% would indicate a moderately important improvement, and
- a reduction in pain of over 50% would indicate a substantial clinically important change.[33,34]

These levels also depend on the baseline severity of pain of the individual patient, and only an average of the differences between patient groups post-treatment will indicate actual treatment

effects.[34] In most of the studies of dry needling the MCID was not defined, and the results focused only on statistically significant changes.[12]

Some systematic reviews[20,21,28] overstated their conclusions which can be common in study reports of pain treatments.[34,35] Actual results were down played, while more positive terms, such as "trending towards" and "potentially significant" were used in the abstracts and conclusions. For example, the results of one systematic review and meta-analysis of dry needling for neck and shoulder pain noted that the meta-analyses found no significant difference between DN and lidocaine at one or three to six month follow-up.[28] Nevertheless, the authors concluded that, *"Although not significant in the meta-analyses, there were interesting patterns favouring lidocaine immediately after treatment and dry needling at three to six months*."[28]

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

Despite the number of systematic reviews on dry needling, evidence to show that it is an effective intervention is still lacking. Most of the systematic reviews, even those with conclusions that favoured dry needling, noted that current evidence is inadequate and better quality trials, with standardized interventions are needed to determine whether there is value in this procedure.

This finding is consistent with coverage policies of two US insurers, Blue Cross Blue Shield, and Aetna, both of which currently deem there is insufficient evidence on this procedure and consider dry needling is "experimental or investigational", and consequently not covered.[36,37]

No information on the cost-effectiveness of dry needling was identified. Similarly, no evidence-based guidelines on the use of dry needling were identified. However, there are recent statements on the practice of dry needling, by physiotherapy and other healthcare professional associations, but these are practitioner guides outlining competencies and safe practices for providing this procedure rather than systematic reviews of the evidence.[38-43]

Many further trials of dry needling are currently underway and evidence from these studies may affect these conclusions.[44,45]

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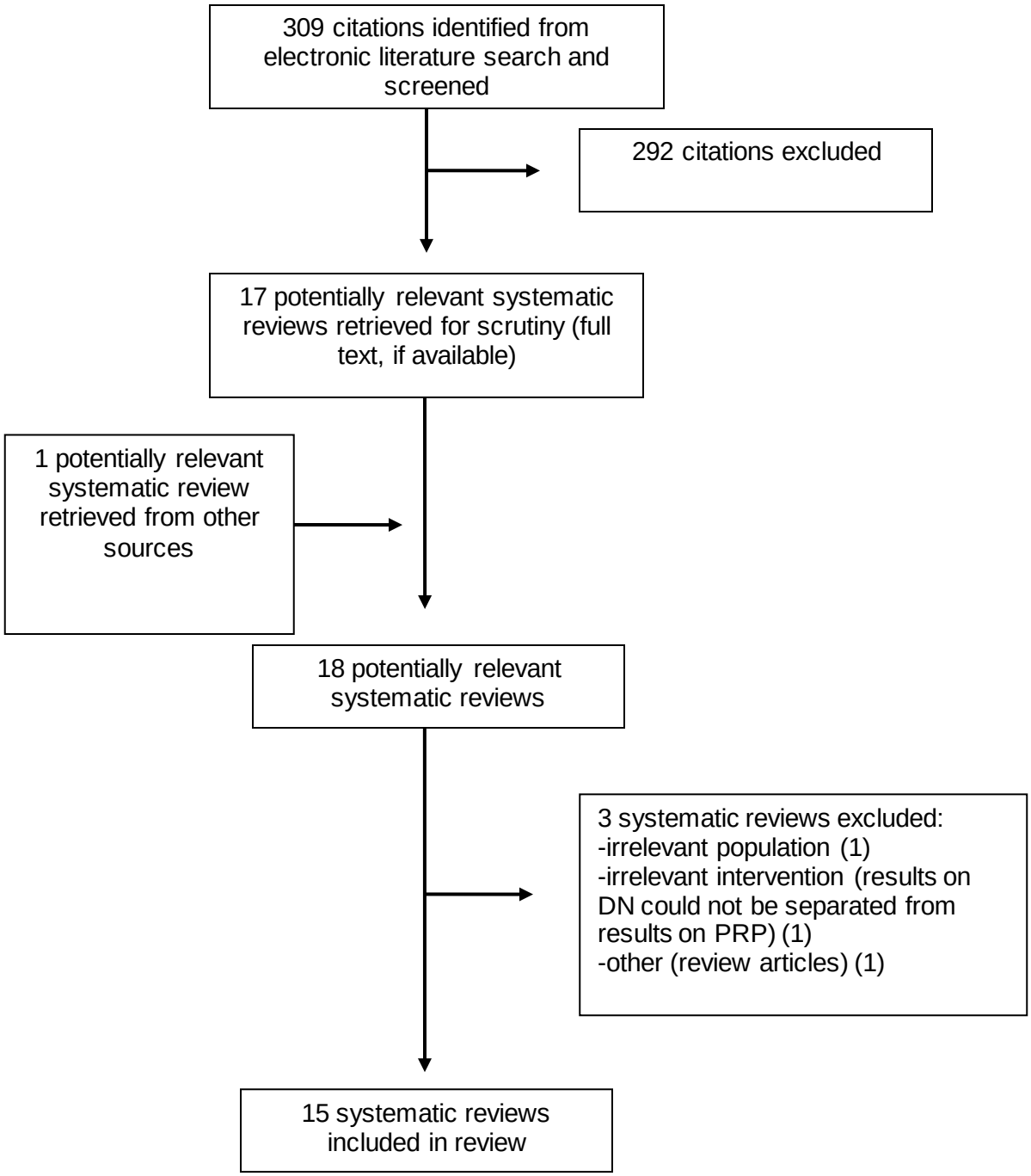
APPENDIX 1: Selection of Included Studies



Abbreviations: DN=dry needling; PRP=platelet-rich plasma injection

APPENDIX 2: Characteristics of Included Systematic Reviews

Table A: Characteristics of Included Systematic Reviews and Meta-Analyses

First Author, Publication Year, Country	Types and numbers of primary studies included	Population Characteristics	Intervention	Comparator(s)	Clinical Outcomes, Length of Follow-Up
Fitzpatrick et al.[17] (2016) Australia	- 18 RCTs (4 used DN as control)	- Tendinopathies (shoulder, elbow, knee, Achilles (heel) - Total 1,066 pts (136 in trials involving DN)	- PRP injections (various types)	- DN; eccentric exercise, injections (saline, local anesthetic, corticosteroid), shockwave treatment	- Outcome: pain - VAS & various pain & disability scales used - Follow-up to 6 months in DN studies
Morihisa et al.[8] (2016) USA	6 RCTs (one not relevant on plantar fasciitis (heel pain))	- Various types of lower body pain: upper & lower body, thigh, lower back, knee & heel - Total 301 pts (217 pts not including 84 pts in study of plantar fasciitis)	- Various forms of DN: needling duration, depth, repetition & # of treatments varied; administered with & without local anesthesia	- Sham DN (applying blunted needle to surface of skin), stretching only, no treatment, standard, superficial or deep acupuncture, TENS	- Outcomes: pain, # of follow-up treatments, hamstring tightness, stiffness, ROM, QoL - VAS and various pain & disability scales used Follow-up: short-term follow-up (from 3 days to 6 months)
Louwerens et al.[22] (2016) The Netherlands	22 studies (including 6 on DN (2 RCTs))	- Calcific rotator cuff tendinopathy (shoulder pain) - 1,258 shoulders (485 pts in DN studies)	- High-energy extracorporeal shockwave therapy versus ultrasound-guided needling (using single or double needle, lavage & aspiration used in double needle studies only)	- Arthroscopic surgery	- Outcomes: functioning and size of calcific deposit (measured by radiology) - Follow-up: ranged from 6 months to 10 years in DN studies
Tsikopoulos et al.[23] (2016) Greece	- 5 RCTs included in meta-analysis (2 used dry needling as the comparator)	- Tendinopathies (shoulder, elbow, knee) + diagnosis confirmed by MRI or US - Total of 190 pts	- Platelet-rich plasma injection	- Placebo (saline or corticosteroid injection) or dry needling	- Outcomes: pain,: functional disability - -Follow-up: at 2 or 3, and at 6 months post intervention for pain; follow-up at 3 months for functional disability

Table A: Characteristics of Included Systematic Reviews and Meta-Analyses					
First Author, Publication Year, Country	**Types and numbers of primary studies included**	**Population Characteristics**	**Intervention**	**Comparator(s)**	**Clinical Outcomes, Length of Follow-Up**
		(mostly men), data on 170 pts			
Rodriguez-Mansilla et al.[24] (2016) Spain	- 19 studies (10 included in meta-analysis)	- "Myofascial pain" (headache, neck, shoulder, back, gluteal, various muscles, jaw, elbow) - Total of 852 pts	- DN	- Stretching exercises, ultrasound therapy, injections with analgesics, lidocaine and corticosteroids, no intervention or placebo	- Outcomes: pain, ROM, PPT - Follow-up: ranged from before & after intervention to 8 months
Boyles et al.[12] (2015) USA	- 19 studies included (1 study retracted by publisher)	- multiple body regions (back, hamstring, neck, jaw, heel, shoulder, knee) - total of 1,102 pts (only 1,071 completed studies)	- DN	- Various: acupuncture, sham laser acupuncture, no treatment, placebo DN, lidocaine injection, stretching exercises, percutaneous electrical nerve stimulation; oral flurbiprofen (drug therapy)	- Outcomes: pain & ROM, various other outcomes assessed - Follow-up: ranged from immediate (10-30 min) to 6 months
Matteo et al.[25] (2015) Italy	- 22 studies (3 were RCTs; only 1 study included DN)	- Tendinopathies (knee & Achilles tendon (heel)) - DN was the comparator in 1 study of 23 pts (10 PRP & 13 DN)	- Platelet-rich plasma injections (PRP)	- ESWT, DN (1 study only), no comparator	- Outcomes: only described generally as positive clinical outcome or no difference - Follow-up: ranged from 6 months to 4 years; follow-up in DN study was 6 months
Krey et al.[20] (2015) USA	- 4 RCTs	- Tendinopathies (shoulder, elbow, Achilles tendon (heel)) - Total of 350 pts (complete follow-up on 333 pts)	- "Tendon needling" (DN, with/without exercise therapy)	DN + Autologous blood products (ACP/PRP/autologous blood)	- Outcomes: pain & function - Follow-up: to 6 months

Table A: Characteristics of Included Systematic Reviews and Meta-Analyses					
First Author, Publication Year, Country	**Types and numbers of primary studies included**	**Population Characteristics**	**Intervention**	**Comparator(s)**	**Clinical Outcomes, Length of Follow-Up**
Cagnie et al.[26] (2015) Belgium	- 15 RCTs (8 on DN)	- Neck pain - Total of 185 pts in the DN studies	- Ischemic compression or DN (with/without exercise/stretching	- Lidocaine injection+exercise/stretching; DN+paraspinal needling, non-TP DN; sham acupuncture, superficial DN	- Outcomes: pain, PPT, & ROM - Follow-up: to 12 weeks
Liu et al.[29] (2015) China	- 20 RCTs (not all included in meta-analyses)	- Neck & shoulder pain - Total of 839 pts	- DN	- Lidocaine or other injections; IMS; IMES; sham acupuncture; placebo; laser; sham laser; physiotherapy; sham DN; compression	- Outcome: pain - Follow-up: ranged from immediate to 24 weeks
Louwerens et al.[27] (2014) The Netherlands	- 20 studies (9 RCTs & 1 prospective non-RCT; 2 studies on needling)	- Rotator cuff (shoulder) tendinopathy - Total of 1,544 pts (# of pts for needling not known)	- Minimally invasive therapies: ESWT+ US-guided needling, US-guided needling, SWT, TENS, laser therapy	- Low ESWT, no treatment, steroid injection (in needling studies)	- Outcomes: pain, function, change in size of calcific deposit - Follow-up: short-mid term (minimum 3 months)
Moon et al.[30] (2014) Korea & UK	- 6 RCTs (only 1 study included DN)	- Whiplash-associated disorders (neck) - Total of 348 pts (34 pts in study of DN)	- Acupuncture, electroacupuncture or DN	- Usual care, physiotherapy, exercise & rest, relaxation, sham acupuncture, sham DN+physiotherapy, drug therapy	- Outcomes: pain intensity, QoL, ROM, function - Follow-up: ranged from 1 day to 6 months
Ong et al.[28] (2014) New Zealand & UK	- 5 RCTs	- MTrP (neck & shoulders) - Total of 266 pts	- DN (techniques varied)	- Lidocaine injection (with/without exercises/stretching); placebo laser	- Outcome: pain - Follow-up: ranged from immediately post-treatment to 6 months
Kietrys et al.[21] (2013) USA	- 12 RCTs	- Upper quarter myofascial pain (neck, shoulder, back) - Total of 696 pts	- DN (with/without stretch & exercise)	- Lidocaine injection; stretch & exercise; sham DN; acupuncture; sham acupuncture; sham laser acupuncture ;laser; sham laser; botulinum toxin injection; IMS;	- Outcome: pain - Follow-up: ranged from immediately post-treatment to 6 months

Table A: Characteristics of Included Systematic Reviews and Meta-Analyses					
First Author, Publication Year, Country	**Types and numbers of primary studies included**	**Population Characteristics**	**Intervention**	**Comparator(s)**	**Clinical Outcomes, Length of Follow-Up**
Kim et al.[31] (2012) Korea & UK	- 4 RCTs	- Headache (1 study), shoulder pain, low back pain - Total of 136 pts not including headache study pts	- IMS ("a DN technique"; needling techniques not clearly reported)	- Sham acupuncture; analgesic drug (Meloxicam); IMES, DN	- Outcome: pain - Follow-up: periods not clear (may have been immediately post-treatment)

ACP=autologous conditioned plasma; DN=dry needling; ESWT=extracorporeal shockwave therapy; IMES=intramuscular electrical stimulation; IMS=intramuscular stimulation; MCID=minimum clinically important difference; min=minutes; MRI=magnetic resonance imaging; MTrP=myofascial trigger point; PPT=pressure pain threshold; PRP=platelet-rich plasma injections; pts = patients; QoL = quality of life; RCTs = randomized controlled trials; ROM = range of movement; SWT=shockwave therapy; TENS = transcutaneous electric nerve stimulation; TP = trigger point; UK=United Kingdom; US=ultrasound; USA=United States of America; VAS = Visual Analog Scale

APPENDIX 3: Critical Appraisal of Included Publications

Table B: Strengths and Limitations of Systematic Reviews and Meta-Analyses [19]

Strengths	Limitations
Fitzpatrick (2016)[17]	
• Comprehensive literature search (5 year limit) • Duplicate study selection & data extraction • Summary of study characteristics & list of included studies provided • Study quality assessed by 2 reviewers • Risk of bias assessed (Cochrane RoB tool) • Appropriate statistical methods used to combine study findings in network meta-analysis	• Unclear if grey literature included • English language studies only
Morihisa (2016)[8]	
• Comprehensive literature search • Duplicate study selection & data extraction • Summary of study characteristics & list of included studies provided • Study quality assessed (PEDro scale)	• Grey literature not included • English language only • Risk of bias only assessed for one study
Louwerens (2016)[22]	
• Comprehensive literature search • Multiple languages included • Duplicate study selection & data extraction • Summary of study characteristics & list of included studies provided • Study quality assessed (Coleman Methodology Score)	• Unclear if grey literature searched • Unclear if risk of publication bias assessed
Tsikopoulos (2016)[23]	
• Comprehensive literature search • Grey literature included • Duplicate study selection & data extraction • Summary of study characteristics & list of included studies provided • Risk of bias assessed (Cochrane RoB tool) • Appropriate statistical methods used to combine study findings in meta-analysis	• Unclear if literature search limited to English language only
Rodriguez-Mansilla (2016)[24]	
• Comprehensive literature search • Duplicate study selection & data extraction • Grey literature included • Summary of study characteristics & list of included studies provided • Study quality assessed (PEDro scale) • Risk of bias assessed • Appropriate statistical methods used to combine study findings in meta-analysis	• None noted
Boyles (2015)[12]	
• Summary of study characteristics & list of included studies provided • Study quality assessed (PEDro scale)	• Unusual search strategy & limited date range (4 years) • Unclear if duplicate study selection and data extraction occurred

Table B: Strengths and Limitations of Systematic Reviews and Meta-Analyses [19]	
Strengths	**Limitations**
	• Unclear if risk of publication bias assessed
Di Matteo (2015)[25]	
• Duplicate study selection • Summary of study characteristics & list of included studies provided	• Limited literature search (1 database only) • Study quality not assessed; only a few included studies were RCTs • Risk of publication bias not assessed
Krey (2015)[20]	
• Comprehensive literature search • Grey literature included • Duplicate study selection & data abstraction • Summary of study characteristics & list of included studies provided	• English language only • Study quality assessed but not clear what criteria were used • Risk of publication bias not assessed
Cagnie (2015)[26]	
• Comprehensive literature search (2 databases but included handsearching) • Duplicate study selection & data abstraction • Summary of study characteristics & list of included studies provided • Study quality assessed (Dutch Cochrane Centre & Dutch Institute for Healthcare Improvement checklists) • Risk of bias assessed	• Unclear if grey literature included & date range of search unclear
Liu (2015)[29]	
• Comprehensive literature search • Grey literature included • Duplicate study selection & data extraction • Summary of study characteristics & list of included studies provided • Study quality assessed (PEDro scale) • Risk of publication bias assessed • Appropriate statistical methods used to combine study findings in meta-analysis	• None noted
Louwerens (2014)[27]	
• Comprehensive literature search • Grey literature included • Duplicate study selection & data extraction • Summary of study characteristics & list of included studies provided (in supplement) • Study quality assessed (Cochrane RoB tool, GRADE level of evidence) • Risk of publication bias assessed	• None noted
Moon (2014)[30]	
• Comprehensive literature search • Search included non-English language publications • Grey literature included • Duplicate study selection • Risk of bias assessed (Cochrane RoB tool) • Summary of study characteristics & list of	• None noted

Table B: Strengths and Limitations of Systematic Reviews and Meta-Analyses [19]	
Strengths	**Limitations**
included studies provided	
Ong (2014)[28]	
• Comprehensive literature search • Duplicate study selection & data extraction • Summary of study characteristics & list of included studies provided • Study quality assessed (PEDro scale) • Risk of publication bias assessed (Cochrane RoB tool) • Appropriate statistical methods used to combine study findings in meta-analysis	• English language only • Grey literature not searched
Kietrys (2013)[21]	
• Study quality assessed & all studies assessed by at least 3 researchers (MacDermid Quality Checklist) • Risk of publication bias assessed (funnel plots) • Summary of study characteristics & list of included studies provided	• Limited search strategy (only one search term used) • Grey literature not searched • Two authors extracted data, but unclear if duplicate study selection & data extraction occurred
Kim (2012)[31]	
• Comprehensive literature search (including non-English language & grey literature sources) • Duplicate study selection & data extraction • Summary of study characteristics & list of included studies provided • Study quality assessed (Cochrane RoB tool) • Risk of publication bias assessed	• None noted

Abbreviations: RCTs=randomized controlled trials; RoB=risk of bias

APPENDIX 4: Main Study Findings and Author's Conclusions

Table C: Summary of Findings of Included Studies

Main Study Findings	Author's Conclusions
Fitzpatrick (2016)[17]	
18 RCTs of various types of platelet-rich plasma (PRP) injection for tendinopathies, including 4 that used DN as a control. This network meta-analysis found that injections (corticosteroid, local anesthetic, or saline) or DN for tendinopathies had similar, non-significant effects on pain (& therefore could appropriately be used as controls). For the control interventions, the meta-analyses reported the standardized mean difference (SMD) in pain from baseline for each: • DN SMD 25.22 (95% CI, 21.27-29.16) • saline injection SMD 14.62 (95% CI, 10.74-18.50) • local anesthetic injection SMD 15.00 (95% CI, 7.66-22.34) • corticosteroid injection SMD 23.82 (95% CI, 10.74-18.50)	• "In assessing the control groups, there was no clear difference between different types of control injections: saline... local anesthetic… corticosteroid… or dry needling…"[17] page 1
Morihisa (2016)[8]	
This systematic review included 6 RCTs on knee, thigh, low back, & plantar fasciitis (heel pain). 4 of the studies were considered high quality & 2 were fair quality. The individual studies reported statistically significant short-term improvement in pain with dry needling, but this improvement was not shown at longer follow-up. None of the studies reported statistically significant improvements in other aspects, including range of motion & functioning.	• "A review of current literature suggests that dry needling is effective in reducing pain associated with lower quarter trigger points in the short-term. However, the findings suggest that dry needling does not have a positive effect on function, quality of life, depression, range of motion, or strength. Further high quality research with long-term follow-up investigating the effect of dry needling in comparison to and in conjunction with other interventions is needed to determine the optimal use of dry needling in treating patients with lower quarter trigger points."[8] page 1
Louwerens (2016)[22]	
22 studies (11 RCTs, remainder were prospective & retrospective cohort studies, and one prospective non-RCT). Most studies involved high-energy extracorporeal shockwave therapy or arthroscopic surgery, but 6 (2 RCTs) involved ultrasound-guided needling, for rotator cuff tendinopathy. (Ultrasound used to visualize calcific deposits to puncture them.)Needling techniques differed between studies, some included aspiration & lavage, and all included corticosteroid injection post-needling with patients under local anesthesia. Based on 4 studies with 1 year follow-up, functional outcomes were improved. Costs (not reported) were said to be similar to that of extracorporeal shockwave therapy. Minor side effects reported,	• "Patients can achieve good to excellent clinical outcomes after high-energy ESWT, US-guided needling, and arthroscopy for calcific tendinopathy of the shoulder. Side effects and post-treatment complications should be taken into account when a decision is being made for each individual patient. Physicians should consider high-energy ESWT and US-guided needling as minimally invasive treatment options when primary conservative treatment fails. Arthroscopy can safely be used as a very effective but more invasive secondary option, although the extent of deposit removal and the additional benefit of subacromial decompression remain unclear."[22] page 165

Table C: Summary of Findings of Included Studies	
Main Study Findings	**Author's Conclusions**
mainly pain during & after treatment. Authors note clinical results may also be affected by natural course of healing.	
Tsikopoulos (2016)[23]	
5 RCTs were included in this meta-analysis which assessed platelet-rich plasma (PRP) injections for pain & function in patients with tendinopathies (shoulder, elbow, knee). Dry needling was used as the control group in 2 trials (others used saline or corticosteroid injections as the control). Although there was a statistically significant difference favouring PRP at the 2-3 month follow-up point, at 6-month follow-up, PRP injections did not show a significant clinical benefit in comparison to needling or injections, except a small clinical benefit in patients with rotator cuff tendinopathy. In PRP for pain relief, at 6 months the SMD was -0.48 (95%CI -0.86 to -0.10), in comparison to SMD -0.82 (CI 95%, -1.57 to -0.07) in the one DN study with 6-month outcomes.	• "…PRP injections did not provide significantly greater clinical relief compared to placebo or dry needling for the treatment of tendinopathy at a six-month follow-up. However, there was a marginal clinical advantage in patients who suffered from rotator cuff tendinopathy. The latter marginal clinical superiority should be further investigated in large-scale RCTs…"[23] page 93
Rodriguez-Mansilla (2016)[24]	
19 RCTs (10 included in the meta-analysis) assessed effectiveness of dry needling on reducing pain in patients with myofascial pain syndrome (jaw, neck, shoulder, back, elbow, gluteal, other muscles, headache pain). Dry needling resulted in some improvement in pain compared to placebo, but other treatments (laser, injections, stretching exercises, ultrasound) were more effective than dry needling for pain & range of movement. For pain reduction measured immediately before & after the intervention, DN was not statistically different from placebo: SMD -0.49 (95% CI, -3.21, 0.42), & superior to control: SMD -9.13 (95% CI, -14.70, -3.56). But, other treatments were more effective at reducing pain immediately after: SMD 2.54 (95% CI, -0.40, 5.48), and at 3-4 weeks post-treatment: SMD 4.23 (95% CI, 0.78, 7.68). Similarly, DN significantly increased range of movement (ROM) immediately after the intervention compared to placebo: SMD 2.00 (95% CI, 1.0, 2.41), but other treatments achieved better results: SMD -1.42 (95% CI, -1.84, -0,99).	• "…Despite clinical practice showing that DN is increasingly used nowadays and that this technique is being applied with positive effects in rehabilitation medicine, especially for the management of MPS, we can observe that the scientific evidence observed in the studies analysed do not have consistent results regarding its effectiveness. In some papers, no significant differences were seen in the improvement of MPS between the groups when DN was compared with a control group or a stimulated DN group. The comparison of DN with other experimental groups showed that the subjects treated with the alternative technique achieved better results than those treated with DN…. Further randomized controlled trials are needed in order to determine the effectiveness of this technique in the management of MPS and consequently, recommend or not its use in physical therapy…."[24] page 11
Boyles (2015)[12]	
19 RCTs (one since retracted) were included to assess the effectiveness of trigger point dry needling in various conditions. Authors considered included studies to be high quality &	• "The majority of the highest-quality studies of TDN [trigger point dry needling] in the literature to date seem to indicate that TDN is effective for reducing pain and tenderness in multiple body

Table C: Summary of Findings of Included Studies	
Main Study Findings	**Author's Conclusions**
support the use of dry needling, however the heterogeneity of studies did not allow a meta-analysis. A commentary on this review noted several issues, most importantly: "… only 47% of the included trials showed a statistically significant decrease in pain when compared to sham or alternative treatments, only 26% displayed a statistically significant decrease in disability and 42% did not include a sham or control intervention group…." (page 2).[11] Moreover, almost a third of the trials only assessed immediate treatment effects (up to 72 hours after needling).[11]	regions, including the head, trunk, upper extremity and lower extremity. Lack of consistency among the articles in this review in regards to patient recruitment, protocol, methodology and outcome measures precludes the formation of any strong conclusions from the available data. Nevertheless, an emerging body of evidence exists to suggest that multiple body regions may benefit from TDN for pain reduction, improved function and improved ROM. More high-quality studies and replication of current studies are needed to further substantiate this trend…"[12] page 292
Di Matteo (2015)[25]	
22 studies (3 RCTs) on platelet-rich plasma injections for knee and Achilles heel tendinopathies were included in this systematic review. One small (23 pts) RCT (knee) used DN as the comparator, and found a benefit with the use of PRP at 3 months, but similar results between the two treatments at 6 months.	• "The main finding of this study was the paucity of high-level literature regarding the application of PRP in the management of patellar and Achilles tendinopathy… "[25] page 1 • Re the small, single study (RCT) that compared PRP to dry needling for patellar tendinopathy (knee pain): "PRP administration contributed to accelerating recovery time at 3 months… even if at 6 months, results were comparable between groups…"[25] page 4
Krey (2015)[20]	
4 RCTs were used to assess dry needling (DN) (with/without autologous blood or platelet-rich plasma injection (PRP)) for tendinopathies (shoulder, elbow, heel). Needling techniques differed and some trials did not use ultrasound guidance. Two trials found no difference between groups - needling with and without autologous blood injections - at 6 months. Based on two trials authors found benefit ("a trend toward improvement") with PRP in addition to needling over needling alone at 6 months.	• "…Based on the results of our systematic review, there is benefit from tendon needling for tendinosis in regard to patient-reported outcomes. Despite these results, more high-quality evidence is needed to further evaluate the benefit of tendon needling for tendinopathy. Randomized controlled trials focusing on the timing of the intervention, ultrasound guidance, the needling technique, and how often to intervene would be beneficial. … the studies in this review demonstrated a trend toward improvement with the addition of blood products. Differences in regard to the blood products used, subjective assessments, and tendons that were studied make it hard to conclude which technique is superior. It is also not known if needling enhances the use of the injected blood products."[20] page 86
Cagnie (2015)[26]	
15 RCTs (8 on dry needling) were included in this assessment of ischemic compression and DN in reducing pain and range of movement (ROM) for patients with neck pain. Different needling techniques were used in the studies and the optimal method is unclear. Evidence was rated as moderate to strong that both ischemic compression and DN can	• "… there is strong evidence that DN has a positive effect on pain reduction. This decrease is greater compared with active ROM exercises as well as no or placebo intervention, but it is similar to other therapeutic approaches. There is moderate evidence that both IC and DN increase side-bending ROM, with similar effects compared with lidocaine injection. There is weak evidence

Table C: Summary of Findings of Included Studies	
Main Study Findings	**Author's Conclusions**
decrease neck pain caused by trigger points in the upper trapezius muscle. 6 studies measured effect of DN on ROM. Most of these studies compared needling to lidocaine injection and found ROM improvements were similar for both interventions. Two studies (by same author) found that lidocaine injection and DN with paraspinal needling resulted in better ROM compared to needling only, but 2 other studies found no difference between groups.	regarding its effects on functionality and quality-of-life. Additional research with high-quality study design and appropriate comparative treatments are needed to develop more conclusive evidence."[26] pages 581-582
Liu (2015)[29]	
20 RCTs were included in this systematic review and meta-analysis of the effectiveness of DN on neck and shoulder pain. The meta-analysis found DN (compared to control or sham treatment) was effective in relieving pain in the short term (immediate to 3 days), SMD -1.91 (95% CI, -3.10 to -.73, P=.002) and medium term (9 to 28 days), SMD -1.07 (5% CI, -1.87 to -.27, P=.009). However, wet needling (injection of lidocaine) was more effective than DN for pain relief in the medium term, SMD 1.69 (95% CI, 0.40 to 2.98, P=.01). Other therapies, including physiotherapy, were also more effective in relieving pain than DN in the medium term, SMD 0.62 (95% CI, 0.02 to 1.21, P=0.04). All SMDs for DN were lower than the reported 1.3cm/1.4cm MCID.	• "… dry needling can be cautiously recommended for relieving MTrP pain in neck and shoulders in the short and medium term than control/sham, but wet needling is found to be more effective than dry needling in relieving MTrP pain in neck and shoulders in the medium term. On the basis of the results of 6 individual RCTs included in the meta-analysis of 7 studies, other treatments can be cautiously recommended for relieving MTrP pain in neck and shoulders in the medium term than dry needling. However, scientific evidence proving the effectiveness of dry needling for MTrPs associated with neck and shoulder pain compared with wet needling and other treatments in the short and long term is insufficient…"[29] page 954
Louwerens (2014)[27]	
This systematic review and meta-analysis included 20 studies for rotator cuff (shoulder) injury. Most of the RCTs were on extracorporeal shock wave treatment (ESWT), 2 RCTs included ultrasound-guided needling. Meta-analysis was conducted, where possible, given heterogeneity of studies. Based on one small moderate level of evidence study, corticosteroid injection was more effective (but not statistically significantly different) in improving function at 6 months than ultrasound-guided needling (mean difference 6.42 (95% CI, -2.56 to 15.40, P=0.16). Based on one other low quality study of needling versus no treatment for pain relief at 3 months, the mean difference was -4.0 (95% CI, -4.5 to -3.5, P <0.0001).	• "Ultrasound-guided needling is safe but has not been proven to be more effective than an ultrasound-guided subacromial corticosteroid injection in recent level I research, and further research will have to prove its effectiveness."[27] page 1240 • "Furthermore, there is no evidence about what the best US-guided needling technique is, because single-needling and double-needling techniques are both used in modern practice."[27] pages 1247-1248
Moon (2014)[30]	
6 RCTs of acupuncture, electroacupuncture or DN for the treatment of whiplash associated disorder (WAD) were included in this systematic review. Meta-analysis of the studies was not feasible. The evidence is limited and most RCTs	• Re the feasibility study (RCT) that compared DN+physiotherapy to sham DN+physiotherapy in 34 women with grade II whiplash associated disorder: "… After six weeks, the authors reported no between group differences … and

Table C: Summary of Findings of Included Studies	
Main Study Findings	**Author's Conclusions**
had methodological flaws. One RCT found DN+physio was no different than sham needling+physio for pain reduction. None of the RCTs found any of the interventions (including DN) to be more effective than the various control interventions for reducing disability/function.	concluded that a large RCT is both feasible and clinically relevant."[30] page 3 • Overall conclusions: "The evidence for the effectiveness of AT/EA/DN for the treatment of WAD is limited. Therefore, more research in this area is warranted.[30] page 1
Ong (2014)[28]	
Five small RCTs (4 rated high quality, 1 rated low quality) were included in this systematic review and meta-analysis on neck and shoulder pain. Where possible, outcomes at different times were assessed (immediately after treatment, and at 1, and 3 to 6 months). The meta-analysis of DN compared to lidocaine injection for pain relief (based on 4 studies) found no significant differences immediately after treatment: SMD 0.41 (95% CI, -0.15 to 0.97), at one month: SMD -1.46 (95% CI, -2.04 to 4.96), and at 3 to 6 months: SMD -0.28 (95% CI, -0.63 to 0.07).	• "The main conclusion of this systematic review with meta-analysis is there is no significant difference between dry needling and lidocaine in the management of MTrPs in the neck and shoulder region. However, it should be acknowledged that these analyses are based on a relatively small number of participants… Further conclusions of this review is that there is limited evidence of no significant difference between dry needling and placebo for pain intensity and activity outcomes immediately after treatment and at 6 month follow-up. There is also limited evidence of no significant difference between dry needling and lidocaine on activity levels immediately after treatment and at 1 month. As dry needling is as effective as lidocaine injection, dry needling may be more favorable and more feasible in the physiotherapy clinical setting due to it being minimally invasive, lower cost, and has less adverse effects than a local anesthetic injection…"[28] page 397
Kietrys (2013)[21]	
12 RCTs were used to assess the effectiveness of DN on various types of upper body myofascial pain. The Interventions and study populations were heterogeneous. A subset of trials was suitable for inclusion in the meta-analyses. Despite the results of the statistical analyses, the authors feel there is good quality evidence (based on 4 studies) that dry needling is more effective than sham or placebo treatment in reducing pain immediately after treatment compared to sham or placebo: SMD 1.06 (95% CI, 0.05, 2.06), but the difference was not statistically significant at 4 weeks (based on 3 studies): SMD 1.07 (95% CI, -0.21, 2.35). In comparing DN to other treatments for immediate pain relief, results of the meta-analysis of 2 studies favoured lidocaine injection or non-localized acupuncture over DN: SMD -0.64 (95% CI, -1.21, -0.06). Comparing DN to other treatments at 4 weeks, meta-analysis of 6 studies also favoured other treatments over DN, but the differences were not	• "… More evidence is needed to establish efficacy of dry needling compared to other interventions for upper-quarter MPS. However, it appears that injection with lidocaine may be superior to dry needling for pain reduction both immediately after treatment and at 4 weeks."[21] page 633

Table C: Summary of Findings of Included Studies	
Main Study Findings	**Author's Conclusions**
statistically significant: SMD -0.07 (95% CI, -1.39, 1.26).	
Kim (2012)[31]	
Four RCTs were included in this systematic review of intramuscular stimulation therapy (IMS) for various types of pain (headache, shoulder, upper body, lower back). Individual studies had positive results for IMS but were subject to high risk of bias. One study found no significant difference between IMS and meloxicam drug therapy for chronic shoulder pain. IMS was superior to DN for shoulder pain in one study. IMS+standard treatment was superior to standard treatment alone in patients with low back pain.	• "… the results of this systematic review do not provide conclusive evidence in support of IMS for several conditions. Although the trial data are positive …. Too many important caveats – including small sample size and only one RCT for each condition – exist to draw firm conclusions."[31] page 290

Abbreviations: AT=acupuncture; CI=confidence interval; EA=electroacpuncture; DN=dry needling; ESWT=extracorporeal shockwave therapy; IC=ischemic compression; MCID=minimum clinically important difference; MPS=myofascial pain; MTrP=myofascial trigger point; platelet-rich plasma injection; RCT=randomized controlled trial; SMD=standardized mean difference; TDN=trigger point dry needling; US=ultrasound; WAD=whiplash associated disorder

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Dry needling in the management of myofascial trigger points: A systematic review of randomized controlled trials

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ARTICLE INFO

Keywords:
Myofascial pain syndrome
Myofascial trigger point
Dry needling
Pain

ABSTRACT

Objective: This systematic review of randomized controlled trials aimed to examine the effectiveness of dry needling in the treatment of myofascial trigger points and to explore the impact of specific aspects of the technique on its effectiveness.
Methods: Relevant studies published between 2000 and 2015 were identified by searching PubMed, Scopus, The Cochrane Library and Physiotherapy Evidence Database. Studies identified by electronic searches were screened against a set of pre-defined inclusion criteria.
Results: Fifteen studies were included in this systematic review. The main outcomes that were measured were pain, range of motion, disability, depression and quality of life. The results suggest that dry needling is effective in the short term for pain relief, increase range of motion and improve quality of life when compared to no intervention/sham/placebo. There is insufficient evidence on its effect on disability, analgesic medication intake and sleep quality.
Conclusions: Despite some evidence for a positive effect in the short term, further randomized clinical trials of high methodological quality, using standardized procedures for the application of dry needling are needed.

1. Introduction

Myofascial Trigger Points (MTrPs) are "hyperirritable points in skeletal muscle that are associated with a hypersensitive palpable nodule in a taut band".[1] It is estimated that MTrPs are the primary cause of pain in 30–85% of those with musculoskeletal disorders.[2–4] The MTrPs seem to be associated with histological (shortening of involved sarcomeres and tissue hypoxia) [5] and biochemical (excessive release of acetylcholine, lowered pH and excessive release of P substance) [6,7] changes, which influence the process of sensitization of the central and peripheral nervous system.[6,8]

Myofascial pain syndrome is a regional muscular pain condition characterized by MTrPs found in one or more muscles and/or connective tissues.[9] It can be associated with pain, muscle spasm, increased sensitivity, stiffness, muscle weakness, decreased range of motion and autonomic dysfunction.[9] The mechanical stimulation of MTrPs can cause local and referred pain, motor dysfunction and autonomic phenomena.[9,10] Despite the clinical acceptance of MTrPs, its role as a relevant clinical entity in the pathogenesis of myofascial pain syndrome is still controversial.[11]

MTrPs and myofascial pain syndrome have been treated with several therapeutic modalities, including therapeutic ultrasound,[12,11] ischemic compression techniques,[12,13] muscle energy techniques,[13] stretching,[13] manipulation,[14] acupuncture [4[4]] and dry needling.[15] During the last decade, evidence on the role of dry needling of MTrPs in the management of several musculoskeletal disorders has been increasing, including plantar heel pain,[16] temporomandibular disorders,[17,18] epicondylalgia [19] or myofascial pain syndrome.[20] Dry needling consists of using a needle, as a physical agent, to create a mechanical stimulus with the goal of deactivating the trigger point.[21] It is an invasive procedure, where the needle is inserted through the skin and muscle into the MTrP.[15] Once the MTrP is deactivated, the needle is removed.[22] It is cheap, easy to learn and with low risks associated.[23] Despite being a technique commonly used by health professionals, its clinical effectiveness is not clear. A recent systematic review on the effectiveness of dry needling has focused on MTrPs associated with the

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Systematic review

Effects of dry needling trigger point therapy in the shoulder region on patients with upper extremity pain and dysfunction: a systematic review with meta-analysis

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Abstract

Question What is the effectiveness and what are the adverse effects.
Design Systematic review with meta-analysis.
Participants Patients with shoulder or upper extremity pain or dysfunction.
Intervention Trigger point dry needling (TDN) compared to control, another intervention or another needling technique.
Outcome measures Primary outcome measures included shoulder or upper limb pain, shoulder or upper limb dysfunction.
Results Eleven randomized trials involving 496 participants were appraised. There was very low evidence that trigger point dry needling of the shoulder region is effective for reducing pain and improving function in the short term. There is some evidence that needling both active and latent trigger points is more effective than needling an active trigger point alone for pain immediately and 1-week after treatment (SMD = −0.74, 95%CI = −1.2 to −0.3; and SMD = −1.0, 95%CI = −1.52 to −0.59).
Conclusion There is very low evidence to support the use of TDN in the shoulder region for treating patients with upper extremity pain or dysfunction. Two studies reported adverse effects to TDN interventions. Most common adverse effects included bruising, bleeding, and pain during or after treatment. Future studies are likely to change the estimates of the effectiveness of TDN for patients with upper extremity pain or dysfunction.

PROSPERO: CRD42016045639.

Keywords: Trigger point; Dry needling; Myofascial pain; Shoulder; Acupuncture

Introduction

Upper extremity pain and disorders are a major worldwide problem and are a huge economic burden, with high healthcare costs and time off work [1]. Shoulder pain is the third most common musculoskeletal reason for primary care consultations in the United Kingdom [2]. The cumulative annual incidence of shoulder pain ranges from 1 to 3% of general practice consultations [3–5], while the 12 month prevalence of upper extremity disorders may reach 41% [1].

Myofascial trigger points (MTPs) are frequently found in the shoulder muscles of patients with upper extremity complaints [6] and can restrict movement, alter muscle timing and cause pain [7]. There are two types of MTPs: latent and active, and both are tender taut bands within muscles that under mechanical stimulation produce local or referred pain, hyperalgesia, allodynia, motor [8] or autonomic changes [9]. Latent MTPs produce pain only on mechanical stimulation, such as direct pressure or needling. Active spontaneously MTPs cause symptoms at rest or during activity [7]. MTPs can be the result of sustained posture or may develop as a result of neuromuscular disorder or injury, and can lead to muscle weakness and inhibition.

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REVIEW ARTICLE (META-ANALYSIS)

Evidence for Dry Needling in the Management of Myofascial Trigger Points Associated With Low Back Pain: A Systematic Review and Meta-Analysis

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Abstract

Objective: To evaluate the current evidence of the effectiveness of dry needling of myofascial trigger points (MTrPs) associated with low back pain (LBP).

Data Sources: PubMed, Ovid, EBSCO, ScienceDirect, Web of Science, Cochrane Library, CINAHL, and China National Knowledge Infrastructure databases were searched until January 2017.

Study Selection: Randomized controlled trials (RCTs) that used dry needling as the main treatment and included participants diagnosed with LBP with the presence of MTrPs were included.

Data Extraction: Two reviewers independently screened articles, scored methodologic quality, and extracted data. The primary outcomes were pain intensity and functional disability at postintervention and follow-up.

Data Synthesis: A total of 11 RCTs involving 802 patients were included in the meta-analysis. Results suggested that compared with other treatments, dry needling of MTrPs was more effective in alleviating the intensity of LBP (standardized mean difference [SMD], −1.06; 95% confidence interval [CI], −1.77 to −0.36; $P=.003$) and functional disability (SMD, −0.76; 95% CI, −1.46 to −0.06; $P=.03$); however, the significant effects of dry needling plus other treatments on pain intensity could be superior to dry needling alone for LBP at postintervention (SMD, 0.83; 95% CI, 0.55−1.11; $P<.00001$).

Conclusions: Moderate evidence showed that dry needling of MTrPs, especially if associated with other therapies, could be recommended to relieve the intensity of LBP at postintervention; however, the clinical superiority of dry needling in improving functional disability and its follow-up effects still remains unclear.

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Low back pain (LBP) is a worldwide health problem and the most common reason for musculoskeletal disorders, especially in sedentary people, and even in highly trained athletes.[1,2] It has been estimated that as many as 85% of citizens in developed countries experience LBP at some point throughout their lifetime; therefore, LBP has become one of the most common reasons for medical visits to physician offices and emergency departments in the United States.[3,4] LBP can result in significant levels of disability, producing significant restrictions on work efficiency and quality of life of patients.[5] More importantly, it also imposes huge economic burden on families and society.[6]

At present, the management of LBP comprises a range of different intervention strategies (eg, minimally invasive surgery, exercise therapy, acupuncture and dry needling, physiotherapy, behavioral therapy, massage, oral drugs).[7,8] Among these strategies, dry needling is becoming an increasingly popular nonsurgical treatment method for relieving LBP and improving functional disability related to pain because of its simple operation and good efficacy.[9,10] In clinical practice, dry needling usually refers to deep dry needling, which is a minimally invasive procedure during which a thin filiform needle is directly inserted into an active myofascial trigger point (MTrP), with the condition of

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Systematic Review

TMJ Disorders

A systematic review of different substance injection and dry needling for treatment of temporomandibular myofascial pain

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E. Machado, P. Machado, V. F. Wandscher, A. M. E. Marchionatti, F. B. Zanatta, O. B. Kaizer: A systematic review of different substance injection and dry needling for treatment of temporomandibular myofascial pain. Int. J. Oral Maxillofac. Surg. 2018; 47: 1420–1432.

Abstract. Temporomandibular myofascial pain presents a major challenge in the diagnosis of temporomandibular disorders (TMD). Due to the characteristics of this condition, intramuscular injection procedures are often needed for adequate control of symptoms and treatment. Thus, the aim of this systematic review was to evaluate the effectiveness of dry needling and injection with different substances in temporomandibular myofascial pain. Electronic databases PubMed, EMBASE, CENTRAL/Cochrane, Lilacs, Scopus, Web of Science and CAPES Catalog of Dissertations and Theses were searched for randomized clinical trials until January 2018. Manual search was performed in relevant journals and in the references/citations of the included studies. The selection of studies was carried out by two independent reviewers according to eligibility criteria. From 7128 eligible studies, 137 were selected for full-text analysis and 18 were included. Due to the heterogeneity of the primary studies it was not possible to perform a meta-analysis. The narrative analysis of the results showed that most of the studies had methodological limitations and biases that compromised the quality of the findings. Dry needling and local anaesthesic injections seem promising, but there is a need to conduct further randomized clinical trials, with larger samples and longer follow-up times, to evaluate the real effectiveness of the technique and evaluated substances.

Key words: myofascial pain dysfunction syndrome; temporomandibular joint disorders; local anaesthetics; botulinum toxins; dry needling.

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Myofascial pain is part of muscle temporomandibular disorder (TMD), and its diagnosis and treatment are a constant challenge for the professional. Estimates indicate that 42% of TMD diagnoses correspond to temporomandibular myofascial pain[1]. In relation to the prevalence, there are rates ranging from 5 to 10%, with greater involvement of the female gender[2–4].

This condition is characterized by the presence of painful trigger points in com-

2020 CPT Code Review
Drug Delivery Devices

Codes:

1) CPT **20700** Manual preparation and insertion of drug-delivery device(s), deep (eg, subfascial) (List separately in addition to code for primary procedure)
2) CPT **20701** Removal of drug-delivery device(s), deep (eg, subfascial) (List separately in addition to code for primary procedure)
3) CPT **20702** Manual preparation and insertion of drug-delivery device(s), intramedullary (List separately in addition to code for primary procedure)
4) CPT **20703** Removal of drug-delivery device(s), intramedullary (List separately in addition to code for primary procedure)
5) CPT **20704** Manual preparation and insertion of drug-delivery device(s), intra-articular (List separately in addition to code for primary procedure)
6) CPT **20705** Removal of drug-delivery device(s), intra-articular (List separately in addition to code for primary procedure

Description: Codes 20700-20705 describe manual preparation and insertion of implants designed to deliver drugs, such as antibiotics, to deep musculoskeletal spaces. The implants may take the form of beads, intramedullary nails or temporary joint spacers, placed when a patient develops an infection around a joint arthroplasty requiring its removal. These codes can also be used for treatment of infected joints, infected fractures, etc.

These codes are secondary codes to the primary procedure code, such as removal of joint hardware.

These procedures were previously coded using CPT 11981 (Insertion, non-biodegradable drug delivery implant) and CPT 11982 (Removal, non-biodegradable drug delivery implant), but these CPT codes have generally been used for devices such as Nexplanon.

HERC staff recommendation:

1) Option 1
    a. Add CPT 20700-20705 to the Ancillary List
        i. Will be covered when primary code is on covered line
2) Option 2
    a. Place CPT 20700-20705 on the following orthopedic lines

2020 CPT Code Review
Drug Delivery Devices

Line	Line Description
47	DEEP ABSCESSES, INCLUDING APPENDICITIES AND PERIORBITAL ABSCESSES
80	FRACTURE OF HIP
82	DEEP OPEN WOUND OF NECK, INCLUDING LARYNX; FRACTURE OF LARYNX OR TRACHEA
98	CARDIOMYOPATHY
107	FRACTURE OF RIBS AND STERNUM, OPEN
131	CRUSH INJURIES OTHER THAN DIGITS; COMPARTMENT SYNDROME
132	OPEN FRACTURE/DISLOCATION OF EXTREMITIES
150	CERVICAL VETEBRAL DISLOCATIONS/FRACTURES, OPEN OR CLOSED…
153	PYOGENIC ARTHRITIS
160	TRAUMATIC AMPUTATION OF ARMS…
183	FRACTURE OF PELVIS, OPEN AND CLOSED
184	ACUTE OSTEOMYELITIS
199	CANCER OF SOFT TISSUE
200	CANCER OF BONES
205	SUPERFICIAL ABSCESSES AND CELLULITIS
207	DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT
235	LIMB-THREATENING VASCULAR DISEASE, INFECTIONS, AND VASCULAR…
254	CHRONIC OSTEOMYELITIS
272	TRAUMATIC AMPUTATION OF FOOT/FEET
285	COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
292	NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
309	CONGENITAL DISLOCATION OF HIP; COXA VARA AND VALGA
346	CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS
355	CLOSED FRACTURE OF EXTREMITIES (EXCEPT MINOR TOES)
356	RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE
359	DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
372	BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS
376	DISRUPTIONS OF THE LIGAMENTS AND TENDONS OF THE ARMS AND LEGS, EXCLUDING THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT
379	CHRONIC ULCER OF SKIN
401	BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS
418	DISORDERS OF SHOULDER, INCLUDING SPRAINS/STRAINS GRADE 4…
424	COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
431	INTERNAL DERANGEMENT OF KNEE AND LIGAMENTOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT
442	MALUNION AND NONUNION OF FRACTURE
505	PERIPHERAL ENTHESOPATHIES
527	DEFORMITIES OF UPPER BODY AND ALL LIMBS
529	CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
558	BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE INCLUDING OSTEOID OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE
578	CAVUS DEFORMITY OF FOOT; FLAT FOOT; POLYDACTYLY AND SYNDACTYLY OF TOES
598	CONGENITAL DEFORMITIES OF KNEE
643	TMJ DISORDERS

2020 CPT Code Review Issues
Preperitoneal Pelvic Packing

Codes

1) CPT **49013** Preperitoneal pelvic packing for hemorrhage associated with pelvic trauma, including local exploration
2) CPT **49014** Re-exploration of pelvic wound with removal of preperitoneal pelvic packing, including repacking, when performed

Description: One of two techniques for treating hemodynamically unstable patients with hemorrhage due to pelvic facture (the other is angioembolization). Preperitoneal pelvic packing is a surgical procedure to address pelvic bleeding originating from the presacral venous plexus and fracture sites. Typically this procedure is done to allow time to address other injuries or to get the patient to definitive operative treatment of the pelvic injuries.

Evidence

1) **Filiberto 2016**, review of preperitoneal pelvic packing
    a. Management of patients with hemodynamically unstable pelvic fractures is challenging and requires a multidisciplinary approach. Although the role of preperitoneal pelvic packing (PPP) in the treatment algorithm is not clearly established, the literature supports PPP as a technique to control massive pelvic hemorrhage. Importantly, this can be life-saving in institutions that do not offer immediate angiography on a 24-hr basis or in patients who are too unstable for transport.

HERC staff summary

There is little published literature regarding preperitoneal pelvic packing. However, this procedure is considered life-saving in some circumstances and is unlikely to be studied in the future. It is highly unlikely to be abused.

HERC staff recommendation:

1) Place CPT **49013** and **49014** on line 183 FRACTURE OF PELVIS, OPEN AND CLOSED

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journal homepage: www.journal-surgery.net

Review

Preperitoneal pelvic packing: Technique and outcomes

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HIGHLIGHTS

- Significant pelvic ring fractures can result in mortality rates ranging from 40 to 60%.
- The major cause of death in the first 24 h after pelvic trauma is attributed to hemorrhage; later mortality is secondary to multisystem organ failure.
- Preperitoneal pelvic packing can be life saving, especially if angioembolization is not immediately available.

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ABSTRACT

Significant pelvic ring fractures are usually secondary to high-energy trauma, and when associated with other life-threatening injuries and hemodynamic instability, result in high mortality rates ranging from 40 to 60%. The major cause of death during the first 24 h after pelvic trauma is attributed to acute blood loss, with later mortality secondary to multisystem organ failure. In a majority of patients, the source of pelvic bleeding is from disruption of the presacral venous plexus and bony fracture sites, while arterial injury is present in only 10–15%. The optimal management algorithm for hemodynamically unstable patients with pelvic fractures remains controversial. The principles of care center on resuscitation, external stabilization of the pelvis, and hemorrhage control with angiography and embolization (AE) and/or preperitoneal pelvic packing (PPP). AE is effective in controlling arterial bleeding and its role in the management of hemodynamically unstable patients with pelvic fractures is supported by the EAST guidelines. However, since most patients suffer from venous bleeding, PPP can be an alternate life saving technique to control hemorrhage, especially if AE is not immediately available.

Significant pelvic ring fractures are usually secondary to high-energy trauma, and when associated with other life-threatening injuries and hemodynamic instability, result in high mortality rates ranging from 40 to 60% [1–4]. The major cause of death during the first 24 h after pelvic trauma is attributed to acute blood loss, with later mortality secondary to multisystem organ failure [5]. In a majority of patients, the source of pelvic bleeding is from disruption of the presacral venous plexus and bony fracture sites, while arterial injury is present in only 10–15% [6]. The optimal management algorithm for hemodynamically unstable patients with pelvic fractures remains controversial. The principles of care center on resuscitation, external stabilization of the pelvis, and hemorrhage control with angiography and embolization (AE) and/or preperitoneal pelvic packing (PPP). AE is effective in controlling arterial bleeding and its role in the management of hemodynamically unstable patients with pelvic fractures is supported by the EAST guidelines [7]. However, since most patients suffer from venous bleeding, PPP can be an alternate life saving technique to control hemorrhage, especially if AE is not immediately available.

In 1926, Logothetopulos first described pelvic packing as a means of controlling massive pelvic bleeding [8]. Other authors described a *trans*-peritoneal approach to tamponade pelvic bleeding using a Pfannenstiel, paramedian, or infraumbilical incision; however packing was often used as a salvage maneuver and early attempts at direct control of pelvic bleeding were abandoned [9,10]. The technique was modified to a preperitoneal approach by Pohlemann in 1995 and most recently described by the Denver group and Totterman et al. [11–13].

For the preperitoneal technique, the patient is placed in a supine position. The pelvis must be mechanically stabilized with a C-clamp, external fixator, or a temporary pelvic binder. Failure to do

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2020 CPT Code Review
Sacroiliac Nerve Procedures

Codes:

1) CPT **64451** Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)
2) CPT **64625** Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)

Description: Anesthetic injections or radiofrequency ablation (RFA) are procedures used to treat SI joint pain. The literature is unclear on what nerves precisely innervate the SI joint. Most of the posterior sensory innervation is thought to be transmitted from the S1, S2, and S3 dorsal rami via the lateral branches, as well as through medial branches from the L4 and L5 dorsal rami. Anesthetic injections can help to diagnose the cause of pain, or can be used therapeutically to relieve pain. When temporary anesthetic SI nerve injections are effective, a more long-term destruction of the nerve with RFA can be done.

Similar codes

CPT 64450 (Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch) is ancillary and governed by the ancillary guideline for nerve blocks. Most other nerve blocks are also ancillary; however, the paravertebral facet joint nerve injections (CPT 64490-64492) are on line 662.

CPT 64640 (Destruction by neurolytic agent; other peripheral nerve or branch) was used for the procedures now broken out into 64624 and 64635. CPT 64640 was on line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS but was only reviewed for radiofrequency ablation of the knee. See Genicular Nerve issue for recommendations on CPT 64640.

Evidence Review

1) **Sun 2018**, systematic review and meta-analysis of radiofrequency ablation for chronic SI joint pain
    a. N=7 studies (240 patients)
        i. 2 RCTs (Nilesh 2016, Steven 2008), 79 patients
        ii. 1 prospective cohort study (Haktan 2011), 15 patients
        iii. 4 retrospective cohort studies (Leonardo 2008, Kok 2013, Andrea 2017, Wolfgang 2017), 177 patients
    b. The overall pooled results demonstrated that pain intensity decreased significantly after cooled radiofrequency procedure compared with that measured before treatment. The mean difference (MD) was 3.81 [95% confidence intervals (95% CIs): 3.29–4.33, P<.001] and 3.78 (95% CIs: 3.31–4.25, P<.001) as measured by the Numerical Rating Scale (NRS) and Visual Analog Scale (VAS), respectively. Disability also relieved significantly after treatment compared with that measured before treatment. The MD was 18.2 (95% CIs: 12.22–24.17, P<.001) as measured by the Oswestry Disability Index (ODI). Seventy-two percent of the patients presented positive results as measured by the Global Perceived Effect (GPE). The OR was 0.01 (95% CIs: 0.00–0.05, P<.001). Only mild complications were observed in the 7 studies, including transienthip pain, soreness, and numbness.
    c. Conclusion: Cooled radiofrequency procedure can significantly relieve pain and disability with no severe complications, and majority of patients are satisfied with this technique.

Thus, it is safe and effective to use this procedure in managing patients with chronic SIJ pain. More high-quality and large-scale randomized controlled trials (RCTs) are required to validate our findings.

d. Limitations: The sample size of the included studies was small and various heterogeneity existed.

2) **King 2015**, systematic review of radiofrequency ablation for sacroiliac pain
   a. N=17 studies
      i. N=2 studies on diagnostic blocks (anesthetic injection)
      ii. N=15 studies on RFA
         1. 4 prospective observational, 9 retrospective observational, 2 "explanatory studies"
         2. The studies had widely different criteria for patient selection and a variety of treatment techniques, which differed both in structures targeted and radiofrequency (RF) technologies used
   b. Results for diagnostic anesthetic injections: 2 RCTS of asymptomatic people (N=15, 20) showed what injections could result in SI joint numbness in 40-70% of people
   c. Results for RFA:
      i. 10 studies showed between 32 and 89% of patients had >50% pain relief
      ii. 6 studies showed 11-44% of patients with 100% pain relief
   d. Conclusions. The literature on sacral lateral branch interventions is sparse. One study demonstrates the face validity of multisite, multidepth sacral lateral branch blocks for diagnosis of posterior sacroiliac complex pain. Some evidence of moderate quality exists on therapeutic procedures, but it is insufficient to determine the indications and effectiveness of sacral lateral branch thermal radiofrequency

<u>Other payer policies</u>

1) Cigna 2019: RFA of the SI joint is considered experimental

<u>HERC staff summary</u>

The evidence base for RFA of the SI joint nerves consists mainly of small observational trials, with variation in diagnostic criteria, patient selection, treatment modality and outcomes measured. The efficacy of RFA for SI joint nerves is therefore insufficient. If ablation of the nerves is not covered, then the anesthetic injection for diagnosis does not need to be covered.

Of note, Guideline Note 161 mentions SI joint anesthetic injections but is referring to joint injections, not nerve injections. This should be clarified.

2020 CPT Code Review
Sacroiliac Nerve Procedures

HERC staff recommendations:

1) Recommend HSD place CPT **64451** (Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)) on line 662/GN173
    a. Similar to paravertebral facet injections which are on line 662
2) Place CPT **64625** (Radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance (ie, fluoroscopy or computed tomography)) on line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS and modify GN173 as shown below
    a. Lack of evidence of effectiveness
3) Modify GN161 as shown below to clarify that SI joint, but not nerve, injections are included in the GN

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

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
64451, 64625	Anesthetic or steroid injection and/or r~~R~~adiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance	Insufficient evidence of effectiveness	November 2019

GUIDELINE NOTE 161, SACROILIAC ~~ANESTHETIC~~ JOINT INJECTIONS AND SACROILIAC JOINT FUSION

Line 527

Sacroiliac joint (SIJ) injection (CPT 20610 and 27096, and HCPCS G0260) is included on this line for diagnostic sacroiliac injections with anesthetic only, but not for therapeutic injections or corticosteroid injections. Injections are only covered for patients for whom SIJ fusion surgery is being considered.

SIJ 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, SIJ 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 SIJ, and consistent with SIJ 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 or PSIS) 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 SIJ that excludes the presence of destructive lesions (e.g. tumor, infection), fracture, traumatic sacroiliac 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 SIJ that indicates evidence of injury and/or degeneration

H) 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 SIJ injection.

Systematic Review and Meta-Analysis

Medicine®

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The efficacy and safety of using cooled radiofrequency in treating chronic sacroiliac joint pain

A PRISMA-compliant meta-analysis

Hui-Hui Sun, MPhil[a,b], Su-Yang Zhuang, PhD[a], Xin Hong, MD[a], Xin-Hui Xie, PhD[a], Lei Zhu, MPhil[a], Xiao-Tao Wu, PhD[a,*]

Abstract

Background: Cooled radiofrequency procedure is a novel minimally invasive surgical technique and has been occasionally utilized in managing chronic sacroiliac joint (SIJ) pain. A meta-analysis was conducted to systematically assess the efficacy and safety of using cooled radiofrequency in treating patients with chronic SIJ pain in terms of pain and disability relief, patients' satisfaction degree as well as complications.

Methods: Studies of using cooled radiofrequency procedure in managing SIJ pain were retrieved from Medline and Web of Science according to inclusion and exclusion criteria. Quality evaluation was conducted using Cochrane collaboration tool for randomized controlled trials and MINORS quality assessment for noncomparative trials. Statistics were managed using Review Manager 5.3.

Results: Totally 7 studies with 240 eligible patients were enrolled. The overall pooled results demonstrated that pain intensity decreased significantly after cooled radiofrequency procedure compared with that measured before treatment. The mean difference (MD) was 3.81 [95% confidence intervals (95% CIs): 3.29–4.33, $P < .001$] and 3.78 (95% CIs: 3.31–4.25, $P < .001$) as measured by the Numerical Rating Scale (NRS) and Visual Analog Scale (VAS), respectively. Disability also relieved significantly after treatment compared with that measured before treatment. The MD was 18.2 (95% CIs: 12.22–24.17, $P < .001$) as measured by the Oswestry Disability Index (ODI). Seventy-two percent of the patients presented positive results as measured by the Global Perceived Effect (GPE). The OR was 0.01 (95% CIs: 0.00–0.05, $P < .001$). Only mild complications were observed in the 7 studies, including transient hip pain, soreness, and numbness.

Conclusion: Cooled radiofrequency procedure can significantly relieve pain and disability with no severe complications, and majority of patients are satisfied with this technique. Thus, it is safe and effective to use this procedure in managing patients with chronic SIJ pain. More high-quality and large-scale randomized controlled trials (RCTs) are required to validate our findings.

Limitations: The sample size of the included studies was small and various heterogeneity existed.

Abbreviations: CIs = confidence intervals, GPE = Global Perceived Effect, MD = mean difference, NRS = Numerical Rating Scale, ODI = Oswestry Disability Index, OR = odds ratio, PSN = posterior sacral network, RCT = randomized controlled trials, SD = standard deviation, SIJ = sacroiliac joint, VAS = Visual Analog Scale.

Keywords: cooled radiofrequency, meta-analysis, sacroiliac joint pain

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Pain Medicine

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SPINE SECTION

Original Research Articles

Diagnosis and Treatment of Posterior Sacroiliac Complex Pain: A Systematic Review with Comprehensive Analysis of the Published Data

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Conflicts of interest: Nileshkumar Patel MD has a consulting agreement with Kimberly Clark, and the study on sacroiliac neurotomy was sponsored by Bayliss Medical, which was subsequently acquired by Kimberly Clark. None of the other authors have any financial conflicts of interest to disclose.

Abstract

Objective. To assess the evidence on the validity of sacral lateral branch blocks and the effectiveness of sacral lateral branch thermal radiofrequency neurotomy in managing sacroiliac complex pain.

Design. Systematic review with comprehensive analysis of all published data.

Interventions. Six reviewers searched the literature on sacral lateral branch interventions. Each assessed the methodologies of studies found and the quality of the evidence presented.

Outcome Measures. The outcomes assessed were diagnostic validity and effectiveness of treatment for sacroiliac complex pain. The evidence found was appraised in accordance with the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) system of evaluating scientific evidence.

Results. The searches yielded two primary publications on sacral lateral branch blocks and 15 studies of the effectiveness of sacral lateral branch thermal radiofrequency neurotomy. One study showed multisite, multidepth sacral lateral branch blocks can anesthetize the posterior sacroiliac ligaments. Therapeutic studies show sacral lateral branch thermal radiofrequency neurotomy can relieve sacroiliac complex pain to some extent. The evidence of the validity of these blocks and the effectiveness of this treatment were rated as moderate in accordance with the GRADE system.

Conclusions. The literature on sacral lateral branch interventions is sparse. One study demonstrates the face validity of multisite, multidepth sacral lateral branch blocks for diagnosis of posterior sacroiliac complex pain. Some evidence of moderate quality exists on therapeutic procedures, but it is insufficient to determine the indications and effectiveness of sacral lateral branch thermal radiofrequency neurotomy, and more research is required.

Key Words. Posterior Sacroiliac Complex Pain; Lateral Branch Block; Radiofrequency Lateral Branch Neurotomy; Sacroiliac Joint

Introduction

The sacroiliac complex includes articulation between the sacrum and ilium, together with its capsule that forms

2020 CPT Code Review
Genicular Nerve Procedures

Codes:

1) CPT **64454** Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed
2) CPT **64624** Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed

Description: Genicular nerve blocks and genicular radiofrequency ablation are procedures used in the treatment of chronic knee pain for individuals that have not been effectively managed by pharmacologic or other alternative therapies. The new code 64624 is to be used for radiofrequency ablation of the nerves innervating the knee.

Review of the literature finds that the only indication for genicular nerve blocks are for preoperative evaluation prior to genicular radiofrequency ablation.

Similar codes

CPT 64450 (Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch) is ancillary and governed by the ancillary guideline for nerve blocks. Most other nerve blocks are also ancillary; however, the paravertebral facet joint nerve injections (CPT 64490-64492) are on line 662.

CPT 64640 (Destruction by neurolytic agent; other peripheral nerve or branch) was previously used for the procedures now broken out into 64624 and 64635. CPT 64640 is on line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS but was only reviewed for radiofrequency ablation of the knee.

Past HERC review

HERC reviewed RFA for knee osteoarthritis in May, 2019. From that review: "The body of evidence to date on radiofrequency ablation for knee osteoarthritis consists of only a few small RCTs at moderate-to-high risk of bias. The WA HTA concluded that the quality of evidence is very low, but is in favor of peripheral nerve ablation for improving short term function and pain. Further research is ongoing for this technology. Other therapies for knee osteoarthritis, including injections, medications, and surgeries, are currently paired with this diagnosis. RFA is not currently included in expert treatment guidelines and is not currently covered by major insurers." Based on this review, knee RFA was placed on current line 662 using the generic CPT code 64640. Prior to this review, CPT 64640 was ancillary.

2020 CPT Code Review
Genicular Nerve Procedures

HERC staff recommendations:

1) Place CPT **64454** (Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed) on line 662/GN173
    a. only use is prior to radiofrequency ablation, which is on line 662
2) Place CPT **64624 (**Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed) on line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS and modify GN173 as shown below
    a. Reflects previous review and HERC decision
3) Remove PCT 64640 from GN 173 and advise HSD to return CPT 64640 to the Ancillary File

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

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
~~64640~~	~~Destruction by neurolytic agent; other peripheral nerve or branch~~	~~Insufficient evidence of effectiveness~~	~~May, 2019 (knee osteoarthritis)~~
64454, 64624	Nerve blocks and/or d~~D~~estruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed	Insufficient evidence of effectiveness	May, 2019

2020 CPT Code Review Nuclear Cardiac Imaging

Question: How should the 2020 CPT Codes on nuclear cardiac imaging be integrated into the Prioritized List?

Question source: 2020 CPT Code review

Issue:
New codes include cardiac PET with or without CT.

Code	Code Description
78429	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study; with concurrently acquired computed tomography transmission scan
78430	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability);
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan
78434	Absolute quantitation of myocardial blood flow (AQMBF), positron emission tomography (PET), rest and pharmacologic stress (List separately in addition to code for primary procedure)

HERC has a Coverage Guidance on Nuclear Cardiac Imaging for Screening, Diagnosis or Risk Stratification of Coronary Artery Disease and made the following recommendations:

> HERC COVERAGE GUIDANCE (2015) https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/Nuclear-Cardiac-Imaging-1-8-2015.pdf
>
> PET is not recommended for coverage for screening or diagnosis of coronary artery disease (CAD) *(strong recommendation).*
>
> Single photon emission computed tomography (SPECT) is not recommended for coverage for screening for CAD in asymptomatic patients *(strong recommendation).*
>
> Stress SPECT is not recommended for coverage for diagnosis or risk stratification of CAD *(strong recommendation)*—except in patients for whom stress ECHO is contraindicated, is unavailable or would provide suboptimal imaging.*

**i.e. pre-existing cardiomyopathy, baseline regional wall motion abnormalities, left bundle branch block, paced rhythm, unsuitable acoustic windows due to body habitus, inability to utilize dobutamine in a setting where exercise is not possible or when the target workload is not achievable.*

Brief evidence update

Kim, 2019 https://www.ncbi.nlm.nih.gov/pubmed/30603894

- Systematic review of use of PET for cardiac sarcoidosis (CS)
- 17 studies (891 patients)
- Results:
    - Pooled sensitivity was 0.84 [95% confidence interval (95% CI) 0.71-0.91] with heterogeneity (I2 = 77.5) and a pooled specificity of 0.83 (95% CI 0.74-0.89) with heterogeneity (I2 = 80.0).
    - Likelihood ratio (LR) syntheses gave an overall LR+ of 4.9 (95% CI 3.3-7.3) and LR- of 0.2 (95% CI 0.11-0.35).
    - The pooled diagnostic odds ratio was 27 (95% CI 14-55). Hierarchical SROC curve indicates that the area under the curve was 0.90 (95% CI 0.87-0.92). Meta-regression showed that combined myocardial perfusion imaging was the source of heterogeneity.
- Author conclusions: The current meta-analysis showed the moderate sensitivity and specificity of F-18 FDG PET or PET/CT for diagnosis of CS. The presence of combined myocardial perfusion imaging could improve diagnostic accuracy of F-18 FDG PET or PET/CT for diagnosis of CS. At present, the literature regarding the use of F-18 FDG PET for detection of CS remains limited; thus, further large multicenter studies would be necessary to substantiate the diagnostic accuracy of F-18 FDG PET for diagnosis of CS.

Juarez-Orozco, 2018 https://www.ncbi.nlm.nih.gov/pubmed/29293983

- Systematic review of myocardial perfusion evaluation with PET and risk of cardiac events in patients with CAD
- Eight studies (n = 6804)
- Myocardial flow reserve (MFR) was independently associated with major adverse cardiovascular events (MACE) in eight studies [range of adjusted hazard ratios (HRs): 1.19-2.93]. The pooling instance demonstrated that MFR significantly associates with the development of MACEs (HR: 1.92 [1.29, 2.84]; P = 0.001). Stress myocardial blood flow (sMBF) was only associated with MACE in two studies that evaluated it, and only one study documented sMBF as a better predictor than MFR.
- Author conclusions: This systematic review demonstrates the prognostic value of quantitative myocardial perfusion evaluated with PET, in the form of MFR and sMBF, for the development of major adverse cardiovascular outcomes in populations with known or suspected CAD. In the qualitative comparison, MFR seems to outperform sMBF as an independent prognostic factor. Evidence is still lacking for assessing quantitative PET for the occurrence of cardiac death and all-cause mortality. There is clear heterogeneity in predictor operationalization and study performances.

HERC Staff Assessment

Multiple new codes are available for myocardial imaging with PET +/- CT. A previous HERC coverage guidance found insufficient evidence to justify use of cardiac PET. It appears an

actively studied area; however, based on a brief look at the evidence, it is not clear that the evidence would rise to a point of addressing clinical utility.

HERC Staff Recommendations

1) Make the following code placements

Code	Code Description	Similar codes	Placement Recommendation
78429	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study; with concurrently acquired computed tomography transmission scan	Similar codes 78459 (Myocardial imaging, positron emission tomography (PET), metabolic evaluation) and 75572 (Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)) are on line 662/GN173	Line 662 and Guideline Note 173
78430	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	Similar codes 78491 Myocardial imaging, positron emission tomography (PET), perfusion; single study at rest or stress and 75572 are on 662/GN173	Line 662 and Guideline Note 173
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	Similar codes 78491 and 75572 are on 662/GN173	Line 662 and Guideline Note 173
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall	Similar codes 78459 and 78491 are on Line 662 and GN 173.	Line 662 and Guideline Note 173

Code	Code Description	Similar codes	Placement Recommendation
	motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability);		
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan	Similar codes 78459 and 78491 and 75572 are on 662/GN173	Line 662 and Guideline Note 173
78434	Absolute quantitation of myocardial blood flow (AQMBF), positron emission tomography (PET), rest and pharmacologic stress (List separately in addition to code for primary procedure)	Similar code is 78459 is on 662/GN173. 93350 and 93351 (Stress echos) are on Diagnostic.	Line 662 and Guideline Note 173

2) Modify Guideline Note 173 as follows (combining two rows for clarity and adding the new codes):

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

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last review
78429-78434, 78459 78491-78492	Myocardial imaging, positron emission tomography (PET), metabolic evaluation and/or perfusion	Insufficient evidence of benefit, unclear harms of radiation exposure	January, 2015 Coverage Guidance Blog Updated November 2019
~~78491-78492~~	~~Myocardial imaging,~~	~~Insufficient evidence~~	~~January, 2015~~

	~~positron emission tomography (PET), perfusion~~	~~of benefit, unclear harms of radiation exposure~~	~~Coverage Guidance Blog~~

2020 CPT Code Review
Oncology

1) PALB2
    a. **CPT 81307** PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) gene analysis; full gene sequence
    b. **CPT 81308** PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) gene analysis; known familial variant
    c. Definition:
        i. This gene encodes a protein that may function in tumor suppression. This protein binds to and colocalizes with the breast cancer 2 early onset protein (BRCA2) in nuclear foci and likely permits the stable intranuclear localization and accumulation of BRCA2
    d. NCCN guidelines
        i. NCCN V3.2019 Breast Cancer: not mentioned
        ii. NCCN V3.2019 High Risk for Breast/Ovarian Cancer
            1. PALB2 positive status changes age of onset for screening for breast cancer and modality of screening—screening beginning at age 30 with consideration for breast MRI as screening modality
            2. Notes that the lifetime breast cancer risk for PALB2+ women is 35%
        iii. NCCN V3.2019 Pancreatic Adenocarcinoma
            1. PALB2 result changes treatment recommendations
        iv. NCCN V1.2019 Myelodysplastic Syndromes
            1. PALB2 mutations noted to be associated with Fanconi anemia
    e. Similar code placement: BRCA testing is diagnostic
    f. GAP discussion: agreed with staff recommendation
    g. HERC staff recommendation
        i. Recommend HSD add CPT codes **81307** and **81308** to the Diagnostic Procedures File

2) PIK3CA
    a. **CPT 81309** PIK3CA (phosphatidylinositol-4, 5-biphosphate 3-kinase, catalytic subunit alpha) (eg, colorectal and breast cancer) gene analysis, targeted sequence analysis (eg, exons 7, 9, 20)
    b. Definition:
        i. Gene amplifications, deletions and more recently, somatic missense mutations in the *PIK3CA* gene have been reported in many human cancer types including cancers of the colon, breast, brain, liver, stomach and lung.
    c. NCCN guidelines
        i. NCCN V3.2019 Breast Cancer
            1. Testing for PIK3CA recommended if considering alpelisib therapy for HR+/HER2- breast cancer
        ii. NCCN V2.2019 Colon Cancer
            1. PIK3CA mutations may predict responsiveness to aspirin, but the data is inconsistent
    d. GAP discussion: agreed with staff recommendation

e. HERC staff recommendation
    i. Add CPT **81309** to line 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER

3) Biomarker tests for cancer tissue
    a. Note: GAP reviewed this at their October 2019 meeting and agreed with staff recommendations
    b. Genome wide microarray testing for cancer
        i. CPT **81277** Cytogenomic neoplasia (genome-wide) microarray analysis, interrogation of genomic regions for copy number and loss-of-heterozygosity variants for chromosomal abnormalities
    c. Review history:
        i. Multiple gene assays for cancer were reviewed in August 2015 by HTAS as part of a biomarkers for cancer review. At that time, one microarray gene expression profiling test (CPT 81504 Oncology (Tissue of origin), microarray gene expression profiling of >2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores) was specifically reviewed. HTAS recommendation was for non-coverage of all multiple gene assays for cancer (weak recommendation).
    d. Similar codes:
        i. This test was previously reported under CPT 81406 (Molecular pathology procedure, Level 7 (eg, analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenomic array analysis for neoplasia) ACADVL (acyl-CoA dehydrogenase, very long chain) (eg, very long chain acyl-coenzyme A dehydrogenase deficiency), full gene sequence ACTN4 (actinin, alpha 4) (eg, focal segmental glomerulosclerosis), full gene sequence AFG3L2 (AFG3 ATPase family gene 3-like 2 [S. cerevisiae]) (eg, spinocerebellar ataxia), full gene sequence AIRE (autoimmune regulator) (eg, autoimmune polyendocrinopathy syndrome type 1), full gene sequence ALDH7A1 (aldehyde dehydrogenase 7 family, member A1) (eg, pyridoxine-dependent epilepsy), full gene sequence ANO5 (anoctamin 5) (eg, limb-girdle muscular dystrophy), full gene sequence ANOS1 (anosmin-1) (eg, Kallmann syndrome 1), full gene sequence APP (amyloid beta [A4] precursor protein) (eg, Alzheimer disease), full gene sequence ASS1 (argininosuccinate synthase 1))
            1. Diagnostic Procedures File
        ii. Evidence
            1. No literature found
        iii. Expert input:
            1. Providence Oncology group agreed with the staff recommendation
        iv. HERC staff recommendation
            1. Add CPT **81277** (Cytogenomic neoplasia (genome-wide) microarray analysis, interrogation of genomic regions for copy number and loss-of-heterozygosity variants for chromosomal abnormalities) to line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN,

HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
2. Add an entry to GN173 as shown below

e. Endopredict for breast cancer
   i. CPT **81522** Oncology (breast), mRNA, gene expression profiling by RT-PCR of 12 genes (8 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk score
   ii. Breast cancer algorithmic tests were reviewed in an HTAS coverage guidance in March, 2018. CPT 81522 appears to represent a test called Endopredict. The coverage guidance recommended that the Endopredict test be covered in certain clinical situations.
   iii. <u>HERC staff recommendation</u>
      1. Add CPT **81522** (Oncology (breast), mRNA, gene expression profiling by RT-PCR of 12 genes (8 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk score) to line 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
      2. Modify Guideline Note 148 as shown below

f. Decipher for prostate cancer
   i. CPT **81542** Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as metastasis risk score
   ii. Description: CPT 81542 appears to represent a test known as Decipher. Prostate cancer algorithmic tests were reviewed in an HTAS coverage guidance in January, 2018. All prostate cancer algorithmic testing, including Decipher, was reviewed, and given a strong recommendation for non-coverage.
   iii. <u>HERC staff recommendation</u>
      1. Add CPT **81542** (Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as metastasis risk score) to line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
      2. Modify Guideline Note 148 as shown below
      3. Add an entry to Guideline Note 173 as shown below

g. Gene expression profiling for uveal melanoma
   i. CPT **81552** Oncology (uveal melanoma), mRNA, gene expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis
   ii. Uveal melanoma is a rare disease of the eye that has a different prognosis and treatment than cutaneous melanoma. CPT 81552 represents DecisionDX, a gene expression profile that determines the molecular signature of a patient's melanoma. The results of the test provide knowledge regarding the risk of near-term metastasis (5 years). Tumors with a Class 1 signature are associated with a good prognosis and a low potential to metastasize, while tumors with a Class 2 signature have a high potential to spread.
   iii. Uveal melanoma (ICD10 C69.9) is on line 112 CANCER OF EYE AND ORBIT

iv. **NCCN** 1.2019 Uveal Melanoma
    1. Footnote: "Biopsy of primary tumor does not improve outcomes, but may provide prognostic information that can help inform frequency of follow up and may be needed for eligibility for clinical trials. Specimen should be sent for cytology, chromosome analysis, and/or gene expression profiling. The risks/benefits of biopsy for prognostic analysis should be carefully considered and discussed."

v. Other guidelines
    1. **Nathan 2015**, UK guideline for uveal melanoma (approved by NICE)
        a. Consider collecting molecular genetic and/or cytogenetic data for research and prognostication purposes where tumour material is available and where patient consent has been obtained as part of an ethically approved research programme. [GPP—expert opinion]

vi. HERC staff summary: gene expression profiling does not have adequate evidence that the test affects clinical outcomes. It is mentioned in the NCCN guideline for uveal melanoma, but only as an option if a biopsy is done. A trusted source (NICE) recommends only as part of a research trial.

vii. <u>HERC staff recommendation</u>
    1. Add CPT **81552** (Oncology (uveal melanoma), mRNA, gene expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis) to line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
    2. Modify GN173 as shown below

GUIDELINE NOTE 148, BIOMARKER TESTS OF CANCER TISSUE

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

The use of tissue of origin testing (e.g. CPT 81504) is included on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

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

- Oncotype DX Breast Recurrence Score (CPT 81519) for breast tumors that are estrogen receptor positive, HER2 negative, and either lymph node negative, or lymph node positive with 1-3 involved nodes.
- EndoPredict (~~using~~ CPT ~~81599~~ <u>81522</u>) and Prosigna (CPT 81520 or PLA 0008M) for breast tumors that are estrogen receptor positive, HER2 negative, and lymph node negative.
- MammaPrint (using CPT 81521 or HCPCS S3854) for breast tumors that are estrogen receptor or progesterone receptor positive, HER2 negative, lymph node negative, and only in those cases categorized as high clinical risk.

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

Oncotype DX Breast DCIS Score (CPT 81479) and Breast Cancer Index (CPT 81518) are included on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

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

For lung cancer, epidermal growth factor receptor (EGFR) gene mutation testing (CPT 81235) is included on Line 263 only for non-small cell lung cancer. KRAS gene mutation testing (CPT 81275) is not included on this line.

For colorectal cancer, KRAS gene mutation testing (CPT 81275) is included on Line 157. BRAF (CPT 81210) and Oncotype DX are not included on this line. Microsatellite instability (MSI) is included on the Line 662.

For bladder cancer, Urovysion testing is included on Line 662.

For prostate cancer, Oncotype DX Genomic Prostate Score, Prolaris Score Assay, and Decipher Prostate RP (CPT 81542) are included on Line 662.

The development of this guideline note was informed by a HERC coverage guidance on Biomarkers Tests of Cancer Tissue for Prognosis and Potential Response to Treatment; the prostate-related portion of that coverage guidance was superseded by a Coverage Guidance on Gene Expression Profiling for Prostate Cancer. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx.

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

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
81277	Cytogenomic neoplasia (genome-wide) microarray analysis, interrogation of genomic regions for copy number and loss-of-heterozygosity variants for chromosomal abnormalities	Insufficient evidence of effectiveness	November 2019

81542	Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as metastasis risk score	Insufficient evidence of effectiveness	January 2018
81552	Oncology (uveal melanoma), mRNA, gene expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis	Insufficient evidence of effectiveness	November 2019

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ScienceDirect

journal homepage: www.ejcancer.com

Review

Uveal Melanoma UK National Guidelines

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Abstract The United Kingdom (UK) uveal melanoma guideline development group used an evidence based systematic approach (Scottish Intercollegiate Guidelines Network (SIGN)) to make recommendations in key areas of uncertainty in the field including: the use and effectiveness of new technologies for prognostication, the appropriate pathway for the surveillance of patients following treatment for primary uveal melanoma, the use and effectiveness of new technologies in the treatment of hepatic recurrence and the use of systemic treatments. The guidelines were sent for international peer review and have been accredited by NICE. A

This project is the independent work of the Uveal Melanoma Guideline Development Group and is funded by Melanoma Focus (http://melanomafocus.com/).

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[1] Ms Curtis and Mr McGuirk shared attendance at GDG meeting. When neither could attend Mr Rob Cheek, another member of OcuMel board, attended. Sadly, Kieran McGuirk died in September 2014.

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2020 CPT Code Review
Computerized Dynamic Posturography

Code:

1) CPT **92549** Computerized dynamic posturography sensory organization test (CDP-SOT), 6 conditions (ie, eyes open, eyes closed, visual sway, platform sway, eyes closed platform sway, platform and visual sway), including interpretation and report; with motor control test (MCT) and adaptation test (ADT)

Similar code:

1) CPT **92548** Computerized dynamic posturography
    a. Line 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS,
    b. Line 416 MENIERE'S DISEASE
    c. Line 510 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM

Description: computerized dynamic posturography (CDP), tests a patient's balance control in situations intended to isolate factors that affect balance in everyday experiences. Posturography provides quantitative information on the degree of imbalance present but is not intended to diagnosis specific types of balance disorders. The sensory organization test is a form of posturography that is designed to assess quantitatively a patient's ability to use visual, proprioceptive, and vestibular cues to maintain postural stability.

Previous review: no previous review was found for computerized dynamic posturography in a search of HERC or HSC minutes. However, the code was limited to its 3 current lines at some point between 2001 and 2010.

Evidence

1) **Mallison 2019**, cohort study comparing computerized dynamic posturography (CDP) to vestibular evoked myogenic potential (VEMP) testing
    a. N=180 patients with vestibular complaints
    b. There was a high rate of VEMP abnormalities seen. The rate of VEMP abnormalities was the same in patients with normal CDP and those with abnormal CDP.
    c. Significance: Our results do not suggest that CDP is unnecessary, but we feel that they emphasize the idea that these tests are measuring two different aspects of balance control. In some patients, all assessments are abnormal, but in some patients only one assessment is abnormal, suggesting that these modalities measure different things and are all important in the diagnostic armamentarium.
2) **Phillips 2011**, cost effectiveness evaluation of vestibular complaints
    a. CDP has been shown to fail in its ability to distinguish the cause or to localize the site of lesion for patients with multiple causes of dizziness
    b. CDP may be used independently to quantify vestibular recovery and compensation; however, for this role, patient-reported measures may be considered to be more cost-effective and indeed this is the mainstay of assessment in many units worldwide.
    c. CDP does play a role in the diagnosis of patients in whom secondary gain may be of primary interest.
    d. Contemporary vestibular testing is expensive, lacks accuracy, is operator dependent and often has little effect on patient outcome

3) **Piirtola 2006**, systematic review of force platform measurements as predictors of falls in the elderly
    a. N=9 articles
    b. In five studies fall-related outcomes were associated with some force platform measures and in the remaining four studies associations were not found.
    c. Measures related to dynamic posturography (moving platforms) were not predictive of falls.
    d. Conclusion: Despite a wide search only a few prospective follow-up studies using the force platform technique to measure postural balance and a reliable registration of subsequent falls were found. The results suggest that certain aspects of force platform data may have predictive value for subsequent falls, especially various indicators of the lateral control of posture. However, the small number of studies available makes it difficult to draw definitive conclusions.

Other payer policies

Wellmark BCBS, Cigna, and United Healthcare all have 2019 policies that computerized dynamic posturography is experimental due to lack of evidence of effectiveness. No payer policy was found on the sensory organization test.

Utilization: computerized dynamic posturography (CPT 92548) had 140 paid claims since 2017, mainly for diagnoses such as dizziness, abnormality of gait, and vestibular abnormalities. There were no claims for Meniere's disease.

2020 CPT Code Review
Computerized Dynamic Posturography

HERC staff summary:
The literature evaluating computerized dynamic posturography is sparse. This test does not appear to be helpful in making a diagnosis, other than in distinguishing secondary gain (malingering). No private insurer surveyed covers this test.

The existing CPT code (92548) is on 3 lines, and evidence of ineffectiveness would be required to remove it and place on line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

HERC staff recommendations:

1) Consider removing CPT **92548** (computerized dynamic posturography) from current lines and adding to line 662/GN173
    a. No evidence of utility for making a diagnosis other than malingering
2) Place CPT **92549** (Computerized dynamic posturography sensory organization test (CDP-SOT)) on line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
3) Add the following entry to Guideline Note 173
    a. Purple wording represents adding 92548 to line 662 depending on decision on #1 above

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

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
92548, 92549	Computerized dynamic posturography ~~sensory organization test~~	Insufficient evidence of effectiveness	November 2019

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Full length article

Computerized Dynamic Posturography does not detect measured CVEMP and OVEMP abnormalities☆

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ABSTRACT

Background: Computerized Dynamic Posturography (CDP)was developed by the American space program to assess imbalance in astronauts, and eventually evolved into a clinical diagnostic tool. However it is not a specific measure of vestibular function. Vestibular Evoked Myogenic Potential testing (VEMPs) is a new clinical tool which is sensitive and specific for measuring otolithic pathology, especially in the atypical vestibular patient.
Research question: As posturography measures ability to maintain balance, and VEMP testing measures the structures responsible for this, we wondered if CDP results would correlate with VEMP abnormalities in the clinical setting.
Methods: We analysed 180 patients sequentially referred to our unit for vestibular complaints. All patients had a full battery of vestibular assessments. We correlated VEMP results with CDP results to look for abnormality patterns and correlations. An occasional patient's only abnormality was on CDP
Results: There was a high rate of VEMP abnormalities seen, which correlates with the fact that our referral base consists of patients with chronic vestibular complaints. The rate of VEMP abnormalities was the same in patients with normal CDP and those with abnormal CDP.
Significance: Our results do not suggest that CDP is unnecessary, but we feel that they emphasize the idea that these tests are measuring two different aspects of balance control. In some patients, all assessments are abnormal, but in some patients only one assessment is abnormal, suggesting that these modalities measure different things and are all important in the diagnostic armamentarium. Hopefully in the near future, the use of virtual reality will reduce the cost of CDP to the point where it can be made widely accessible to patients and clinicians.

1. Introduction

During the early years of spaceflight it was discovered by NASA researchers that on return to earth astronauts were extremely imbalanced and quite incapacitated. This has been elegantly summarized and discussed by Black et al in 1999 [1].

In order to investigate and quantify the deficit in returning astronauts, a new technology - Computerized Dynamic Posturography® (CDP) - had been devised by Nashner [2]. CDP subsequently was introduced as an effective clinical tool. (Neurocom International; Clackamas USA) [3]. This was commercialized as Equitest® in the mid 1980's (Neurocom International; Clackamas USA). It was the first generally available investigation into the balance system that had been developed subsequent to standard caloric test, which was described by Barany about 70 years previously. At the time it was developed, it was new technology, highly complex, and extremely advanced. Although expensive, this system was acquired by many research laboratories in the balance and dizziness field. Comparison of CDP investigations from one location to another made direct collaboration between institutions possible. This was one of its main benefits over a "home-made" force plate, (the so-called "foam and dome") developed by Shumway-Cook and Horak in 1986 [4] which has the major limitation of not being precisely applicable to any other institution.

In the clinical setting, CDP can be used to measure static sway and

☆ Presented at the XXIX meeting of the Barany Society; June 5–8, 2016.

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Cost-effective evaluation of the vestibular patient

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Purpose of review

There is in existence a large array of sophisticated equipment to assess patients with complaints of dizziness and imbalance. Many vestibular tests are expensive to administer. In an era of evidence-based medicine and economic austerity, the appropriate utilization of such tests is of paramount importance. This review examines the clinical value together with costs involved in performing the various components of the vestibular assessment battery.

Recent findings

Vestibular testing is expensive. To date, publications to support the use of specialist tests for the confident diagnosis of specific vestibular pathologies are severely lacking. In fact, over the last 12 months, the literature illustrates a reduction in the enthusiasm for some tests that were popularized over recent decades.

Summary

Tests of vestibular function are expensive and their ability to diagnose specific vestibular pathologies is lacking. However, there are some tests that, when used in specific circumstances, may be very helpful in the diagnosis and management of patients with these complaints.

Keywords

assessment, dizziness, vertigo

Curr Opin Otolaryngol Head Neck Surg 19:403–409

1068-9508

Introduction

Currently, there is a wide array of sophisticated equipment available to assess the vestibular patient. Many vestibular tests are expensive to acquire, often requiring the purchase of sophisticated hardware or proprietary software.

However, despite the popularity of performing specialist vestibular testing, there is a great deal of ambiguity as to the effectiveness of certain vestibular tests in improving patient outcome. As an underlying principle, as physicians, we should only be requesting tests that can confidently diagnose or exclude disease, provide additional information that is otherwise unavailable or lead to a beneficial change in the management of the patient [1]. The specialist physician must always be aware of what information a given vestibular assessment can provide, but must always be mindful of any supplementary caveats.

The following review considers the role of the various diagnostic tests employed in a modern vestibular laboratory and questions their necessity from the consensus perspective of three assessors of vestibular patients, from three different healthcare systems, with three different clinical backgrounds: one from Europe (UK), one from Canada (Vancouver) and one from the USA (Cleveland).

Vestibular tests

Because of the differences in provision of healthcare between continents, it is difficult to compare like for like costs between different countries. Therefore, Table 1 outlines the costs involved in purchasing the various pieces of vestibular testing equipment in the UK alongside tariff costs for administering these tests in Canada and the USA (Table 1).

Caloric testing, electronystagmography and videonystagmography

First described in 1906 by Bárány [2], caloric testing is often considered to be a gold standard test of peripheral vestibular function. However, the vestibular physician must be mindful of the drawbacks of this test. Caloric testing, in combination with either electronystagmography (ENG) or videonystagmography (VNG), assesses the function of only the lateral semicircular canal and only at low-frequency stimulation [3]. Bakr and Saleh [4] considered the role of ENG and remarked with respect to its inability to significantly aid diagnosis, although they felt that it may confirm a peripheral abnormality in certain

Review

Gerontology

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Force Platform Measurements as Predictors of Falls among Older People – A Review

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Key Words
Fall prediction · Force platform · Measurement · Older people · Review · Sway

Abstract
Background: Poor postural balance is one of the major risk factors for falling. A great number of reports have analyzed the risk factors and predictors of falls but the results have for the most part been unclear and partly contradictory. Objective data on these matters are thus urgently needed. The force platform technique has widely been used as a tool to assess balance. However, the ability of force platform measures to predict falls remains unknown. ***Objective:*** The purpose of this systematic review was to extract and critically review the findings of prospective studies where force platform measurements have been used as predictors of falls among elderly populations. ***Methods:*** The study was done as a systematic literature review. PubMed, the Cochrane Central Register of Controlled Trials, and CINAHL databases from 1950 to April 2005 were used. The review includes prospective follow-up studies using the force platform as a tool to measure postural balance. ***Results:*** Nine original prospective studies were included in the final analyses. In five studies fall-related outcomes were associated with some force platform measures and in the remaining four studies associations were not found. For the various parameters derived on the basis of the force platform data, the mean speed of the mediolateral (ML) movement of the center of pressure (COP) during normal standing with the eyes open and closed, the mean amplitude of the ML movement of the COP with the eyes open and closed, and the root-mean-square value of the ML displacement of COP were the indicators that showed significant associations with future falls. Measures related to dynamic posturography (moving platforms) were not predictive of falls. ***Conclusion:*** Despite a wide search only a few prospective follow-up studies using the force platform technique to measure postural balance and a reliable registration of subsequent falls were found. The results suggest that certain aspects of force platform data may have predictive value for subsequent falls, especially various indicators of the lateral control of posture. However, the small number of studies available makes it difficult to draw definitive conclusions.

Introduction

Approximately 1 out of 3 subjects aged 65 or over and living in the community falls at least once during a year. Among older individuals living in institutions, the rate of falls is even higher [1, 2]. Every second fall leads to an injury [3] and 5–10% of falls cause some type of fracture [1]. Among older subjects 70% of the injuries caused by accidents are related to falls [4], and aging seems to increase the severity and amount of injuries [5]. The cost and health-impairing effects of injurious falls depend on the severity of the injury. Hip fractures are among the most expensive incidents [6].

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2020 CPT Code Review Issues
Speckle Tracking Echocardiography

Code:

1) **93356** Myocardial strain imaging using speckle tracking-derived assessment of myocardial mechanics (List separately in addition to codes for echocardiography imaging)

Description: Speckle tracking echocardiography (STE) is an echocardiographic imaging technique that analyzes the motion of tissues in the heart by using the naturally occurring speckle pattern in the myocardium or blood when imaged by ultrasound. This speckle pattern is a mixture of interference patterns and natural acoustic reflections. These reflections are also described as speckles or markers. The pattern being random, each region of the myocardium has a unique speckle pattern that allows the region to be traced from one frame to the next, and this speckle pattern is relatively stable, at least from one frame to the next. In post-processing this can be tracked consecutively frame-to-frame and ultimately resolved into angle-independent two-dimensional (2D) and three-dimensional strain-based sequences (3D). These sequences provide both quantitative and qualitative information regarding tissue deformation and motion.

Evidence

1) **Luis 2019**, review of STE
    a. Compared with its predecessor, tissue Doppler imaging-based strain, 2D STE is superior because of improved correlation with MRI, improved feasibility, and reduced interobserver and intraobserver variability
    b. The American Society of Echocardiography and the European Association of Cardiovascular Imaging have formed a taskforce with industry partners to standardize strain imaging across the different vendors. This effort is ongoing, and although recent studies have found improvement in intervendor agreement, full compatibility has not yet been achieved.
    a. Conclusions:
        a. Strain imaging that uses speckle tracking in 2D and 3D offers promise for quantifying LV function, particularly for patients with borderline LV function, because of the potential to identify subclinical disease
        b. Although further investigation is yet required to define the role and usefulness of this technique for a range of cardiac conditions, strain imaging will undoubtedly have a meaningful role in the future of echocardiographic imaging.
2) **Smiseth 2016**, review of myocardial strain imaging
    a. Key points
        i. Global longitudinal strain (GLS) by STE is more sensitive than left ventricular ejection fraction (LVEF) as a marker of left ventricle (LV) dysfunction
        ii. The strain imaging methodology is still undergoing development and further clinical trials are needed to determine if clinical decisions based on strain imaging results in better outcomes
        iii. Strain may be applied clinically as a supplementary diagnostic method and in the following conditions it appears to be useful.
            1. In patients with preserved or normal LVEF, reduced GLS may be used to identify systolic dysfunction.
            2. Strain imaging can be used to identify sub-clinical LV dysfunction in individuals who are evaluated for cardiomyopathy. This includes family screening for hypertrophic cardiomyopathy and the finding of reduced GLS indicates early disease

3. In patients with valvular heart disease reduced GLS reflects negative impact of the valve lesion on myocardial function prior to fall in LVEF, but so far this application is not recommended for use in clinical routine.
4. Strain imaging is recommended in addition to LVEF in patients undergoing chemotherapy to identify sub-clinical LV dysfunction.
5. Mechanical dispersion as a measure of dyssynchrony, can identify patients with high risk of ventricular arrhythmias, but this approach is not ready for clinical implementation. Strain may be used to diagnose myocardial ischemia, but the technology is not sufficiently standardized to be recommended as a general tool for this purpose. In unclear clinical cases, however, it may be considered as a supplementary method.
6. Strain imaging may be applied in patients eligible for cardiac resynchronization therapy (CRT) to guide placement of the LV pacing lead, but is currently not recommended for selection of CRT responders.
7. Peak systolic longitudinal left atrium strain is a promising supplementary index of LV filling pressure, but needs further validation in prospective trials.

HERC staff summary:
Speckle tracking echocardiography appears to be a promising technique to diagnose left ventricular dysfunction. However, this technique is still undergoing standardization, and studies need to be done to determine the clinical utility of this technique.

HERC staff recommendation

1) Add CPT **93356** (Myocardial strain imaging using speckle tracking-derived assessment of myocardial mechanics (List separately in addition to codes for echocardiography imaging)) to Line 662/Guideline Note 173 due to lack of evidence of effectiveness

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

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
93356	Myocardial strain imaging using speckle tracking-derived assessment of myocardial mechanics	Insufficient evidence of effectiveness	November 2019

MAYO CLINIC

REVIEW

Echocardiographic Assessment of Left Ventricular Systolic Function: An Overview of Contemporary Techniques, Including Speckle-Tracking Echocardiography

Sushil A. Luis, MBBS; Jonathan Chan, MBBS, PhD; and Patricia A. Pellikka, MD

Abstract

Assessment of left ventricular systolic function has a central role in the evaluation of cardiac disease. Accurate assessment is essential to guide management and prognosis. Numerous echocardiographic techniques are used in the assessment, each with its own advantages and disadvantages. This review is based on a literature search of the PubMed, MEDLINE, EMBASE, and Scopus databases from inception through December 30, 2017, using the terms *strain echocardiography*, *tissue Doppler strain*, and *speckle-tracking echocardiography*. We provide the internist with a contemporary overview of current echocardiographic techniques used in the evaluation of left ventricular systolic function. In particular, we focus on the role of speckle-tracking echocardiography, including its utility in the detection of subclinical left ventricular dysfunction and the associated prognostic implications.

 ■ Mayo Clin Proc. 2019;94(1):125-138

Myocardial function begins at the cellular level with the coordinated contraction of cardiac myocytes. Cellular depolarization causes the release of calcium ions into the muscle sarcoplasm, leading to the excitation-contraction coupling of actin and myosin in the sarcomere.[1] This interaction of actin and myosin results in the shortening of thousands of sarcomeres that compose the cardiac myocyte ultrastructure, and it manifests macroscopically as cardiac contraction.[1]

The 3-dimensional (3-D) arrangement of myocardial fiber bundles in the ventricular myocardium is complex, with fibers arranged to maximize the efficiency of cardiac contraction. Myocardial fibers are arranged in a helical and perpendicular orientation, with clockwise epicardial and counterclockwise subendocardial fibers (Figure 1A).[2,3] This orthogonal fiber orientation causes opposing directions of rotation at the left ventricular (LV) base and apex, resulting in a "wringing-like" cardiac emptying effect during ventricular systole.[4]

Most cardiac myofibers are oriented in the circumferential direction, with a proportionally smaller number oriented in a longitudinal direction.[5] The ratio of circumferential to longitudinal fibers is approximately 10:1 in canine models, with a higher proportion of circumferential fibers at the base and a lower proportion at the cardiac apex.[5] Myofiber orientation varies throughout the myocardial wall, with a predominantly oblique fiber orientation in the subepicardium, transverse fiber orientation in the midmyocardium, and longitudinal fiber orientation in the subendocardium (Figure 1B).

Herein we review the conventional assessment of LV systolic function and examine the role of speckle-tracking echocardiography (STE), a new method to assess LV function. We also highlight the role of STE in the assessment and management of cardiac and noncardiac disease, including detection of subclinical LV dysfunction. To provide a contemporary overview of STE and its clinical applications, we conducted a literature search of the PubMed,

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REVIEW

Imaging

Myocardial strain imaging: how useful is it in clinical decision making?

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Myocardial strain is a principle for quantification of left ventricular (LV) function which is now feasible with speckle-tracking echocardiography. The best evaluated strain parameter is global longitudinal strain (GLS) which is more sensitive than left ventricular ejection fraction (LVEF) as a measure of systolic function, and may be used to identify sub-clinical LV dysfunction in cardiomyopathies. Furthermore, GLS is recommended as routine measurement in patients undergoing chemotherapy to detect reduction in LV function prior to fall in LVEF. Intersegmental variability in timing of peak myocardial strain has been proposed as predictor of risk of ventricular arrhythmias. Strain imaging may be applied to guide placement of the LV pacing lead in patients receiving cardiac resynchronization therapy. Strain may also be used to diagnose myocardial ischaemia, but the technology is not sufficiently standardized to be recommended as a general tool for this purpose. Peak systolic left atrial strain is a promising supplementary index of LV filling pressure. The strain imaging methodology is still undergoing development, and further clinical trials are needed to determine if clinical decisions based on strain imaging result in better outcome. With this important limitation in mind, strain may be applied clinically as a supplementary diagnostic method.

Keywords Left ventricular function • Heart failure • Strain imaging • Left atrial strain • Ventricular arrhythmia • Chemotherapy • Cardiomyopathy • Hypertrophic cardiomyopathy

Principles of strain

In echocardiography, the term 'strain' is used to describe local shortening, thickening and lengthening of the myocardium as a measure of regional LV function. The term originates from the field of continuum mechanics and is used to describe a general 3D deformation of a small cube during a short time interval. The strain tensor has six components (numbers), three of them giving the shortening along three orthogonal axes (x, y, z) in an external coordinate system, and three share strain numbers giving the skew in the x–y, x–z, and y–z planes. By dividing the myocardium into a large number of cubes, the complex and detailed deformation can be described by one strain tensor for each small cube at each time during the cardiac cycle.[1] This description is, however, too detailed for practical use in echocardiography, where there is a need for a limited number of measurable parameters representing the average deformation within a segment of the myocardium. It is more convenient to use an internal coordinate system aligned with the three cardiac axes: longitudinal, circumferential, and radial, and to measure the shortening and elongation in the three directions through the cardiac cycle, with reference to the size at the time of the QRS-complex.

If we denote $L(t)$ as the segment length along one of these directions at any time t in the cardiac cycle and L_0 as initial length, 1D strain is defined as $\varepsilon(t) = (L(t) - L_0)/L_0$. This is also called *Lagrange strain*, and it is measured by the distance between two material points in the myocardium, both following the motion during contraction and relaxation. Note that positive strain means elongation, whereas negative strain is shortening. To avoid

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2020 CPT Code Review Issues
Remote Physiologic Monitoring

New CPT Codes

Code	Code Description
99458	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)
99473	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration
99474	Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient

Similar codes

Code	Code Description	Prioritized List Placement	Fee Schedule
99457	Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month	Never Reviewed	$22.55/$35.70
93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS	Not on fee schedule
99453	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment	Never Reviewed	$13.35
99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days	Never Reviewed	$44.13

99091	Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days	Ancillary Procedures File	$40.59

Relevant evidence
USPSTF, 2015
https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/high-blood-pressure-in-adults-screening

The USPSTF recommends screening for high blood pressure in adults aged 18 years or older. The USPSTF recommends obtaining measurements outside of the clinical setting for diagnostic confirmation before starting treatment (see the Clinical Considerations section).

Grade "A" recommendation.

Information from others
https://www.foley.com/en/insights/publications/2018/11/medicareremote-patient-monitoring-reimbursement-fa
Many advocates asked CMS to clarify the kinds of technology covered under CPT codes 99453, 99454, and 99457. Some groups gave examples of the kinds of technology they believe these codes should cover, such as software applications that could be integrated into a beneficiary's smartphone, Holter-Monitors, Fitbits, or artificial intelligence messaging. Other examples included behavioral health data and data from wellness applications, or results of patients' self-care tasks. CMS has decided they need to be FDA-approved.

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM11063.pdf
Published prior to CMS issuing rules

HERC Staff Summary
Ambulatory blood pressure monitoring is recommended by USPSTF. This should be placed on Line 3 and hypertensive management lines.

Providing an FDA approved device for physiologic monitoring with teaching seems appropriate when medically necessary. These ought to pair on cardiac, pulmonary, and (some on) diabetic lines. Medical management by clinicians is appropriate to be reimbursed.

CPT code 99454 appears to just be receiving 30-day transmissions without any medical interpretation or management. Without necessary medical decision making, coverage of this seems unnecessary and subject to waste. This code is recommended for line 502.

Recommendations:

1) **Place the ambulatory blood pressure management codes (99473 and 99474) on the following lines:**
    a. 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
    b. 75 HYPERTENSION AND HYPERTENSIVE DISEASE
    c. 97 HEART FAILURE
    d. 172 HYPERTENSIVE HEART AND RENAL DISEASE
    e. 264 CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE
    f. 534 HYPOTENSION
2) **Place the following codes on cardiac and pulmonary lines:**

CODES

a. **99453** *Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment*
b. **99457** *Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month*
c. **99458** *Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)*
d. **99091** *Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days*
    i. **Remove from Ancillary File**
    ii. **Also add 99091 to diabetes lines**
        1. Line 1 PREGNANCY
        2. Line 8 TYPE 1 DIABETES MELLITUS
        3. Line 27 TYPE 2 DIABETES MELLITUS

CARDIAC AND PULMONARY LINES

6 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION
9 ASTHMA
20 CYSTIC FIBROSIS
48 CHRONIC RESPIRATORY DISEASE ARISING IN THE NEONATAL PERIOD
58 BRONCHIECTASIS

75 HYPERTENSION AND HYPERTENSIVE DISEASE
81 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS
97 HEART FAILURE
98 CARDIOMYOPATHY
110 CONGENITAL HEART BLOCK, OTHER OBSTRUCTIVE ANOMALIES OF HEART
172 HYPERTENSIVE HEART AND RENAL DISEASE
189 CHRONIC ISCHEMIC HEART DISEASE
202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER
213 ACUTE PULMONARY HEART DISEASE AND PULMONARY EMBOLI
219 PULMONARY FIBROSIS
222 OCCUPATIONAL LUNG DISEASES
223 DISEASES AND DISORDERS OF AORTIC VALVE
225 ACUTE INFLAMMATION OF THE HEART DUE TO RHEUMATIC FEVER
233 ADULT RESPIRATORY DISTRESS SYNDROME; ACUTE RESPIRATORY FAILURE; RESPIRATORY CONDITIONS DUE TO PHYSICAL AND CHEMICAL AGENTS
257 DISEASES OF MITRAL, TRICUSPID, AND PULMONARY VALVES
CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE
281 LIFE-THREATENING CARDIAC ARRHYTHMIAS
283 CHRONIC OBSTRUCTIVE PULMONARY DISEASE; CHRONIC RESPIRATORY FAILURE
304 VIRAL PNEUMONIA
341 RHEUMATIC FEVER
347 CARDIAC ARRHYTHMIAS
366 ALLERGIC BRONCHOPULMONARY ASPERGILLOSIS
464 ATELECTASIS (COLLAPSE OF LUNG)
566 PLEURISY
635 CHRONIC BRONCHITIS
647 AGENESIS OF LUNG
653 CARDIOVASCULAR CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
657 RESPIRATORY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

3) Place 99454 on Line 502

a. 99454 is *Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30*

b. Add an entry to Guideline Note 172

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

Line 502

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

Procedure Code	Intervention Description	Rationale	Last Review
99454	Remote monitoring of physiologic parameters, 30 days	This code does not require medical decision making nor communication with a patient.	November, 2019

Telephone and eConsult Guideline Update

Question: How should the guideline on telephone and virtual consultations be updated?

Question source: Holly Jo Hodges, WVP Health Authority

Issue: The Prioritized List guideline on telephone and email consultations was adopted in 2008 and has not been edited since then. However, models of care for delivering telephonic, virtual, and electronic interventions have changed substantially since this time.

This issue summary addresses non-face-to-face visits (telephonic or electronic) and between patient and clinician or clinician to clinician.

From Holly Jo Hodges…

> As you all know, specialty access can be limited by many things including lack of enough specialists to afford for timely consults, transportation and other barriers on the part of the member, and so many other issues.
>
> It has been stated that Kaiser Permanente plans to do 50% of primary care visits virtually, this year, in our region. We need to get this right.
>
> First off, it appears to me that Guideline notes 64 and 65 need to be ancillary as they apply to EVERY line of the prioritized list, correct?
> Listing them on every line is reductant and confusing, especially for new users of OHP.
>
> Secondly, it is time to do a comprehensive review of Guideline Note 65 and bring it up to our times.
> Line "1) Patient **must have a pre-existing relationship with the provider** as demonstrated by at least one prior office visit within the past 12 months" completely defeats the purpose of what most of us are trying to do with particularly specialty consults. I think the rest of the first set of requirements makes sense and are things we have discussed in our work group. However, the things that are reimbursable and the things that are not reimbursable, appear to need reviewed in the current climate of trying to care for our population with fewer PCPs and specialists overall.
>
> I have highlighted in red things that seem like they need removed or changed. I have added in italics, things that I think could be added.
> I realize this would not take effect until October 1, 2019, at the earliest, but I feel this is something that should be elevated to the top of the agenda after the March VbBS/HERC meetings.

Also, all of the CPT codes listed under eConsults below, are not called out in Guideline Note #65, but appear to be listed on every line of the Prioritized list. However, they show either manual for pricing on the OHP FFS fee schedule or not listed at all. This will need remedied quickly, which I recognize is not a HERC issue, but I am hoping you could direct this to the correct folks to address that issue urgently.

And lastly, the current OAR does not match the Guideline note and the OAR appears to be more up-to-date.

There are also brand new CPT codes to be reviewed.

Current Prioritized List Status

Code	Description	Placement	Fee Schedule
98966	Telephone assessment and management service provided by a qualified **nonphysician health care professional** to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; **5-10 minutes of medical discussion**	638 lines	$9.01 (Professional Physician fee in a facility, ie: Hospital)/$10.00 (Professional Physician fee in a clinic
98967	Telephone assessment and management service provided by a **qualified nonphysician health care professional** to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; **11-20 minutes of medical discussion**	638 lines	$17.96/$18.96
98968	Telephone assessment and management service provided by a **qualified nonphysician health care professional** to an established patient, parent, or guardian not originating from a related assessment and management service provided within	638 lines	$26.97/$27.96

Code	Description	Placement	Fee Schedule
	the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; **21-30 minutes of medical discussion**		
98969	Online assessment and management service provided by a **qualified nonphysician health care professional** to an established patient or guardian, not originating from a related assessment and management service provided within the previous 7 days, **using the Internet or similar electronic communications network**	638 lines	Not on fee schedule
99441	Telephone evaluation and management service by a **physician or other qualified health care professional** who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; **5-10 minutes of medical discussion**	638 lines	$9.01/$10.00
99442	Telephone evaluation and management service by a **physician or other qualified health care professional** who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; **11-20 minutes of medical discussion**	638 lines	$17.96/$18.96
99443	Telephone evaluation and management service by a **physician or other qualified health care professional** who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related	638 lines	$26.97/$27.96

Code	Description	Placement	Fee Schedule
	E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; **21-30 minutes of medical discussion**		
99444	Online evaluation and management service provided by a **physician or other qualified health care professional** who may report evaluation and management services provided to an established patient or guardian, not originating from a related E/M service provided within the previous 7 days, **using the Internet or similar electronic communications network**	638 lines	Manual
99446	**Interprofessional** telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; **5-10 minutes of medical consultative discussion and review**	638 lines	Not on Fee Schedule
99447	**Interprofessional** telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; **11-20 minutes of medical consultative discussion and review**	638 lines	Not on Fee Schedule
99448	**Interprofessional** telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; **21-30 minutes of medical consultative discussion and review**	638 lines	Not on Fee Schedule

Code	Description	Placement	Fee Schedule
99449	**Interprofessional** telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; **31 minutes or more of medical consultative discussion and review**	638 lines	Not on Fee Schedule
99451	**Interprofessional** telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a written report to the patient's treating/requesting physician or other qualified health care professional**, 5 minutes or more of medical consultative time**	638 lines	$26.03
99452	**Interprofessional** telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified health care professional, **30 minutes**	638 lines	$26.03
99453	**Remote monitoring** of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment	Never Reviewed	$13.35
99454	**Remote monitoring** of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days	Never reviewed	$44.13
99457	**Remote physiologic monitoring treatment management** services, 20 minutes or more of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month	Never reviewed	$22.55/$35.70

Code	Description	Placement	Fee Schedule
99091	**Collection and interpretation of physiologic data** (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days	Never Reviewed	$40.59
G2012	**Brief communication technology-based service,** e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m servi	638 lines	

New 2020 CPT codes

Code	Code Description
98970	**Qualified nonphysician health care professional online** digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes
98971	**Qualified nonphysician health care professional online** digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes
98972	**Qualified nonphysician health care professional online** digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes
99421	**Online digital evaluation and management service**, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes
99422	**Online digital evaluation and management service**, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes
99423	**Online digital evaluation and management service**, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes

GUIDELINE NOTE 65, TELEPHONE AND EMAIL CONSULTATIONS

Included on all lines with evaluation & management (E&M) codes

Telephone and email consultations (CPT 98966-98969, 99441-99443) must meet the following criteria:

1) Patient must have a pre-existing relationship with the provider as demonstrated by at least one prior office visit within the past 12 months.
2) E-visits must be provided by a physician or licensed provider within their scope of practice.
3) Documentation should model SOAP charting; must include patient history, provider assessment, and treatment plan; follow up instructions; be adequate so that the information provided supports the assessment and plan; must be retained in the patient's medical record and be retrievable.
4) Telephone and email consultations must involve permanent storage (electronic or hard copy) of the encounter.
5) Telephone and email consultations must meet HIPAA standards for privacy.
6) There needs to be a patient-clinician agreement of informed consent for E-visits by email. This should be discussed with and signed by the patient and documented in the medical record.

Examples of reimbursable telephone and email consultations include but are not limited to:

1) Extended counseling when person-to-person contact would involve an unwise delay.
2) Treatment of relapses that require significant investment of provider time and judgment.
3) Counseling and education for patients with complex chronic conditions.

Examples of non-reimbursable telephone and email consultations include but are not limited to:

1) Prescription renewal.
2) Scheduling a test.
3) Scheduling an appointment.
4) Reporting normal test results.
5) Requesting a referral.
6) Follow up of medical procedure to confirm stable condition, without indication of complication or new condition.
7) Brief discussion to confirm stability of chronic problem and continuity of present management.

OARs
https://www.oregon.gov/oha/HSD/OHP/Policies/130rb090918.pdf (Note: differs from 5/25/18 version found on Secretary of State website)

410-130-0610 – Telemedicine
(1) For the purposes of this rule, telemedicine is defined as the use of medical information, exchanged from one site to another, via telephonic or electronic communications, to improve a patient's health status.

(2) Provider Requirements:
(a) The referring and evaluating practitioner must be licensed to practice medicine within the state of Oregon or within the contiguous area of Oregon and must be enrolled as a Division of Medical Assistance Programs (Division) provider.
(b) Providers billing for covered telemedicine services are responsible for the following:
(A) Complying with HIPAA and/or Oregon Health Authority (Authority) (OHA) Confidentiality and Privacy Rules and security protections for the patient in connection with the telemedicine communication and related records requirements. Examples of applicable OHA rules are Confidentiality and Privacy and Financial, Clinical and other record Rules include: OAR 943-120-0170, 410-120-1360, and 410-120-1380, and OAR 943 Division 14. Examples of federal and state privacy and security laws that may apply include HIPAA, if applicable and 42 CFR Part 2, if applicable and ORS 646A.600 to 646A.628 (Oregon Consumer Identity Theft Protection Act);
(B) Obtaining and maintaining technology used in the telemedicine communication that is compliant with privacy and security standards in HIPAA and/or Department Privacy and Confidentiality Rules described in subsection (A).
(C) Ensuring policies and procedures are in place to prevent a breach in privacy or exposure of patient health information or records (whether oral or recorded in any form or medium) to unauthorized persons.
(D) Complying with the relevant Health Service Commission (HSC) practice guideline for telephone and email consultation.
(E) Maintaining clinical and financial documentation related to telemedicine services as required in OAR 410-120-1360.
(3) Coverage for telemedicine services:
(a) The telemedicine definition encompasses different types of programs, services and delivery mechanisms for medically appropriate covered services within the patient's benefit package.
(b) Patient consultations using telephone and online or electronic mail (E-mail) are covered when billed services comply with the practice guidelines set forth by the Health Service Commission (HSC) and the applicable HSC-approved CPT code requirements, delivered consistent with the HSC practice guideline.
(c) Patient consultations using videoconferencing, a synchronous (live two-way interactive) video transmission resulting in real time communication between a medical practitioner located in a distant site and the client being evaluated and located in an originating site, is covered when billed services comply with the Billing requirements stated in (5).
(d) Telephonic codes may be used in lieu of videoconferencing codes, if videoconferencing equipment is not available.
(4) Telephone and E-mail billing requirements: Use the E/M code authorized in the HSC practice guideline.
(5) Videoconferencing billing requirements:

(a) Only the transmission site (where the patient is located) may bill for the transmission:
(A) Bill the transmission with Q3014;
(B) The referring practitioner may bill an E/M code only if a separately identifiable visit is performed. The visit must meet all of the criteria of the E/M code billed.
(C) The referring provider is not required to be present with the client at the originating site.
(b) The evaluating practitioner at the distant site may bill for the evaluation, but not for the transmission (Q3014):
(A) Bill the most appropriate E/M code for the evaluation;
(B) Add modifier GT to the E/M code to designate that the evaluation was made by a synchronous (live and interactive) transmission.
(6) Other forms of telecommunications, such as telephone calls, images transmitted via facsimile machines and electronic mail are services not covered:
(a) When those forms are not being used in lieu of videoconferencing, due to limited videoconferencing equipment access, or
(b) When those forms and specific services are not specifically allowed per the Health Service Prioritized List and Practice Guideline.

410-120-1360 – Requirements for Financial, Clinical and Other Records (January 1, 2018 Rulebook
OAR 410-120-1360 (rev. 7/1/2015) 100)
https://www.oregon.gov/oha/HSD/OHP/Policies/120rb010118.pdf

(1) The Authority shall analyze, monitor, audit, and verify the accuracy and appropriateness of payment, utilization of services, medical necessity, medical appropriateness, quality of care, and access to care of the Medical Assistance Programs and the Children's Health Insurance Program.
(2) The provider or the provider's designated billing service or other entity responsible for the maintenance of financial, clinical, and other records shall develop and maintain adequate financial and clinical records and other documentation that supports the specific care, items, or services for which payment has been requested. Payment shall be made only for services that are adequately documented. Documentation shall be completed before the service is billed to the Division and meet the following requirements:
(a) All records shall document the specific service provided, the number of services or items comprising the service provided, the extent of the service provided, the dates on which the service was provided, and the individual who provided the service. Patient account and financial records shall also include documentation of charges, identify other payment resources pursued, indicate the date and amount of all debit or credit billing actions, and support the appropriateness of the amount billed and paid. For cost reimbursed services, the provider shall maintain adequate

records to thoroughly explain how the amounts reported on the cost statement were determined. The records shall be accurate and in sufficient detail to substantiate the data reported;
(b) Clinical records, including records of all therapeutic services, shall document the client's diagnosis and the medical need for the service. The client's record shall be annotated each time a service is provided and signed or initialed by the individual who provided the service or shall clearly indicate the individual(s) who provided the service. For purposes of medical review, the Authority adopts Medicare's electronic signature policy as outlined in the CMS Medicare Program Integrity Manual. Information contained in the record shall be appropriate in quality and quantity to meet the professional standards applicable to the provider or practitioner and any additional standards for documentation found in this rule, the individual provider rules and any relevant contracts;
c) Electronic Data Transmissions shall comply with the Uniform Electronic Transactions Act cited in ORS chapter 84 and OAR 943-120-0100;
(d) Policies and procedures shall ensure the maintenance of the confidentiality of medical record information. These procedures ensure the provider may release information in accordance with federal and state statutes, ORS 179.505 through 179.507, ORS 411.320, and ORS 433.045, 42 CFR part 2, 42 CFR subpart F, 45 CFR 205.50.
General Rules
99 OAR 410-120-1360 (rev.7/1/2015)
(e) Retain clinical records for seven years and financial and other records described in paragraph (a) and (b) of this rule for at least five years from the date(s) of service.
(3) Upon written request from the Authority, the Medicaid Fraud Unit, Oregon Secretary of State, the Department of Health and Human Services (DHHS), or their authorized representatives furnish requested documentation immediately or within the time-frame specified in the request. Copies of the documents may be furnished unless the originals are requested. At their discretion, official representatives of the Authority, Department, Medicaid Fraud Unit, or DHHS may review and copy the original documentation in the provider's place of business. Upon the written request of the provider, the program or the unit may, at their sole discretion, modify or extend the time for providing records if, in the opinion of the program or unit, good cause for an extension is shown. Factors used in determining whether good cause exists include:

(a) Whether the written request was made in advance of the deadline for production;

(b) If the written request is made after the deadline for production, the amount of time elapsed since that deadline;

(c) The efforts already made to comply with the request;

(d) The reasons the deadline cannot be met;

(e) The degree of control that the provider had over its ability to produce the records prior to the deadline;

(f) Other extenuating factors.

(4) Access to records, inclusive of medical charts and financial records does not require authorization or release from the client if the purpose is:

(a) To perform billing review activities;

(b) To perform utilization review activities;

(c) To review quality, quantity, and medical appropriateness of care, items, and services provided;

(d) To facilitate payment authorization and related services;

(e) To investigate a client's contested case hearing request;

(f) To facilitate investigation by the Medicaid Fraud Unit or DHHS; or

(g) Where review of records is necessary to the operation of the program.

(5) Failure to comply with requests for documents and within the specified time-frames means that the records subject to the request may be deemed by the Authority not to exist for purposes of verifying appropriateness of payment, medical appropriateness, the quality of care, and the access to care in an audit or overpayment determination may subject the provider to possible denial or recovery of payments made by the Division or to sanctions.

[Publications: Publications referenced are available from the agency.]
Stat. Auth.: ORS 413.042
Stats. Implemented: ORS 414.025, 414.065, 414.115, 414.125, 414.135, 414.145

Current Utilization for OHP of these codes

Telemedicine billing CY 2018		
Procedure	**CCO**	**FFS**
98966-Hc Pro Phone Call 5-10 Min	2292	116
98967-Hc Pro Phone Call 11-20 Min	1382	82
98968-Hc Pro Phone Call 21-30 Min	788	71
98969-Online Service By Hc Pro	2	
99441-Phone E/M Phys/Qhp 5-10 Min	13751	1041
99442-Phone E/M Phys/Qhp 11-20 Min	8755	543
99443-Phone E/M Phys/Qhp 21-30 Min	1751	121
99444-Online E/M By Phys/Qhp	396	30
99446-Ntrprof Ph1/Ntrnet/Ehr 5-10	11	1
99447-Ntrprof Ph1/Ntrnet/Ehr 11-20	55	3
99448-Ntrprof Ph1/Ntrnet/Ehr 21-30	85	5
99449-Ntrprof Ph1/Ntrnet/Ehr 31/>	1	4

Evidence Summary

AHRQ, 2019 *https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-216-telehealth-final-report.pdf*

- Systematic review of telehealth consultations. Defined as: the use of telehealth to facilitate collaboration between two or more providers, often involving a specialist, or among clinical team members, across time and/or distance. Consultations may focus on the prevention, assessment, diagnosis, and/or clinical management of acute or chronic conditions.
- 233 articles included
    - 54 articles evaluated inpatient consultations
    - 73 articles evaluated telehealth in emergency care
    - 106 articles evaluated telehealth in outpatient care
- More studies were of real time consultations (about two-thirds) rather than asynchronous (about one-third).
    - Fewer studies with real time consultations reported a benefit (44%) than studies with asynchronous consultations (76%). This may be because the asynchronous studies more often measured access and time to treatment, and these are consistently better with telehealth. The difference is similar when comparing the percentage of one-time (43%) and continuing (70%) consultations that reported results favoring telehealth.

- **Clinical outcomes:**
  - Better healing in wound care (moderate strength)
  - Higher response to treatment in psychiatry (moderate strength)
  - Improvement in chronic condition outcomes care (moderate strength)
  - Dermatology - no difference in clinical outcomes (low strength of evidence).
  - Outcomes for cancer, infectious disease, and multiple specialties had inconsistent results (insufficient evidence).
- **Intermediate outcomes**
  - Access: Telehealth consultations improved access by reducing wait times and time to treatment and by increasing the number of patients receiving indicated diagnostic tests or treatment (moderate strength of evidence).
  - Management and utilization:
    - Telehealth consultations reduced utilization (the number of in-person specialist and hospital visits; number of hospitalizations, and shorter lengths of stay) in most studies.
    - Findings were inconsistent about agreement on diagnosis and management (low strength of evidence).
    - Satisfaction: Patients were generally more satisfied with telehealth consultations, particularly when telehealth saved time or expense compared with the alternative. Clinicians tended to be less satisfied with telehealth than in-person consultations, though differences were rarely statistically significant (low strength of evidence).
- **Costs:** Studies report lower costs and, in most cases, savings are attributable to reductions in transfers or less transportation. However, the rigor of the measurement, imprecision of estimates and inconsistency in the magnitude of the effects, limits confidence in these findings (low strength of evidence).
- **Harms:** Only two of studies explicitly examined harms, reporting lower rates of complications with telehealth (insufficient evidence).

Table C. Outpatient care telehealth consultations: strength of evidence

Outcome (KQ)	Number of Studies (N)	Main Findings	Strength of Evidence (Insufficient, Low, Moderate, High)
Clinical Outcomes (KQ1): Dermatology	3	No significant different in clinical course	Low
Clinical Outcomes (KQ1): Wound Care	5	Better healing and fewer amputations	Moderate
Clinical Outcomes (KQ1): Ophthalmology	0	No studies reported data on clinical outcomes	Insufficient
Clinical Outcomes (KQ1): Orthopedics	0	No studies reported data on clinical outcomes	Insufficient
Clinical Outcomes (KQ1): Dental	0	No studies reported data on clinical outcomes	Insufficient
Clinical Outcomes (KQ1): Cancer	1	Rate of serious side effects from chemotherapy reported in 1 study.	Insufficient
Clinical Outcomes (KQ1): Psychiatry	3 (in five articles)	Decrease in symptoms and high remission rates	Moderate
Clinical Outcomes (KQ1): Infectious Disease	3	Inconsistent results for virologic suppression across studies	Insufficient
Clinical Outcomes (KQ1):): Single Conditions with Diagnostic Technology	0	No studies reported data on clinical outcomes	Insufficient
Clinical Outcomes (KQ1): Single Specialties	6	Positive effects on clinical outcomes such as response to treatment.	Moderate
Clinical Outcomes (KQ1):Multiple Specialties	4	Inconsistent results across studies for unanticipated or avoidable health services utilization	Insufficient
Cost (KQ1)	32	Most studies report cost saving with telehealth but calculations vary and most are dependent on patient avoided travel and loss of time	Low
Intermediate Outcomes: Access (KQ2)	35	Access in terms of time to, or comprehensiveness of, service is improved with telehealth	Moderate
Intermediate Outcomes: Management and Utilization (KQ2)	31	Mixed results with majority finding some benefit in terms of avoiding visits and similar diagnosis or management but a subset of studies report differences in diagnosis and management with telehealth compared with standard care	Low
Intermediate Outcomes: Satisfaction (KQ2)	22	Satisfaction generally the same; patients higher with telehealth if time/travel is avoided. Providers the same or slightly worse for telehealth.	Low
Harms (KQ3)	0	No studies reported data on harms	Insufficient

KQ = Key Question

Conclusions:

Results vary by setting and condition, with telehealth consultations producing generally either better outcomes or no difference from comparators in settings and clinical indications studied. (moderate strength of evidence in favor of telehealth)

- Remote inpatient consultations:
    - Remote intensive care unit consultations likely reduce mortality.
    - Specialty telehealth consultations likely reduce patient time in the emergency department.
    - Telehealth consultations in emergency services likely reduce heart attack mortality.
- Remote consultations for outpatient care likely improve access and clinical outcomes. (moderate strength of evidence in favor of telehealth)

- May reduce outpatient visits and costs due to less travel (low strength of evidence in favor of telehealth).
- No difference in satisfaction with outpatient telehealth consultations (low strength of evidence of no difference).
- Too few studies reported information on potential harms from outpatient telehealth consultations for conclusions to be drawn (insufficient evidence).

MED, 2019

- Rapid review and key informant interviews of asynchronous electronic consultation (eConsult)
- eConsults are defined as directed communication between providers over a secure electronic medium that involves sharing of patient-specific information and discussing clarification or guidance regarding clinical care
- Teleconsultation mechanisms differ based on whether 1) the service provides real-time/live consultation (video, phone) or is asynchronous 2) provides general recommendations (email consultation) or review of patient-specific data; or 3) provides specific recommendations from a team of specialists (Project ECHO) versus a single specialty provider.
- eConsult systems can be voluntary or mandatory
- 4 good-methodological-quality systematic reviews and 36 individual studies were included
- 2 systematic reviews examined harms and adverse events. Outcomes included eConsults resulting in need for emergency department evaluation and/or inpatient admission based on the eConsultation.
- Key findings:
    - Use of eConsults is associated with improved access to care, more efficient health care utilization, and high patient and provider satisfaction compared to traditional referral processes. However, there is significant variation across and within specialties on the magnitude of the effects. (Moderate strength)
    - No significant differences in patient-important or clinical outcomes with the use of eConsults compared to traditional referral processes (Very low to Moderate strength)
    - eConsults are safe and less costly than traditional consultation pathways (Low strength)
- For calendar year (CY) 2019, Medicare has set its reimbursement rates at $37.48 for both the consultant (99451) and requesting provider's (99452) time spent conducting an eConsult.

MED, 2018

- Rapid review
- Focus on telehealth in the home, involving provider to patient communication in real-time (synchronous)
- Evidence was available for 3 types of home telehealth: (1) in-home telehealth visits for disease or case management, (2) in-home telerehabilitation, and (3) direct-to-consumer telehealth visits originating from various nonclinical settings.
- In-home telehealth visits for disease management and telerehabilitation generally led to fewer in-person follow-up visits and less health care utilization than emergency department or physician office visits for patients with chronic and acute conditions.
- Studies of direct-to-consumer telehealth reported that telehealth visits generally led to fewer follow-up consultations or referrals to higher levels of care compared with in-person health care visits. One study in a large health maintenance organization (HMO) reported that the majority of direct-to-consumer telehealth visits represented new utilization as opposed to substitution of in-person visits for telehealth consultations.

Other Payer Policies

CMS rules, 2018
https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-24170.pdf
Interprofessional Internet Consultation (CPT codes 99451, 99452, 99446, 99447, 99448, and 99449)

In summary, we are finalizing separate payment for CPT codes 99451, 99452, 99446, 99447, 99448, and 99449 describing interprofessional consultations. We are finalizing a policy to require the patient's verbal consent that is noted in the medical record for each interprofessional consultation service. We note that cost sharing will apply for these services. These interprofessional services may be billed only by practitioners that can bill Medicare independently for E/M services.

For CY 2019, the CPT Editorial Panel created two new codes to describe additional consultative services, including a code describing the work of the treating physician when initiating a consult, and the RUC recommended valuation for new codes, CPT codes **99452** (Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes) and **99451** (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 or more minutes of medical consultative time).

The RUC also reaffirmed their prior recommendations for the existing CPT codes. The six codes describe assessment and management services conducted through telephone, internet, or electronic health record consultations furnished when a patient's treating physician or other qualified healthcare professional requests the opinion and/or treatment advice of a consulting physician or qualified healthcare professional with specific specialty expertise to assist with the diagnosis and/or management of the patient's problem without the need for the patient's face-to-face contact with the consulting physician or qualified healthcare professional. Currently, the resource costs associated with seeking or providing such a consultation are considered bundled, which in practical terms means that specialist input is often sought through scheduling a separate visit for the patient when a phone or internet-based interaction between the treating practitioner and the consulting practitioner would have been sufficient. We believe that proposing payment for these interprofessional consultations performed via communications technology such as telephone or Internet is consistent with our ongoing efforts to recognize and reflect medical practice trends in primary care and patient-centered care management within the PFS.

CMS rules to go live 11/15/19
https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-24086.pdf
(69) Online Digital Evaluation Service (e-Visit) (CPT Codes 98970, 98971, and 98972)
In September 2018, the CPT Editorial Panel deleted two codes and replaced them with six new non-face-to-face codes to describe patient-initiated digital communications that require a clinical decision that otherwise typically would have been provided in the office. The HCPAC reviewed and made recommendations for CPT code 98970 (*Qualified nonphysician healthcare professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 5-10 minutes*), CPT code 98971 (*Qualified nonphysician healthcare professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11-20 minutes*), and CPT code 98972 (*Qualified nonphysician qualified healthcare professional online digital evaluation and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes*). CPT codes 99421-99423 are for practitioners who can independently bill E/M services while CPT codes 98970-98972 are for practitioners who cannot independently bill E/M services.

Medicare (from MED, 2019)

For calendar year (CY) 2019, Medicare has set its reimbursement rates at $37.48 for both the consultant (99451) and requesting provider's (99452) time spent conducting an eConsult.

99451 and 99452 are set at 0.7 relative value units (RVUs) for requesting and consulting providers. Consulting providers are required to spend at least 5 minutes on the eConsult, whereas requesting providers are required to spend at least 16 minutes

submitting the eConsult, and following up with the patient after the specialist's recommendations are received.

Medicare Criteria for CPT 99451 and 99452

For Calendar Year 2019, CMS established new codes for the coverage of interprofessional consultation through a review of electronic health record data in addition to telephone and email consultations. Medicare's established criteria for using these new codes are described below.

Consulting Providers (99451)

- New or established patients
- New or exacerbated conditions
- Only reported by a consultant when requested by another provider
- Cannot be reported > 1 time per 7 days for the same patient
- Cumulative time spent reported, even if time occurs over multiple days
- Cannot be reported if a transfer of care or request for face-to-face visit occurs as a result of the consultation within the next 14 days
- Cannot be reported if the patient was seen by the consultant within the past 14 days
- Request and reason for consultation request must be documented in the patient's medical record
- Requires a minimum of 5 minutes
- Documentation of patient/family's verbal consent for interprofessional consultation

Requesting Providers (99452)

- Reported by requesting provider (not for the transfer of a patient or request for face-to-face consult)
- Providers must be able to independently bill Medicare for E/M visits
- Reported only when the patient is not on-site and with the provider at the time of consultation
- Cannot be reported more than 1 time per 14 days per patient
- Includes time for referral prep and/or communicating with the consultant
- Requires a minimum of 16 minutes
- Can be reported with prolonged services, non-direct
- Provider must obtain verbal consent (that is documented in the medical record) because of the cost sharing component

Other Medicaid agencies *(from Med, 2019)*

- Connecticut Medicaid
    - CPT 99451 (consultant) is reimbursed at $34.28, and CPT 99452 is reimbursed at $17.34 (requesting provider)

- Arizona reimburses 99451 and 99452 at the same rate of $29.09
- Minnesota Department of Health reimburses 99451 and 99452 at the same rate of $28.17
- Oklahoma uses a PMPM and $20 per eConsult rate
- Alaska reimburses at the same rate as face-to-face visits

United Healthcare, 2019
https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-reimbursement/COMM-Telehealth-and-Telemedicine-Policy.pdf

The following are covered:

- 99446-99449
- 99451-99452
- 99453, 99454, 99457, and 99091 – remote monitoring of physiologic parameters
- G2010 - remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward),
- G2012 - brief communication technology-based service, e.g., virtual check-in, by a physician or other qualified health care professional

The following are not covered

- T1014 Telehealth transmission, per minute, professional services
- 98966-98968 or 99441-99443 – non-face-to-face evaluation codes
- 98969
- 99444

BCBS, 2019
https://www.excellusbcbs.com/wps/wcm/connect/0dae5aa5-7671-4599-bfde-099f53671b02/mp+telemed+mpc3+19.pdf?MOD=AJPERES&CACHEID=0dae5aa5-7671-4599-bfde-099f53671b02

- Appears to cover a wide range of the telemedicine codes without specific limitations

Washington Medicaid, 2019
https://www.hca.wa.gov/assets/billers-and-providers/physician-related-serv-bg-20190101.pdf

The agency pays for telephone services when used by a physician to report and bill for episodes of care initiated by an established patient (i.e., someone who has received a face-to-face service from you or another physician of the same specialty in your group in the past three years) or by the patient's guardian. Report and bill for telephone services using the following CPT codes:

• CPT code 99441 - Telephone evaluation and management (E/M) service provided by a physician to an established patient, parent or guardian not originating from a related E/M service provided within the previous seven days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion.

• CPT code 99442 - Same as CPT code 99441 except call includes 11–20 minutes of medical discussion

• CPT code 99443 - Same as CPT code 99441 except call includes 21–30 minutes of medical discussion.

Additional information when billing with these codes for telephone services:

1. Telephone services that are billed with CPT codes 99441, 99442 or 99443 must be personally performed by the physician.
2. If the telephone service relates to and takes place within the postoperative period of a procedure provided by the physician, the service is considered part of the procedure and should not be billed separately.
3. Telephone services should not be billed when the same services are billed as care plan oversight or anticoagulation management (CPT codes 99339-99340, 99374-99380 or 99363-99364).
4. When a telephone service refers to an E/M service performed and billed by the physician within the previous seven days, it is not separately billable, regardless of whether it is the result of patient-initiated or physician-requested follow-up.
5. This service should not be billed if the service results in the patient being seen within 24 hours or the next available appointment.

HERC Staff Summary

The current guideline on telephone consultations is outdated and does not take into account clinician-to-clinician consultations. Changing the guideline from a guideline note to a diagnostic guideline makes sense, for simplicity on the Prioritized List and also to clarify intent regarding the use of telephone and electronic consultations for funded diagnoses.

Teleconsultations (clinician-to-clinician) have some evidence that they improve some clinical and intermediate outcomes, and may be cost-neutral to cost-saving. They help to increase access to care but do not result in overall increases in utilization. Some of this evidence specifically evaluated the use of eConsult in Medicaid populations and finds economic benefit.

Direct-to-consumer telemedicine is associated with unnecessary utilization.

There are also new 2020 CPT codes that require placement.

Face-to-face telehealth visits are not addressed in this issue summary.

HERC Staff Recommendations:

1. **Make the following coding changes**

Code	Description	Placement	Fee Schedule	Recommended Placement
98969	Online assessment and management service provided by a **qualified nonphysician health care professional**	638 lines	Not on fee schedule	Delete code from Prioritized

	to an established patient or guardian, not originating from a related assessment and management service provided within the previous 7 days, **using the Internet or similar electronic communications network**		(Medicare does not cover this) Obsolete 2020	List, obsolete in 2020
98970	Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes	New Code	New Code	Add to all lines with E&M codes
98971	Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes	New Code	New Code	Add to all lines with E&M codes
98972	Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes	New Code	New Code	Add to all lines with E&M codes
99421	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes	New Code	New Code	Add to all lines with E&M codes
99422	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes	New Code	New Code	Add to all lines with E&M codes
99423	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes	New Code	New Code	Add to all lines with E&M codes
99444	Online evaluation and management service provided by a **physician or other qualified health care professional** who may report evaluation and management services provided to an established patient or guardian, not originating from	638 lines	Manual (Medicare does not cover this)	Delete code from Prioritized List, obsolete in 2020

	a related E/M service provided within the previous 7 days, **using the Internet or similar electronic communications network**			
99446	**Interprofessional** telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; **5-10 minutes of medical consultative discussion and review**	638 lines	Not on Fee Schedule	Recommend to HSD to add to Fee Schedule
99447	**Interprofessional** telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; **11-20 minutes of medical consultative discussion and review**	638 lines	Not on Fee Schedule	Recommend to HSD to add to Fee Schedule
99448	**Interprofessional** telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; **21-30 minutes of medical consultative discussion and review**	638 lines	Not on Fee Schedule	Recommend to HSD to add to Fee Schedule
99449	**Interprofessional** telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; **31 minutes or more of medical consultative discussion and review**	638 lines	Not on Fee Schedule	Recommend to HSD to add to Fee Schedule

99451	**Interprofessional** telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a written report to the patient's treating/requesting physician or other qualified health care professional**, 5 minutes or more of medical consultative time**	638 lines	$26.03	Adopt a diagnostic guideline delineating appropriate use of this code
99452	**Interprofessional** telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified health care professional, **30 minutes**	638 lines	$26.03	Adopt a diagnostic guideline delineating appropriate use of this code
G2012	**Brief communication technology-based service, e.g. virtual check-in,** by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m service	638 lines	Not on fee schedule	Recommend to HSD to add to Fee Schedule

2. **Delete Guideline Note 65 from 638 lines of the Prioritized List.**
3. **Adopt a diagnostic guideline**

DIAGNOSTIC GUIDELINE NOTE XX, TELECONSULTATIONS AND NON-FACE-TO - FACE TELEHEALTH SERVICES

Patient to Clinician Services (via telephone or electronic)

Telephonic and electronic services (CPT 98966-98968, 99441-99443, 99421-99423, 98970-98972, G2012) between a patient and clinician must meet the following criteria:

1) Ensure pre-existing relationship as demonstrated by at least one prior office visit within the past CHOOSE 12/36 months.
2) Documentation must:
   a. model SOAP charting, or be as described in program's OAR;
   b. include patient history, provider assessment, treatment plan and follow-up instructions;
   c. support the assessment and plan;
   d. be retained in the patient's medical record and be retrievable.
3) Medical decision making (or behavioral health intervention/ psychotherapy) is necessary.

4) Ensure permanent storage (electronic or hard copy) of the encounter.
5) Meet HIPAA standards for privacy.
6) Include a patient-clinician agreement of informed consent, which is discussed with and signed by the patient and documented in the medical record.
7) Not be billed when the same services are billed as care plan oversight or anticoagulation management (CPT codes 99339-99340, 99374-99380 or 99363-99364).
8) When a telephone or electronic service refers to an E/M service performed and billed by the physician within the previous seven days, it is not separately billable, regardless of whether it is the result of patient-initiated or physician-requested follow-up.
9) This service is not billed if the service results in the patient being seen within 24 hours or the next available appointment.
10) If the service relates to and takes place within the postoperative period of a procedure provided by the physician, the service is considered part of the procedure and is not be billed separately.

Examples of reimbursable telephone or electronic services include but are not limited to:

1) Extended counseling when person-to-person contact would involve an unwise delay.
2) Treatment of relapses that require significant investment of provider time and judgment.
3) Counseling and education for patients with complex chronic conditions.

Examples of non-reimbursable telephone consultations include but are not limited to:

1) Prescription renewal.
2) Scheduling a test.
3) Reporting normal test results.
4) Requesting a referral.
5) Follow up of medical procedure to confirm stable condition, without indication of complication or new condition.
6) Brief discussion to confirm stability of chronic problem and continuity of present management.

Clinician-to-Clinician Telehealth Consultations (telephonic and electronic)

Telehealth consultations are defined as the use of telehealth to facilitate collaboration between two or more clinicians, one being a specialist. Requirements for coverage of electronic consultation or telephonic interprofessional consultation are as follows:

Consulting Providers (99451, 99446-9)

- Consult must be requested by another provider
- Can be for a new or exacerbated condition
- Cannot be reported more than 1 time per 7 days for the same patient
- Cumulative time spent reported, even if time occurs over multiple days
- Cannot be reported if a transfer of care or request for face-to-face visit occurs as a result of the consultation within the next 14 days
- Cannot be reported if the patient was seen by the consultant within the past 14 days
- Request and reason for consultation request must be documented in the patient's medical record
- Requires a minimum of 5 minutes

Requesting Providers (99452)

- eConsult must be reported by requesting provider (not for the transfer of a patient or request for face-to-face consult)
- Reported only when the patient is not on-site and with the provider at the time of consultation
- Cannot be reported more than 1 time per 14 days per patient
- Requires a minimum of 16 minutes. Includes time for referral prep and/or communicating with the consultant.
- Can be reported with prolonged services, non-direct

Limited information provided by one clinician to another that does not contribute to collaboration (e.g., interpretation of an electroencephalogram, report on an x-ray or scan, or reporting the results of a diagnostic test) is not considered a consultation.

<u>HERC Staff Recommendations (Cont'd)</u>

4. Recommend HSD update OARs (still refers to Health Services Commission and new language is indicated)
5. Recommend HSD add the following codes to the fee schedule
    a. 99446-99449
    b. 98970-98972
    c. 99421-99423
    d. G2012
6. Delete 99444 and 98969 from all lines on the Prioritized List. Codes obsolete.

Comparative Effectiveness Review
Number 216

Telehealth for Acute and Chronic Care Consultations

Agency for Healthcare
Research and Quality

Telehealth for Acute and Chronic Care Consultations

Structured Abstract

Objectives. To conduct a systematic review to identify and summarize the available evidence about the effectiveness of telehealth consultations and to explore using decision modeling techniques to supplement the review. Telehealth consultations are defined as the use of telehealth to facilitate collaboration between two or more providers, often involving a specialist, or among clinical team members, across time and/or distance. Consultations may focus on the prevention, assessment, diagnosis, and/or clinical management of acute or chronic conditions.

Data sources. We searched Ovid MEDLINE®, the Cochrane Central Register of Controlled Trials (CCRCT), and the Cumulative Index to Nursing and Allied Health Literature (CINAHL®) to identify studies published from 1996 to May 2018. We also reviewed reference lists of identified studies and systematic reviews, and we solicited published or unpublished studies through an announcement in the *Federal Register*. Data for the model came both from studies identified via the systematic review and from other sources.

Methods. We included comparative studies that provided data on clinical, cost, or intermediate outcomes associated with the use of any technology to facilitate consultations for inpatient, emergency, or outpatient care. We rated studies for risk of bias and extracted information about the study design, the telehealth interventions, and results. We assessed the strength of evidence and applicability, and then synthesized the findings using quantitative and qualitative methods. An exploratory decision model was developed to assess the potential economic impact of telehealth consultations for traumatic brain injuries in adults.

Results. The search yielded 9,366 potentially relevant citations. Upon review, 8,356 were excluded and the full text of 1,010 articles was pulled for review. Of these, 233 articles met our criteria and were included—54 articles evaluated inpatient consultations; 73, emergency care; and 106, outpatient care.

The overall results varied by setting and clinical topic, but generally the findings are that telehealth improved outcomes or that there was no difference between telehealth and the comparators across the settings and for the clinical indications studied.

Remote intensive care unit (ICU) consultations likely reduce ICU and total hospital mortality with no significant difference in ICU or hospital length of stay; specialty telehealth consultations likely reduce the time patients spend in the emergency department; telehealth for emergency medical services likely reduces mortality for patients with heart attacks; and remote consultations for outpatient care likely improve access and a range of clinical outcomes (moderate strength of evidence in favor of telehealth). Findings with lower confidence are that inpatient telehealth consultations may reduce length of stay and costs; telehealth consultations in emergency care may improve outcomes and reduce costs due to fewer transfers, and also may reduce outpatient visits and costs due to less travel (low strength of evidence in favor of telehealth). Current evidence shows no difference in clinical outcomes with inpatient telehealth specialty consultations, no difference in mortality but also no difference in harms with telestroke consultations, and no difference in satisfaction with outpatient telehealth consultations (low strength of evidence of no difference). Too few studies reported information on potential harms from outpatient telehealth consultations for conclusions to be drawn (insufficient evidence).

An exploratory cost model underscores the importance of perspective and assumptions in using modeling to extend evidence, and the need for more detailed data on costs and outcomes when telehealth is used for consultations. For example, a model comparing telehealth to transfers and in-person neurosurgical consultations for acute traumatic brain injury identified that the impact of telehealth on costs may depend on multiple factors, including how alternatives are organized (e.g., if the telehealth and in-person options are part of the same healthcare system) and whether the cost of a telehealth versus an in-person consultation differ.

Conclusions. In general, the evidence indicates that telehealth consultations are effective in improving outcomes or providing services, with no difference in outcomes; however, the evidence is stronger for some applications, and less strong or insufficient for others. However, as specific details about the implementation of telehealth consultations and the environment were rarely reported, it is difficult to assess generalizability. Exploring the use of a cost model underscored that the economic impact of telehealth consultations depends on the perspective used in the analysis. The increase in both interest and investment in telehealth suggests the need to develop a research agenda that emphasizes rigor and focuses on standardized outcome comparisons that can inform policy and practice decisions.

Section 6.0

Previously Discussed Items

Lower Extremity Chronic Venous Disease

Question: Should coverage of lower extremity chronic venous disease (e.g. varicose veins) on the Prioritized List be moved to a higher priority line?

Question source: HERC Staff

Issue: At the August 2019 VbBS meeting, coverage of lower extremity chronic venous disease (LECVD) was discussed. Based on the evidence reviewed at the August meeting, HERC staff concluded that there was insufficient evidence to determine if treatment of chronic lower extremity venous disease with surgery or minimally invasive treatments results in improved outcomes (pain, quality of life, symptom scores) compared to placebo or usual (non-surgical) care. HERC staff recommended adding limited additional coverage for patients with recurrent episodes of thrombophlebitis.

Currently, varicose veins that cause swelling or pain are including on line 639 VARICOSE VEINS OF LOWER EXTREMITIES WITHOUT ULCER OR OTHER MAJOR COMPLICATION, with various treatments pairing on that line. A similar condition to varicose veins, post-thrombotic syndrome, is included on line 519 POSTTHROMBOTIC SYNDROME. If a varicose vein is associated with an ulcer, treatment is paired on line 379 CHRONIC ULCER OF SKIN. If the varicose vein is causing inflammation (phlebitis), then the diagnosis is included on line 516 PHLEBITIS AND THROMBOPHLEBITIS, SUPERFICIAL.

Testimony was heard at the August meeting from Dr. Ed Boyle, a vein surgeon from Bend, as well as a representative of Medtronix. Dr. Boyle testified that the HERC coverage only treats the end stage of CLEVD, and he recommended expanding coverage to include refractory lower extremity edema, pain, bleeding from a varicosity, and stasis dermatitis. He testified about NICE guidelines which cover more complications of CLEVD than OHP. The VbBS requested that HERC staff identify and summarize all NICE guidelines on CLEVD, as well as other literature submitted or referred to by the testifiers, and bring back to a future VbBS meeting for further discussion.

Staff have subsequently been in communication with Dr. Boyle, who provided written testimony in response to staff questions as well as additional literature.

Excerpts from Dr. Edward Boyle's submitted testimony:

> **HERC Question #1: Is conservative treatment significantly less effective than any type of invasive procedure (sclerotherapy, vein stripping, etc.) for non-ulcerated varicose veins?**
>
> **My Response:** YES, interventions are more effective than conservative therapy. I have attached two separate randomized controlled trials by JA Michaels and colleagues that compared outcomes between a cohort randomized to conservative measures only and those that had a procedure to treat saphenous vein reflux. These were used by the NICE review that supported coverage for varicose vein interventions in the UK. In these high-quality published clinical trials there was clear evidence that surgical treatment is superior to provide symptoms relief and quality of life improvement compared to conservative therapy. Surgical treatment also showed a significant economic benefit over conservative therapy…the national guidelines from the Society of Vascular Surgery/American Venous Forum (attached) concluded there is "weak evidence to support compression as a primary treatment for patients with symptomatic varicose veins if a patient is a candidate for saphenous vein ablation."

SUMMARY OF MAIN REPLY POINT: Yes there is high quality evidence that interventions targeted to reduce venous reflux by eliminating the saphenous veins and its varicose branches are superior to conservative therapy. From a payer policy perspective, however, there is ample predicate to support a policy that defines the indication that a procedure should be for patients with moderate to severe venous symptoms who have tried and failed conservative measures. In a system with constrained financial resources, this is an approach where utilization can be best directed to those who need it most.

HERC Question #2: Do lower grades of varicose veins progress to higher grades? Specifically address that NICE comments say that this is an area with low to very low level evidence, and they also comment that there is no high quality evidence that lower grades of varicose veins will progress to higher grades.

- **Chronic venous insufficiency is progressive:** We know from epidemiological studies like the Bonn studies, Edinburgh studies and others that venous insufficiency generally does progress over time. However, it does not progress at the same speed in all patients. And there are some patients that have little or no progression. There are others that have rapid progression. And there are some patient factors more correlated with progression.
- **Is there evidence that treatment with surgery prevents progression?:**
    - No…not enough. Thus we concur that prevention of progression is not an indication for surgical intervention. The indications should be to reduce *current symptoms*….not prevention of future symptoms.
    - As you referenced, according to NICE…section 2.1 on Natural History of Varicose Veins: "the understanding of factors leading to progression are an "area of low evidence." What they specifically say is: **The results of future studies should help to more accurately identify which patients are at risk of developing more serious disease so that interventions can be offered at an early stage to those who will benefit most."** This is to say that in the future, if the evidence supports this, maybe prevention of progression will be an indication for treatment. But it is not now. We agree. As emphasized above, since prevention of progression is not an indication for treatment, my opinion is the natural history discussion is less relevant to your consideration in revising the coverage policy. Rather, using the coverage policy we are advocating for therapy will be reserved only for those that have moderate to severe venous symptoms NOW, negatively impacting their life NOW, that have not responded to a trial of conservative therapy NOW.

SUMMARY: Its clear venous disease is a progressive problem. The NICE guidelines reference the Edinburgh and Bonn studies that demonstrate this. However, the specific comment cited by the HERC about low evidence is addressing if there is not enough evidence that prevention of progression should be an indication for surgery. We concur that prevention of progression is not an indication for a procedure based on current evidence. The indications that are supported by class I evidence are to reduce current symptoms, not prevent future symptoms. The policy we advocate for accomplishes this goal from a payer policy perspective.

Evidence

1) **NICE 2013**, varicose vein management evidence review
    a. Overall quality of evidence
        i. Overall, the quality of evidence was of low to very low quality. The main limitations were methodological, such as a lack of allocation concealment or intention to treat in some studies. In addition there was a high level of imprecision for most outcomes.
    b. Evidence for compression treatment vs no therapy
        i. Studies
            1. N=3 trials (two crossover trials, one parallel trial); N=311 patients
            2. N=5 observational studies; N=1214 patients
        ii. Compression led to a reduction in pain and swelling (very low quality evidence)
        iii. Compression led to a reduction in a feeling of heaviness and reduction in overall complaints (low quality evidence)
        iv. Conclusions: There was no evidence for the outcome of health-related quality of life. Compression stockings reduce patient ratings of ankle swelling, cramps and the feeling of tired/ heavy legs, but these reductions are small (under 10 points on a scale ranging from 0-100).
    c. Evidence for compression treatment vs surgery
        i. Threes studies (N=173, 91, 179 patients) showed better quality of life at 1 or 2 years for surgery compared to compression., but the effect was not large (low quality evidence)
        ii. One study (N=78 patients) found no difference in quality of life at 2 yrs (moderate quality evidence)
        iii. One study (172 patients) found significant clinical benefit of surgery at reducing aching, itching, and swelling at 1 year (moderate quality evidence)
        iv. Three cost-utility analyses found surgery to be cost effective compared to conservative care
            1. Based on 3 studies, compression did not appear to be cost effective compared to interventional treatment. ICERs comparing surgery to conservative care were between £2,895 and £4,687 per QALY gained, based on directly applicable evidence.
        v. Conclusions: There was evidence of benefit in terms of quality of life for surgery compared with compression, although the effect was not large enough to show clearly appreciable clinical benefit. There were clear clinical benefits for surgery in terms of patient satisfaction and patient assessed symptoms. There was a paucity of evidence for adverse events (only foot drop recorded).
    d. Evidence for surgery vs foam sclerotherapy
        i. There was too great an uncertainty in the data to draw conclusions about the relative effects of vein stripping vs foam sclerotherapy on pain and quality of life and on physician rated vein scores, or return to work
        ii. Conclusion: No clinically important differences were noted in the critical outcomes.
    e. Evidence for surgery vs endothermal ablation therapy
        i. There was too great an uncertainty to determine the relative effects of these interventions on quality of life, pain, edema, DVT formation, limb discoloration, or return to work

   ii. One study (N=316 patients) found no difference in physician scoring of disease at one or two years between these interventions (Low quality evidence)
   iii. Conclusions: No clinically important differences between the two interventions were noted for the critical outcomes
   iv. Cost effectiveness: Our original economic analysis found endothermal treatment to dominate surgery; endothermal treatment was also cost-effective when considering the other comparators in the model
f. Evidence for foam sclerotherapy vs endothermal ablation
   i. There was too great an uncertainty in the data to draw conclusions about the relative effects of foam sclerotherapy vs endothermal ablation on pain and quality of life and on physician rated vein scores, or need for further treatment
   ii. Conclusions: No clinically important differences were noted between endothermal ablation as a single modality and foam sclerotherapy for the critical outcomes
g. Conclusions: Endothermal ablation was found to dominate surgery and conservative care, and to be cost-effective in 71% of model simulations.
h. Other comments
   i. Symptomatic varicose veins: treatment recommended based mainly on the evidence from the review of interventional treatments. Cost effectiveness analysis showed that interventional treatment is highly cost effective for the patients included within the clinical trials reviewed.
   ii. Skin changes: patients with skin changes in legs affected by venous hypertension are at greater risk of developing venous leg ulceration
   iii. Bleeding from varicose veins: May be life threatening
   iv. Superficial vein thrombosis: DVT was present in approximately 20% of legs with superficial vein thrombosis
   v. The evidence review for the guideline showed a lack of high-quality evidence on the progression of varicose veins from CEAP stage C2 or C3 to more serious varicose vein disease
   vi. A large-scale RCT that compares the 4 main treatments (compression, surgery, endothermal ablation and foam sclerotherapy) in subgroups with varicose veins at different stages is needed

<u>Submitted literature on conservative vs surgical therapy</u>

1) **Michaels 2006**, RCT of conservative therapy vs vein stripping for symptomatic varicose veins
   a. N=246 patients (122 conservative; 124 surgical)
      i. eligible for the study if they had varicose veins with evidence of saphenofemoral or saphenopopliteal reflux.
      ii. Patients were excluded if they had coexisting disease or disability that would preclude surgical treatment, complications of varicose veins (skin change, bleeding, phlebitis or ulceration), or if the veins were less than 5 mm diameter in fewer than two quadrants below the knee or less than 5 mm diameter in the lower thigh
      iii. Further analysis of this RCT in Michaels 2006 below reports that BMI>32 was an exclusion criteria
      iv. Conservative management consisted of lifestyle advice relating to exercise, leg elevation, management of weight and diet, and the use of compression hosiery.

v. Surgical intervention: vein stripping and phlebectomies

b. Thirty-one percent of patients reported that they had some relief of symptoms through the use of compression hosiery. For all reported symptoms, there was significantly greater relief at 1 year with surgery than with conservative treatment. The differences at 2 years were not significant, but this was based on intention-to-treat analysis, and a significant proportion of patients in the conservative treatment group had opted to undergo surgery by this time.

c. In the first 2 years after treatment there was a significant quality of life benefit for surgery of 0.083 (95 per cent confidence interval (c.i.) 0.005 to 0.16) quality-adjusted life years (QALYs) based on the SF-6Dscore and 0.13 (95 per cent c.i. 0.016 to 0.25) based on the EQ-5D score [note: These calculations were based on imputed discounted values using a 3.5 per cent discount rate in line with current Department of Health recommendations and straight line interpolation]

i. Minimal clinically important difference for the SF-6D is 0.041

ii. Minimal clinically important difference for the EQ-5D is 0.074

d. Conclusion: Surgical treatment provides symptomatic relief and significant improvements in quality of life in patients referred to secondary care with uncomplicated varicose veins.

2) **Michaels 2006,** further analysis of RCT reported in Michaels 2006 above

a. Patients were broken down into 3 subgroups: mild, moderate or severe vein reflux

i. Group 1: No significant reflux in the groin/LSV or popliteal fossa. Varicose veins restricted to below the knee or <5 mm in diameter in the lower two-thirds of the thigh

ii. Group 2: Reflux >1 s at groin, LSV or popliteal fossa. Varicose veins <5 mm in the lower two-thirds of thigh and/or below the knee (any extent below knee varicose veins but must not be >5 mm in more than one quadrant)

iii. Group 3: Any patient with significant skin changes, reflux >1 s in the groin, LVS or popliteal fossa. Above-knee varicose veins >5 mm in diameter of any varicose veins in upper third of thigh. Below-knee varicose veins >5 mm in more than one quadrant

b. No difference in quality of life or symptoms were found between conservative and surgical treatment in the mild (N=34) or moderate (N=77) group

c. In the severe group (N=246), The surgical arm of the trial showed better results for symptoms, anatomical extent, HRQoL and patient satisfaction at 1-year follow-up.

i. Note: only the severe group results reported in the Michaels 2006 RCT above

d. Cost-effectiveness analysis based on the Group 3 trial showed that the surgery produced an estimated discounted benefit of 0.054 quality adjusted life-year (QALY) over a 2-year period, with an additional discounted cost of £387.45, giving an incremental cost-effectiveness ratio (ICER) of £7175 per QALY. Injection sclerotherapy produced an incremental benefit of approximately 0.044 QALY at a cost of £155 when compared with conservative treatment, giving an ICER of £3500 per QALY.

<u>Submitted literature on progression of disease</u>

1) **Lee 2015**, cohort study of progression of CLEVD

a. N=334 patients

i. Edinburgh Vein Study

ii. Follow up was 13 years after initial exam

   b. Progression was found in 193 (57.8%), equivalent to 4.3% (95% confidence interval [CI], 3.7-4.9) annually. In 270 subjects with only varicose veins at baseline, 86 (31.9%) developed CVI, with the rate increasing consistently with age (P [.04). Almost all subjects (98%) with both varicose veins and CVI at baseline deteriorated. Progression of chronic venous disease did not differ by gender or leg, but a family history of varicose veins and history of deep venous thrombosis increased risk (odds ratio [OR], 1.85 [95% CI, 1.14-1.30] and 4.10 [95% CI, 1.07-15.71], respectively). Overweight was associated with increased risk of CVI in those with varicose veins (OR, 1.85; 95% CI, 1.10-3.12). Reflux in the superficial system increased the likelihood of progression, especially in combination with deep reflux (OR, 2.57; 95% CI, 1.55-4.25) and when located in the small saphenous vein (OR, 4.73; 95% CI, 1.37-16.39).
   c. Conclusions: Nearly half of the general population with chronic venous disease deteriorated during 13 years, and almost one third with varicose veins developed skin changes of CVI, increasing their risk of ulceration. Age, family history of varicose veins, history of deep venous thrombosis, overweight, and superficial reflux, especially in the small saphenous vein and with deep reflux, might influence the risk of progression.

1) **Labropoulos 2015**, cohort study of CLEVD progression
   a. N=116 limbs (90 patients)
      i. Patients who declined surgical intervention
      ii. Follow up 1-43 months after initial exam
   b. Eighty-five limbs (73.3%) were unchanged. Thirteen limbs (11.2%) had progression of clinical stage, and seven had progression on DU scanning as well. Seven limbs progressed from C2 to C3, four limbs from C3 to C4, and two limbs from C4 to C6. Thirty-four limbs had a documented change on repeat DU scanning. In 3 of these limbs, reflux was missed on the initial exam; therefore, 31 limbs had progression of disease.
   c. Seventeen limbs (14.7%) had extension of pre-existing reflux, and 14 (12.1%) had reflux in a new segment. In 11 of these limbs, a change in the initial plan for treatment was required. Symptomatic or DU changes were noted 6 months or later in 95% of limbs and 74.2% of limbs with disease progression were diagnosed at 12 months or later.
   d. *Conclusion:* Nearly one third of patients with venous reflux had progression. Anatomic extension is frequent with disease progression but not a pre-requisite. Progression was found in most limbs 6 months after the initial study.

<u>Other evidence found in additional review</u>

1) **Vemulapalli 2018**, systematic review and meta-analysis of interventions for chronic lower extremity venous disease
   a. Endovascular therapy was compared with compression in 2 fair- and 1 poor-quality RCTs comprising 117 patients. Insufficient study numbers, heterogeneity in outcomes, and outcome timing prevented meta-analysis of any outcomes. Additionally, findings regarding outcomes of interest were found to be of insufficient SOE primarily due to suspected reporting bias, imprecision, and lack of allocation concealment within included studies
   b. There was no difference in effectiveness between subtypes of endovascular therapies or between endovascular therapies versus surgical therapies. Additionally, existing randomized trials of endovascular therapies in LECVD are limited by (1) heterogeneity of outcomes; (2) suboptimal study design manifested by lack of allocation concealment,

lack of double blinding, and reporting bias; and (3) insufficient reporting of important anatomic, gender, and racial subgroups.

Trusted source guidelines

1) **NICE 2019** treatment pathway for lower extremity varicose veins (for non-pregnant adult patients)
    a. Recommend referral to a vascular surgeon:
        i. Bleeding varicose veins
        ii. Symptomatic primary or recurrent varicose veins (typically pain, aching, discomfort, swelling, heaviness, and itching)
        iii. Lower limb skin changes, such as pigmentation changes, thought to be caused by chronic venous insufficiency
        iv. Superficial vein thrombosis
        v. Venous ulcer (active or healed)
    b. Offer interventional treatment to patients with the above conditions and truncal reflux
        i. First line therapy is endothermal ablation and endovenous laser treatment
        ii. If endothermal ablation is unsuitable, offer ultrasound guided foam sclerotherapy
        iii. If ultrasound guided foam sclerotherapy is unsuitable, offer surgery
    c. Offer compression hosiery only if interventional treatment is unsuitable

Other expert guidelines

1) **Gloviczki 2011**, Society for Vascular Surgery guidelines for varicose veins
    a. We suggest compression therapy for patients with symptomatic varicose veins (GRADE 2C) but recommend against compression therapy as the primary treatment if the patient is a candidate for saphenous vein ablation (GRADE 1B).
    b. We recommend compression therapy as the primary treatment to aid healing of venous ulceration (GRADE 1B).
    c. To decrease the recurrence of venous ulcers, we recommend ablation of the incompetent superficial veins in addition to compression therapy (GRADE 1A).
    d. For treatment of the incompetent great saphenous vein (GSV), we recommend endovenous thermal ablation (radiofrequency or laser) rather than high ligation and inversion stripping of the saphenous vein to the level of the knee (GRADE 1B).
    e. We recommend phlebectomy or sclerotherapy to treat varicose tributaries (GRADE 1B) and suggest foam sclerotherapy as an option for the treatment of the incompetent saphenous vein (GRADE 2C)

HERC staff summary

The majority of the literature on treatment of lower extremity chronic venous disease focuses on comparing various endovascular or surgical treatments against other such interventions. For the purposes of HERC coverage determination, the question of interest is comparing no or standard therapy (compression therapy) against invasive interventions. For this question, the literature is sparse, and studies are generally of low quality. NICE concluded that compression therapy vs no therapy reduced patient symptoms, but reductions were small and possibly not clinically significant. NICE concluded that, based on 5 studies, surgery resulted in better quality of life compared to compression therapy, but the effect was small and possibly not clinically significant (low quality evidence); surgery also resulted in significant clinical benefit at reducing patients' symptoms (aching, itching, and swelling). NICE concluded that surgery was cost effect compared to conservative care. There was no evidence review found comparing compression or other conservative therapy vs endovenous interventions. Based on systematic reviews and meta-analyses, there is no difference in outcomes between the various surgical and endovenous interventions.

Expert submitted literature included an RCT of conservative vs surgical therapy for varicose veins (Michaels 2006). In this study of 246 patients with severe reflex (significant skin changes, reflux >1 s in the groin, LVS or popliteal fossa, above-knee varicose veins >5 mm in diameter of any varicose veins in upper third of thigh, below-knee varicose veins >5 mm in more than one quadrant) and a BMI <32, there was a clinically significant improvement in quality of life, and a subsequent economic evaluation found a cost per QALY of £3500-£7175 depending on the type of surgery. Of note, no significant differences in any measured outcome were found in patients with mild or moderate vein reflux between conservative and surgical therapy groups.

NICE found a lack of high-quality evidence on the progression of varicose veins from CEAP stage C2 or C3 to more serious disease. Submitted literature found that up to 50% of patients with venous insufficiency will progress over a 13-year period.

Expert groups and NICE recommend treatment of lower extremity chronic venous disease for a much wider range of indications that is currently included on the Prioritized List.

HERC staff recommendations:

1) Add coverage of chronic lower extremity venous disease for patients with recurrent thrombophlebitis, consistent with prior HSC/HERC intent to cover with "cellulitis;" add coverage for bleeding varicose veins
    a. Add varicose veins with other complications to line 379 CHRONIC ULCER OF SKIN and keep on line 519 POSTTHROMBOTIC SYNDROME/639 VARICOSE VEINS OF LOWER EXTREMITIES WITHOUT ULCER OR OTHER MAJOR COMPLICATION
        i. ICD10 I83.89 (Varicose veins of lower extremities with other complications)
        ii. ICD10 I87.09 (Postthrombotic syndrome with other complications of lower extremity)
    b. Adopt a new guideline note to line 379 as shown below
2) Clarify when ulceration is an indication for varicose vein treatment in the new guideline
3) Modify the line title of line 379 to CHRONIC ULCER OF SKIN; VARICOSE VEINS WITH MAJOR COMPLICATIONS

GUIDELINE NOTE XXX, TREATMENT OF CHRONIC LOWER EXTREMITY VENOUS DISEASE

Lines 379,519,639

Treatment of chronic lower extremity venous disease is only included on line 379 when

1) The patient has had an adequate 3-month trial of conservative therapy and failed; AND
2) The patient has one of the following:
    a. Non-healing skin ulceration in the area of the varicose vein(s), OR
    b. Recurrent episodes of superficial thrombophlebitis, OR
    c. Serious bleeding from varicose vein(s)

Otherwise, these diagnoses are included on lines 519 or 639.

National Clinical Guideline Centre

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Varicose veins in the legs

The diagnosis and management of varicose veins

Clinical guideline

Methods, evidence and recommendations

July 2013

Final Version

Commissioned by the National Institute for Health and Care Excellence

4 Guideline summary

4.1 Key priorities for implementation

From the full set of recommendations, the GDG selected 4 key priorities for implementation. The criteria used for selecting these recommendations are listed in detail in The Guidelines Manual.[74] The reasons that each of these recommendations was chosen are shown in the table linking the evidence to the recommendation in the relevant chapter.

- Refer people to a vascular service[1] if they have any of the following.
  - Symptomatic[2] primary or symptomatic recurrent varicose veins.
  - Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency.
  - Superficial vein thrombosis (characterised by the appearance of hard, painful veins) and suspected venous incompetence.
  - A venous leg ulcer (a break in the skin below the knee that has not healed within 2 weeks).
  - A healed venous leg ulcer.

  [1]A team of healthcare professionals who have the skills to undertake a full clinical and duplex ultrasound assessment and provide a full range of treatment.

  [2]Veins found in association with troublesome lower limb symptoms (typically pain, aching, discomfort, swelling, heaviness and itching).

- Use duplex ultrasound to confirm the diagnosis of varicose veins and the extent of truncal reflux, and to plan treatment for people with suspected primary or recurrent varicose veins.

- For people with confirmed varicose veins and truncal reflux:
  - Offer endothermal ablation (see Radiofrequency ablation of varicose veins [NICE interventional procedure guidance 8] and Endovenous laser treatment of the long saphenous vein [NICE interventional procedure guidance 52]).
  - If endothermal ablation is unsuitable, offer ultrasound-guided foam sclerotherapy (for guidance on ultrasound-guided foam sclerotherapy (see Ultrasound-guided foam sclerotherapy for varicose veins [NICE interventional procedure guidance 440]).
  - If ultrasound-guided foam sclerotherapy is unsuitable, offer surgery.

  If incompetent varicose tributaries are to be treated, consider treating them at the same time.

- Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable.

4.2 Full list of recommendations

All recommendations relate to adults aged 18 years and over.

Information for people with varicose veins

1. **Give people who present with varicose veins information that includes:**
   - **An explanation of what varicose veins are.**
   - **Possible causes of varicose veins.**
   - **The likelihood of progression and possible complications, including deep vein thrombosis, skin changes, leg ulcers, bleeding and thrombophlebitis. Address any misconceptions the person may have about the risks of developing complications.**
   - **Treatment options, including symptom relief, an overview of interventional treatments and the role of compression.**
   - **Advice on:**
   - **weight loss (for guidance on weight management see Obesity [NICE clinical guideline 43])**
   - **light to moderate physical activity**
   - **avoiding factors that are known to make their symptoms worse if possible**
   - **when and where to seek further medical help.**

2. **When discussing treatment for varicose veins at the vascular service[3] tell the person:**
   - **What treatment options are available.**
   - **The expected benefits and risks of each treatment option.**
   - **That new varicose veins may develop after treatment.**
   - **That they may need more than 1 session of treatment.**
   - **That the chance of recurrence after treatment for recurrent varicose veins is higher than for primary varicose veins.**

   [3]A team of healthcare professionals who have the skills to undertake a full clinical and duplex ultrasound assessment and provide a full range of treatment

Referral to a vascular service

3. **Refer people with bleeding varicose veins to a vascular service immediately.**

4. **Refer people to a vascular service* if they have any of the following.**
   - **Symptomatic[4] primary or symptomatic recurrent varicose veins.**
   - **Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency.**
   - **Superficial vein thrombosis (characterised by the appearance of hard, painful veins) and suspected venous incompetence.**
   - **A venous leg ulcer (a break in the skin below the knee that has not healed within 2 weeks).**
   - **A healed venous leg ulcer.**

   *A team of healthcare professionals who have the skills to undertake a full clinical and duplex ultrasound assessment and provide a full range of treatment.

   [4]Veins found in association with troublesome lower limb symptoms (typically pain, aching, discomfort, swelling, heaviness and itching).

Assessment and treatment in a vascular service

Assessment

5. **Use duplex ultrasound to confirm the diagnosis of varicose veins and the extent of truncal reflux, and to plan treatment for people with suspected primary or recurrent varicose veins.**

Interventional treatment

6. **For people with confirmed varicose veins and truncal reflux:**
   - **Offer endothermal ablation(see Radiofrequency ablation of varicose veins [NICE interventional procedure guidance 8] and Endovenous laser treatment of the long saphenous vein [NICE interventional procedure guidance 52]).**
   - **If endothermal ablation is unsuitable, offer ultrasound-guided foam sclerotherapy (see Ultrasound-guided foam sclerotherapy for varicose veins [NICE interventional procedure guidance 440).**
   - **If ultrasound-guided foam sclerotherapy is unsuitable, offer surgery.**

   If incompetent varicose tributaries are to be treated, consider treating them at the same time.

7. **If offering compression bandaging or hosiery for use after interventional treatment, do not use for more than 7 days.**

Non-interventional treatment

8. **Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable.**

Management during pregnancy

9. **Give pregnant women presenting with varicose veins information on the effect of pregnancy on varicose veins.**

10. **Do not carry out interventional treatment for varicose veins during pregnancy other than in exceptional circumstances.**

11. **Consider compression hosiery for symptom relief of leg swelling associated with varicose veins during pregnancy.**

4.3 Key research recommendations

1. **In people with varicose veins at CEAP (Clinical, etiological, anatomical and pathophysiological) stage C2 or C3, what are the factors that influence progression of the disease to CEAP stages C5 or C6?**

2. **What is the clinical and cost effectiveness of compression hosiery versus no compression for the management of symptomatic varicose veins?**

3. **What is the clinical and cost effectiveness of compression bandaging or hosiery after interventional treatment for varicose veins compared with no compression? If there is benefit, how long should compression bandaging or hosiery be worn for?**

4. **What is the clinical and cost effectiveness of concurrent phlebectomies or foam sclerotherapy for varicose tributaries during truncal endothermal ablation for varicose veins compared with:**
   - **truncal endothermal ablation without concurrent phlebectomies or foam sclerotherapy?**
   - **truncal endothermal ablation with phlebectomies or foam sclerotherapy, if needed, 6–12 weeks later?**

5. **What is the optimal treatment (compression, surgery, endothermal ablation or foam sclerotherapy) for varicose veins at each of the CEAP stages, that is CEAP stages 2–3, CEAP stage 4 and CEAP stages 5–6?**

Randomized clinical trial

Randomized clinical trial comparing surgery with conservative treatment for uncomplicated varicose veins

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Background: **Surgical treatment of medically uncomplicated varicose veins is common, but its clinical effectiveness remains uncertain.**

Methods: **A randomized clinical trial was carried out at two large acute National Health Service hospitals in different parts of the UK (Sheffield and Exeter). Some 246 patients were recruited from 536 consecutive referrals to vascular outpatient clinics with uncomplicated varicose veins suitable for surgical treatment. Conservative management, consisting of lifestyle advice, was compared with surgical treatment (flush ligation of sites of reflux, stripping of the long saphenous vein and multiple phlebectomies, as appropriate). Changes in health status were measured using the Short Form (SF) 6D and EuroQol (EQ) 5D, quality of life instruments based on SF-36 and EuroQol, complications of treatment, symptomatic measures, anatomical extent of varicose veins and patient satisfaction.**

Results: **In the first 2 years after treatment there was a significant quality of life benefit for surgery of 0·083 (95 per cent confidence interval (c.i.) 0·005 to 0·16) quality-adjusted life years (QALYs) based on the SF-6D score and 0·13 (95 per cent c.i. 0·016 to 0·25) based on the EQ-5D score. Significant benefits were also seen in symptomatic and anatomical measures.**

Conclusion: **Surgical treatment provides symptomatic relief and significant improvements in quality of life in patients referred to secondary care with uncomplicated varicose veins.**

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Introduction

Visible varicose veins of the leg affect approximately 25–30 per cent of adult women and 15 per cent of men in Europe and the USA[1,2]. Many providers of healthcare consider varicose veins to be relatively minor and undeserving of treatment, and hospital admissions for intervention produce a considerable burden on health services. As a result, the availability of treatment may be explicitly restricted or subject to significant waiting lists. In England and Wales there are approximately 45 000 hospital admissions per year for varicose vein surgery. There have been attempts to produce guidelines to limit the availability of intervention for varicose veins in the UK National Health Service (NHS)[3] and access to treatment varies from one area to another[4]. In many other countries varicose vein treatments are provided largely in the private sector.

The symptoms reported in relation to varicose veins are common in the general population[5] and the degree of benefit obtained from surgical treatment or sclerotherapy is not clear. Surgery has become the preferred treatment option for most patients with symptomatic varicose veins. Sclerotherapy has been abandoned by many hospitals, resulting in further variation in the access to different treatments for varicose veins. A systematic literature review has suggested that surgery may have long-term benefits over sclerotherapy[6]. An extensive literature search for this Cochrane review identified no randomized controlled trial of surgery *versus* conservative treatment that would allow the benefits of these treatments to be quantified.

Numerous generic and disease-specific questionnaires have been used to assess venous disease, but few are applicable to patients with varicose veins[7] and, of those that have been used in this situation, only the generic

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Progression of varicose veins and chronic venous insufficiency in the general population in the Edinburgh Vein Study

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Objective: **The natural history in the general population of chronic venous disease in the legs is not well understood. This has limited our ability to predict which patients will deteriorate and to assign clinical priorities. The aims of this study were to describe the progression of trunk varicose veins and chronic venous insufficiency (CVI) in the general population, to identify important lifestyle and clinical prognostic factors, and to determine the relationship between venous reflux and progression.**
Methods: **The Edinburgh Vein Study is a population-based cohort study in which randomly selected adults aged 18 to 64 years had an examination at baseline. This included a questionnaire on lifestyle and clinical factors, standardized assessment and classification of venous disease in the legs, and duplex scan to detect venous reflux in eight segments of each leg. A follow-up examination 13 years later included a reclassification of venous disease to ascertain progression in the development or increase in severity of varicose veins and CVI.**
Results: **Among 1566 adults seen at baseline, 880 had a follow-up examination, of whom 334 had trunk varicose veins or CVI at baseline and composed the study sample. The mean (standard deviation) duration of follow-up was 13.4 (0.4) years. Progression was found in 193 (57.8%), equivalent to 4.3% (95% confidence interval [CI], 3.7-4.9) annually. In 270 subjects with only varicose veins at baseline, 86 (31.9%) developed CVI, with the rate increasing consistently with age ($P = .04$). Almost all subjects (98%) with both varicose veins and CVI at baseline deteriorated. Progression of chronic venous disease did not differ by gender or leg, but a family history of varicose veins and history of deep venous thrombosis increased risk (odds ratio [OR], 1.85 [95% CI, 1.14-1.30] and 4.10 [95% CI, 1.07-15.71], respectively). Overweight was associated with increased risk of CVI in those with varicose veins (OR, 1.85; 95% CI, 1.10-3.12). Reflux in the superficial system increased the likelihood of progression, especially in combination with deep reflux (OR, 2.57; 95% CI, 1.55-4.25) and when located in the small saphenous vein (OR, 4.73; 95% CI, 1.37-16.39).**
Conclusions: **Nearly half of the general population with chronic venous disease deteriorated during 13 years, and almost one third with varicose veins developed skin changes of CVI, increasing their risk of ulceration. Age, family history of varicose veins, history of deep venous thrombosis, overweight, and superficial reflux, especially in the small saphenous vein and with deep reflux, might influence the risk of progression.**
(J Vasc Surg: Venous and Lym Dis 2015;3:18-26.)

Chronic venous disease in the legs occurs commonly in Western countries,[1] with varicose veins affecting around one quarter to one third of adults.[2,3] Chronic venous insufficiency (CVI) comprising skin changes is less frequent,[1,2] but ulceration is serious, is difficult to heal, and recurs in at least two thirds of patients.[4] Demands for treatment are often not easily met.[5]

Little is known about the natural history of chronic venous disease in the general population. A major longitudinal study was conducted in pharmaceutical workers in Basle, Switzerland,[6] but this was some years ago before the use of current, more stringent methods of measurement. This lack of knowledge of natural history and of prognostic factors has meant that few advances have been made in identifying patients who might benefit from early intervention and in evaluating preventive measures.

The aims of our study were to describe the progression of trunk varicose veins and CVI in the general population, to identify important lifestyle and clinical prognostic factors, and to determine the relationship between presence of venous reflux and progression.

METHODS

Study design. The Edinburgh Vein Study is a population-based cohort study in which subjects examined at baseline from 1994 to 1996 underwent a follow-up examination from 2007 to 2009. The study was approved by

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Study of the venous reflux progression

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Background: **Patients with chronic venous disease (CVD) often ask whether elective vein surgery could be delayed without consequences. Because the natural history of CVD is not well known, this study was designed to determine its progression in such patients.**

Methods: **One hundred and sixteen limbs in 90 patients who had at least 2 exams with duplex ultrasound (DU) scanning prior to vein surgery at a university medical center were studied. These were patients who were offered an operation but for various reasons were treated at a later stage. Patients were classified by the CEAP system.**

Results: **The mean age of the patients was 49 years (range, 23 to 81 years). A second DU scan was performed 1 to 43 months after the initial exam (median, 19 months). Eighty-five limbs (73.3%) were unchanged. Thirteen limbs (11.2%) had progression of clinical stage, and seven had progression on DU scanning as well. Seven limbs progressed from C2 to C3, four limbs from C3 to C4, and two limbs from C4 to C6. Thirty-four limbs had a documented change on repeat DU scanning. In 3 of these limbs, reflux was missed on the initial exam; therefore, 31 limbs had progression of disease. The great saphenous vein and tributaries were the most often anatomic sites affected by a change, followed by perforators. Seventeen limbs (14.7%) had extension of pre-existing reflux, and 14 (12.1%) had reflux in a new segment. In 11 of these limbs, a change in the initial plan for treatment was required. Symptomatic or DU changes were noted 6 months or later in 95% of limbs and 74.2% of limbs with disease progression were diagnosed at 12 months or later. All but one of the 13 symptomatic limbs developed symptoms at least a year later.**

Conclusion: **Nearly one third of patients with venous reflux had progression. Anatomic extension is frequent with disease progression but not a pre-requisite. Progression was found in most limbs 6 months after the initial study. Patients undergoing treatment for their veins may need another DU exam if this time interval is exceeded. (J Vasc Surg 2005;41: 291-5.)**

Chronic venous disease (CVD) is the most common vascular disorder.[1] It is caused by venous hypertension due to either reflux, outflow obstruction, or both,[2] and its clinical presentation varies from a small cosmetic imperfection to chronic ulceration. The quality of life of patients with CVD may be impaired because of pain, physical limitation, immobility, and social seclusion.[3]

The management of CVD has been mainly empirical throughout the years, given that its pathophysiology, distribution, and natural history are not fully known. The advent of duplex ultrasound (DU) technology and recent improvements in the classification of CVD[4] have significantly enhanced our understanding. Studies on its natural history and progression are scarce; therefore, no available information accurately describes the evolution of CVD.

This study was conducted to determine the progression of CVD and, more specifically, to identify changes in the distribution and extent of reflux in patients with CVD who are waiting for treatment.

METHODS

Data on patients with evidence of CVD were prospectively entered in a customized database. These patients were offered treatment for varicose veins, but for several reasons, they did not undergo a timely intervention. Rather, treatment was given at a later stage. They had to have at least two DU examinations prior to intervention to be included. A history and physical examination were performed in all patients in the original as well as in subsequent visits. The CEAP classification was used to grade the severity of CVD.[4]

Color-flow DU scanning was used for reflux determination. Multifrequency 4-7–MHz linear array transducers were most commonly used. For veins located 1 cm from the skin within the subcutaneous tissues, 10-MHz transducers were used instead. For veins located more than 6 cm from the skin, 3-MHz transducers were preferred. The veins were evaluated in the standing position. The examination, which included the femoropopliteal, deep calf veins, great (GSV) and small (SSV) saphenous veins and their tributaries, and nonsaphenous veins (when present), followed techniques that have been described elsewhere.[5]

The distribution and patterns of reflux were registered. Reflux was induced by distal limb compression followed by sudden release using rapid-inflation pneumatic cuffs (Aircast, Summit, NJ) with a maximum pressure of 80 mm Hg. It was considered to be present when retrograde flow lasted more than 0.5 seconds for the superficial or the deep calf veins, more than 350 milliseconds for the perforator veins, and more than 1 second for the femoropopliteal veins.[6] New reflux sites or anatomic extension of reflux at a previously documented site were sought. A detailed map of the normal and the incompetent sites was drawn on a specially

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Competition of interest: none.

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Systematic review and meta-analysis of endovascular and surgical revascularization for patients with chronic lower extremity venous insufficiency and varicose veins

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Background Chronic lower extremity venous disease (LECVD) is twice as prevalent as coronary heart disease, and invasive therapies to treat LECVD accounted for an estimated $290 million in Medicare expenditures in 2015. Despite increasing use of these invasive therapies, their comparative effectiveness is unknown.

Methods We conducted a systematic review and meta-analysis of treatments for patients (symptomatic and asymptomatic) with lower extremity varicosities and/or lower extremity chronic venous insufficiency/incompetence/reflux. We searched PubMed, Embase, and the Cochrane Database of Systematic Reviews for relevant English-language studies published from January 2000 to July 2016. We included comparative randomized controlled trials (RCTs) with >20 patients and observational studies with >500 patients. Short-, intermediate-, and long-term outcomes of placebo, mechanical compression therapy, and invasive therapies (surgical and endovascular) were included. Quality ratings and evidence grading was performed. Random-effects models were used to compute summary estimates of effects.

Results We identified a total of 57 studies representing 105,878 enrolled patients, including 53 RCTs comprised of 10,034 patients. Among the RCTs, 16 were good quality, 28 were fair quality, and 9 were poor quality. Allocation concealment, double blinding, and reporting bias were inadequately addressed in 25 of 53 (47%), 46 of 53 (87%), and 15 of 53 (28.3%), respectively. Heterogeneity in therapies, populations, and/or outcomes prohibited meta-analysis of comparisons between different endovascular therapies and between endovascular intervention and placebo/compression. Meta-analysis evaluating venous stripping plus ligation (high ligation/stripping) compared with radiofrequency ablation revealed no difference in short-term bleeding (odds ratio [OR] = 0.30, 95% CI –0.16 to 5.38, P = .43) or reflux recurrence at 1-2 years (OR = 0.76, 95% CI 0.37-1.55, P = .44). Meta-analysis evaluating high ligation/stripping versus endovascular laser ablation revealed no difference in long-term symptom score (OR 0.02, 95% CI –0.19 to 0.23, P = .84) or quality of life at 2 years (OR 0.06, 95% CI –0.12 to 0.25, P = .50).

Conclusions The paucity of high-quality comparative effectiveness and safety data in LECVD is concerning given the overall rise in endovascular procedures. More high-quality studies are needed to determine comparative effectiveness and guide policy and practice. (Am Heart J 2018;196:131-43.)

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Lower extremity chronic venous disease (LECVD), defined as venous reflux disease and varicose veins, is thought to affect 11 million men and 22 million women between the ages of 40 and 80 years in the United States.[1] This makes LECVD twice as prevalent as coronary heart disease and 5 times more prevalent than peripheral artery disease.[2] LECVD has been associated with significant morbidity as well as diminished quality of life (QOL) with 6% of US adults having markers of advanced disease including skin changes, venous edema, and venous ulcers.[3] As a result of this burden, the direct medical costs attributable to LECVD are estimated to be between $2.5 billion and $3 billion annually.[4]

Over the past 2 decades, multiple nonsurgical endovascular procedures and hybrid endovascular-surgical

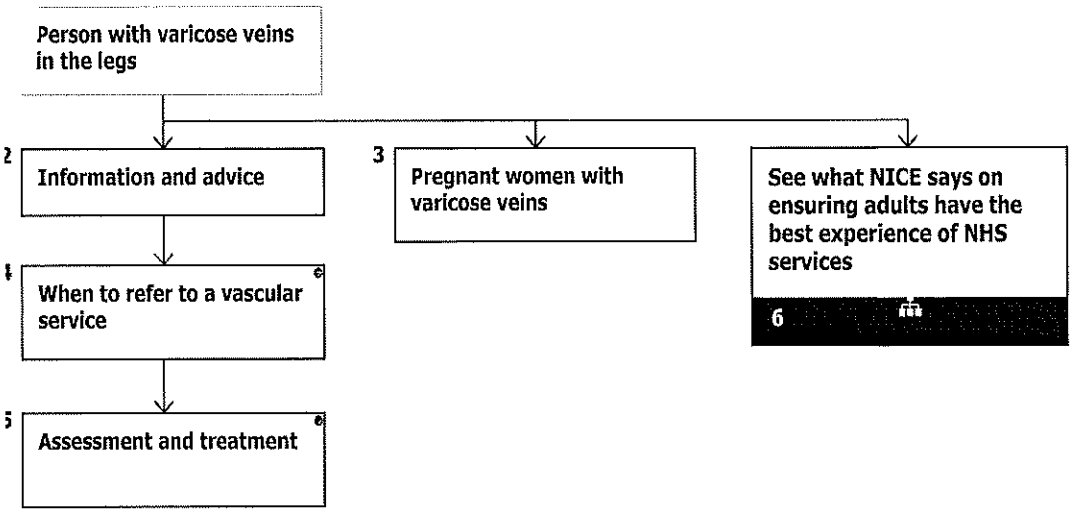
Varicose veins in the legs overview

NICE Pathways bring together everything NICE says on a topic in an interactive flowchart. NICE Pathways are interactive and designed to be used online.

They are updated regularly as new NICE guidance is published. To view the latest version of this NICE Pathway see:

http://pathways.nice.org.uk/pathways/varicose-veins-in-the-legs
NICE Pathway last updated: 03 May 2019

This document contains a single flowchart and uses numbering to link the boxes to the associated recommendations.



1 Person with varicose veins in the legs

No additional information

2 Information

Give people who present with varicose veins information that includes:

- An explanation of what varicose veins are.
- Possible causes of varicose veins.
- The likelihood of progression and possible complications, including deep vein thrombosis, skin changes, leg ulcers, bleeding and thrombophlebitis. Address any misconceptions the person may have about the risks of developing complications.
- Treatment options, including symptom relief, an overview of interventional treatments and the role of compression.
- Advice on:
  - weight loss (for guidance on weight management see what NICE says on obesity)
  - light to moderate physical activity (for example, walking or swimming)
  - avoiding factors that are known to make their symptoms worse if possible
  - when and where to seek further medical help.

For guidance on diet and physical activity see what NICE says on diet.

NICE has written information for the public on varicose veins in the legs.

3 Pregnant women with varicose veins

Give pregnant women presenting with varicose veins information on the effect of pregnancy on varicose veins.

Do not carry out interventional treatment for varicose veins during pregnancy other than in exceptional circumstances.

Consider compression hosiery for symptom relief of leg swelling associated with varicose veins during pregnancy.

4 When to refer to a vascular service

Refer people with bleeding varicose veins to a vascular service immediately.

Refer people to a vascular service if they have any of the following.

- Symptomatic primary or symptomatic recurrent varicose veins.
- Lower-limb skin changes, such as pigmentation or eczema, thought to be caused by chronic venous insufficiency.
- Superficial vein thrombosis (characterised by the appearance of hard, painful veins) and suspected venous incompetence.
- A venous ulcer (a break in the skin below the knee that has not healed within 2 weeks).
- A healed venous leg ulcer.

See what NICE says on venous leg ulcers

Quality standards

The following quality statement is relevant to this part of the interactive flowchart.

1. Referral to a vascular service

5 Assessment and treatment

Assessment

Use duplex ultrasound to confirm the diagnosis of varicose veins and to plan treatment for people with suspected primary or recurrent varicose veins.

Information for patients

When discussing treatment for varicose veins at the vascular service tell the person:

- What treatment options are available.
- The expected benefits and risks of each treatment option.
- That new varicose veins may develop after treatment.
- That they may need more than 1 session of treatment.
- That the chance of recurrence after treatment for recurrent varicose veins is higher than for

- primary varicose veins.

NICE has written information for the public on varicose veins in the legs.

Interventional treatment

For people with confirmed varicose veins and truncal reflux:

- Offer endothermal ablation.
- If endothermal ablation is unsuitable, offer ultrasound-guided foam sclerotherapy.
- If ultrasound-guided foam sclerotherapy is unsuitable, offer surgery.
- If incompetent varicose tributaries are to be treated, consider treating them at the same time.

If offering compression bandaging or hosiery for use after interventional treatment, do not use for more than 7 days.

See what NICE says on preoperative tests.

Compression hosiery

Offer compression hosiery only if interventional treatment is unsuitable.

Interventional procedures

NICE has published guidance on the following procedures with **standard or normal arrangements** for consent, audit and clinical governance:

- endovenous mechanochemical ablation for varicose veins
- ultrasound-guided foam sclerotherapy for varicose veins
- endovenous laser treatment of the long saphenous vein
- radiofrequency ablation of varicose veins.

NICE has published guidance on the following procedures with **special arrangements** for clinical governance, consent, and audit or research:

- cyanoacrylate glue occlusion for varicose veins
- lower limb deep vein valve reconstruction for chronic deep venous incompetence
- subfascial endoscopic perforator vein surgery
- transilluminated powered phlebectomy for varicose veins.

Quality standards

The following quality statements are relevant to this part of the interactive flowchart.

2. Duplex ultrasound

3. Treatment of varicose veins

6 See what NICE says on ensuring adults have the best experience of NHS services

See Patient experience in adult NHS services

The care of patients with varicose veins and associated chronic venous diseases: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum

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The Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) have developed clinical practice guidelines for the care of patients with varicose veins of the lower limbs and pelvis. The document also includes recommendations on the management of superficial and perforating vein incompetence in patients with associated, more advanced chronic venous diseases (CVDs), including edema, skin changes, or venous ulcers. Recommendations of the Venous Guideline Committee are based on the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system as strong (GRADE 1) if the benefits clearly outweigh the risks, burden, and costs. The suggestions are weak (GRADE 2) if the benefits are closely balanced with risks and burden. The level of available evidence to support the evaluation or treatment can be of high (A), medium (B), or low or very low (C) quality. The key recommendations of these guidelines are: We recommend that in patients with varicose veins or more severe CVD, a complete history and detailed physical examination are complemented by duplex ultrasound scanning of the deep and superficial veins (GRADE 1A). We recommend that the CEAP classification is used for patients with CVD (GRADE 1A) and that the revised Venous Clinical Severity Score is used to assess treatment outcome (GRADE 1B). We suggest compression therapy for patients with symptomatic varicose veins (GRADE 2C) but recommend against compression therapy as the primary treatment if the patient is a candidate for saphenous vein ablation (GRADE 1B). We recommend compression therapy as the primary treatment to aid healing of venous ulceration (GRADE 1B). To decrease the recurrence of venous ulcers, we recommend ablation of the incompetent superficial veins in addition to compression therapy (GRADE 1A). For treatment of the incompetent great saphenous vein (GSV), we recommend endovenous thermal ablation (radiofrequency or laser) rather than high ligation and inversion stripping of the saphenous vein to the level of the knee (GRADE 1B). We recommend phlebectomy or sclerotherapy to treat varicose tributaries (GRADE 1B) and suggest foam sclerotherapy as an option for the treatment of the incompetent saphenous vein (GRADE 2C). We recommend against selective treatment of perforating vein incompetence in patients with simple varicose veins (CEAP class C_2; GRADE 1B), but we suggest treatment of pathologic perforating veins (outward flow duration ≥500 ms, vein diameter ≥3.5 mm) located underneath healed or active ulcers (CEAP class C_5-C_6; GRADE 2B). We suggest treatment of pelvic congestion syndrome and pelvic varices with coil embolization, plugs, or transcatheter sclerotherapy, used alone or together (GRADE 2B). (J Vasc Surg 2011;53:2S-48S.)

Abbreviations ACCP, American College of Chest Physicians; ASVAL, ablation sélective des varices sous anesthésie locale (ie, ambulatory selective varicose vein ablation under local anesthesia); AVF, American Venous Forum; AVVQ, Aberdeen Varicose Vein Questionnaire; CHIVA, cure conservatrice et hémodynamique de l'insuffisance veineuse en ambulatiore (ie, ambulatory conservative hemodynamic treatment of varicose veins); CI, confidence interval; CT, computed tomography; CVI, chronic venous insufficiency; CVD, chronic venous disease; DVT, deep venous thrombosis; EVLA, endovenous laser ablation; EVLT, endovenous laser therapy; FDA, U.S. Food and Drug Administration; GRADE, Grading of Recommendations, Assessment, Development, and Evaluation; GSV, great saphenous vein; HL/S,

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Competition of interest: none.

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Falls prevention and vestibular rehabilitation

Question: Should coverage of vestibular rehabilitation be modified on the Prioritized List?

Question source: Physical therapists at Providence

Issue: As part of the HERC Coverage Guidance topic nomination process, HERC staff received multiple nominations from Providence physical therapists about coverage of vestibular rehabilitation for vestibular disorders.

The submitters identified a number of codes that are repeatedly denied for coverage by OHP and are requesting reconsidering of coverage of vestibular rehabilitation for OHP patients.

This was discussed at the August 2019 meeting. Public comment from physical therapists advocated for coverage of vestibular rehabilitation on Line 292 as vertigo can increase risk of falls. They also spoke about needing to cover preventive physical therapy even in those who had not yet fallen, but were at increased risk of falls.

Relevant Codes

Codes requested by the advocates for coverage

Code	Code Description	Current Prioritized List Placement
H81.X	Benign paroxysmal vertigo, vestibular neuronitis	510 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM
H81.9X	Unspecified disorder of vestibular function	510 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM
H83.0X	Labrynthitis	572 ACUTE NON-SUPPURATIVE LABYRINTHITIS
G43.109	Migraine with aura, not intractable, without status migrainosus	409 MIGRAINE HEADACHES
95992	Canalith repositioning procedure(s) (eg, Epley maneuver, Semont maneuver), per day	510 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility	31,46,57,68,71,72,74,81 and 56 other lines (not including 510)

Code	Code Description	Current Prioritized List Placement
97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities	31,46,57,68,71,72,81,91 and 51 other lines (not including 510)
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes	31,46,57,68,71,72,81,91 and 52 other lines (not including 510)

Other relevant codes currently placed on Prioritized List

Code	Code Description	Current Prioritized List Placement
Z74.09	Other reduced mobility	Informational Diagnosis File
Z91.81	History of falling *(includes at risk for falling, at minimum, moderate, or maximum risk for fall, at very low, standard, and high risk for fall)*	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
R26.2	Difficulty in walking, not elsewhere classified	Diagnostic Workup File (DWF)
R26.81	Unsteadiness on feet	Diagnostic Workup File (DWF)
R26.89	Other abnormalities of gait and mobility	Diagnostic Workup File (DWF)
R26.9	Unspecified abnormalities of gait and mobility	Diagnostic Workup File (DWF)
R29.6	Repeated falls	Diagnostic Workup File (DWF)
W19.XXD	Unspecified fall, subsequent encounter	Informational Diagnosis File
92533	Caloric vestibular test, each irrigation (binaural, bithermal stimulation constitutes 4 tests)	292,416,510
92534	Optokinetic nystagmus test	292,416,510
92537	Caloric vestibular test with recording, bilateral; bithermal (ie, one warm and one cool irrigation in each ear for a total of four irrigations)	292,416,510

Code	Code Description	Current Prioritized List Placement
92538	Caloric vestibular test with recording, bilateral; monothermal (ie, one irrigation in each ear for a total of two irrigations)	292,416,510
92540	Basic vestibular evaluation, includes spontaneous nystagmus test with eccentric gaze fixation nystagmus, with recording, positional nystagmus test, minimum of 4 positions, with recording, optokinetic nystagmus test, bidirectional foveal and peripheral stimulation, with recording, and oscillating tracking test, with recording	292,416,510
92541	Spontaneous nystagmus test, including gaze and fixation nystagmus, with recording	292,416,510
92542	Positional nystagmus test, minimum of 4 positions, with recording	292,416,510
92544	Optokinetic nystagmus test, bidirectional, foveal or peripheral stimulation, with recording	292,416,510
92545	Oscillating tracking test, with recording	292,416,510
92546	Sinusoidal vertical axis rotational testing	292,416,510
92547	Use of vertical electrodes (List separately in addition to code for primary procedure)	292,416,510
92548	Computerized dynamic posturography	292,416,510
S9476	Vestibular rehabilitation program, non-physician provider, per diem	Never Reviewed

Line 510 Prioritization

Line 510 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM
Category 7
Healthy Life Years 2
Suffering 1
Population effects 0
Vulnerable populations 0
Tertiary prevention 1
Effectiveness 2
Need 0.8
Net cost 3
Score 128

Evidence Summary

USPSTF, 2018

https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/falls-prevention-in-older-adults-interventions1

Population	Recommendation	Grade (What's This?)
Adults 65 years or older	The USPSTF recommends exercise interventions to prevent falls in community-dwelling adults 65 years or older who are at increased risk for falls.	B
Adults 65 years or older	The USPSTF recommends that clinicians selectively offer multifactorial interventions to prevent falls to community-dwelling adults 65 years or older who are at increased risk for falls. Existing evidence indicates that the overall net benefit of routinely offering multifactorial interventions to prevent falls is small. When determining whether this service is appropriate for an individual, patients and clinicians should consider the balance of benefits and harms based on the circumstances of prior falls, presence of comorbid medical conditions, and the patient's values and preferences.	C

Brief Risk Assessment

When determining to whom these recommendations apply, primary care clinicians can reasonably consider a small number of risk factors to identify older adults who are at increased risk for falls. Age is strongly related to risk for falls. Studies most commonly used a history of falls to identify increased risk for future falls; history of falls is generally considered together or sequentially with other key risk factors, particularly impairments in mobility, gait, and balance. A pragmatic approach to identifying persons at high risk for falls, consistent with the enrollment criteria for intervention trials, would be to assess for a history of falls or for problems in physical functioning and limited mobility. Clinicians could also use assessments of gait and mobility, such as the Timed Up and Go test.

Kundakci, 2018

- Systematic review of vestibular rehabilitation for chronic dizziness in adults
- 4 trials included
- Comparison to usual medical care (3 studies) or placebo eye exercise (1 study).
    - Hall
        - 3 times a day vestibular exercises, comparison placebo eye exercises. Both groups received a balance and gait home exercise program.
        - There were no significant differences between the intervention and comparison group with the exception of Dynamic Gait Index (4 other scales had no difference). The intervention group showed a significant decrease in fall risk. While 90% of the intervention group showed an improvement in fall risk, in the comparison group it was 50%.
    - Yardley
        - Booklet-based vestibular rehabilitation (VR) only and booklet-based VR with telephone support. Daily exercises at home for up to twelve weeks. Telephone support, up to three brief sessions from a vestibular therapist.
        - At 12 weeks, the treatment and comparison groups did not show any significant difference on the vertigo symptom scale. After one year follow-up there was a significant improvement in the intervention groups compared to the comparison group.
    - Yardley
        - 30–40 minute Vestibular Compensation Exercises after assessment at baseline and 6-week follow-up. Eight sets of standard head and body movements performed twice daily. Comparison standard medical care.
        - The intervention group improved on all measures (Vertigo symptom scale, Hospital Anxiety and Depression Scale, Vertigo Handicap Questionnaire, Provocative movements, and Sharpened Romberg Tests), while the comparison group demonstrated no improvement.
    - Yardley
        - Nurse-delivered VR exercises. Patients were seen individually for 30 to 40 minutes to take them the booklet and additional support, after first session advice by telephone at one and three weeks. Comparison of usual medical care.
        - There was a greater improvement on all primary outcome measures (series of subjective scales) in the treatment group compared to the usual medical care.

- **Author Conclusions:** This review suggests that exercise-based vestibular rehabilitation shows benefits for adult patients with chronic dizziness with

regard to improvement in the vertigo symptom scale, fall risk, balance and emotional status.

McDonnell, 2015
https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD005397.pub4/full

- Cochrane systematic review of vestibular rehabilitation for unilateral peripheral vestibular dysfunction
- 39 studies involving 2441 participants with unilateral peripheral vestibular disorders
- Individual and pooled analyses of the primary outcome, frequency of dizziness, showed a statistically significant effect in favour of vestibular rehabilitation over control or no intervention (odds ratio (OR) 2.67, 95% confidence interval (CI) 1.85 to 3.86; four studies, 565 participants).
- Secondary outcomes measures related to levels of activity or participation measured, for example, with the Dizziness Handicap Inventory, which also showed a strong trend towards significant differences between the groups (standardised mean difference (SMD) -0.83, 95% CI -1.02 to -0.64). The exception to this was when movement-based vestibular rehabilitation was compared to physical manoeuvres for benign paroxysmal positional vertigo (BPPV), where the latter was shown to be superior in cure rate in the short term (OR 0.19, 95% CI 0.07 to 0.49). There were no reported adverse effects.
- Author conclusions: There is moderate to strong evidence that vestibular rehabilitation is a safe, effective management for unilateral peripheral vestibular dysfunction, based on a number of high-quality randomised controlled trials. There is moderate evidence that vestibular rehabilitation resolves symptoms and improves functioning in the medium term. However, there is evidence that for the specific diagnostic group of BPPV, physical (repositioning) manoeuvres are more effective in the short-term than exercise-based vestibular rehabilitation; although a combination of the two is effective for longer-term functional recovery. There is insufficient evidence to discriminate between differing forms of vestibular rehabilitation.

Others policies
Aetna, 2019
http://www.aetna.com/cpb/medical/data/200_299/0238.html

Aetna considers vestibular rehabilitation for chronic vertigo medically necessary when all of the following criteria are met:

1. Symptoms (e.g., vertigo and imbalance) have existed for more than 6 months; *and*

2. The member has confirmed diagnosis of a vestibular disorder or has undergone ablative vestibular surgery; *and*
3. The member has failed medical management (e.g., use of vestibular suppressant medications to reduce symptoms).

Aetna considers vestibular rehabilitation experimental and investigational for all other indications because its effectiveness for indications other than the one listed above has not been established.

Note: Up to 12 visits (generally given 2 times a week for 6 weeks) are considered medically necessary initially. Up to 12 additional visits are considered medically necessary if, upon medical review, there is evidence of clinically significant improvement. If there is no evidence of improvement after 12 visits, additional visits are not considered medically necessary.

Excerpt from evidence summary

The literature indicates that the following groups of patients are generally not good candidates for vestibular rehabilitation:

- Patients with an unstable lesion, usually indicative of a progressive degenerative process (e.g., autoimmune inner ear disease);
- Patients with endolymphatic hydrops, Meniere's disease, or perilymphatic fistula;
- Patients with vertiginous symptoms from a demyelinating disease, epilepsy, or migraine.

HERC Staff Summary

Most of the concerns about non-pairing relate to the prioritization of vertiginous syndromes on Line 512, below the funding line. There is evidence of the efficacy of vestibular rehabilitation for a variety of vertiginous conditions. A few codes are missing from line 512.

The Prioritized List needs updating to enable intended coverage for fall prevention in alignment with the USPSTF recommendation. Currently Z91.81, which includes history of falling and at risk for fall, is on Line 3, but there are no exercise therapy interventions that pair on this line.

Recommendations:

1. Add the following codes to Line 512 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM

97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination,

	kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
S9476	Vestibular rehabilitation program, non-physician provider, per diem

2. Add Z91.81 *History of falling (and including those at risk of falling)* to Line 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
    a. Delete Z91.81 from Line 3
        i. Rationale: Pairing on the dysfunction line rather than Line 3 seems most appropriate as PT/OT codes are here already. Placing all the PT codes on line 3 could result in unintended consequences. Therefore, Z91.81 would pair with all the PT codes. The one exception is 95992 Canalith repositioning which is only on line 512 currently.
    b. Add CPT code 95992 *Canalith repositioning* to Line 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT
    c. Adopt a coding specification to Line 292
    CPT code 95992 Canalith repositioning procedure(s) is included on this line only when paired with ICD 10 code Z91.81 for patients 65 and older at risk of falls due to vertiginous symptoms.

3. Modify Guideline Note 106 as follows to clarify the intent of covering falls prevention:

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Lines 3,622

Included on Line 3 are the following preventive services:

A) US Preventive Services Task Force (USPSTF) "A" and "B" Recommendations in effect and issued prior to January 1, 2017.
    1) http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/
        a. Treatment of falls prevention with exercise interventions is included on Line 292.
    2) USPSTF "D" recommendations are not included on this line or any other line of the Prioritized List.

B) American Academy of Pediatrics (AAP) Bright Futures Guidelines:
    1) http://brightfutures.aap.org. Periodicity schedule available at http://www.aap.org/en-us/professional-resources/practice-support/Periodicity/Periodicity Schedule_FINAL.pdf.
    2) Screening for lead levels is defined as blood lead level testing and is indicated for Medicaid populations at 12 and 24 months. In addition, blood lead level screening of any child between ages 24 and 72

months with no record of a previous blood lead screening test is indicated.

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

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

Colorectal cancer screening is included on Line 3 for average-risk adults aged 50 to 75, using one of the following screening programs:

A) Colonoscopy every 10 years
B) Flexible sigmoidoscopy every 5 years
C) Fecal immunochemical test (FIT) every year
D) Guaiac-based fecal occult blood test (gFOBT) every year

Colorectal cancer screening for average-risk adults aged 76 to 85 is covered only for those who

A) Are healthy enough to undergo treatment if colorectal cancer is detected, and
B) Do not have comorbid conditions that would significantly limit their life expectancy.

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

JAMA | US Preventive Services Task Force | RECOMMENDATION STATEMENT

Interventions to Prevent Falls in Community-Dwelling Older Adults

US Preventive Services Task Force Recommendation Statement

US Preventive Services Task Force

IMPORTANCE Falls are the leading cause of injury-related morbidity and mortality among older adults in the United States. In 2014, 28.7% of community-dwelling adults 65 years or older reported falling, resulting in 29 million falls (37.5% of which needed medical treatment or restricted activity for a day or longer) and an estimated 33 000 deaths in 2015.

OBJECTIVE To update the 2012 US Preventive Services Task Force (USPSTF) recommendation on the prevention of falls in community-dwelling older adults.

EVIDENCE REVIEW The USPSTF reviewed the evidence on the effectiveness and harms of primary care–relevant interventions to prevent falls and fall-related morbidity and mortality in community-dwelling older adults 65 years or older who are not known to have osteoporosis or vitamin D deficiency.

FINDINGS The USPSTF found adequate evidence that exercise interventions have a moderate benefit in preventing falls in older adults at increased risk for falls and that multifactorial interventions have a small benefit. The USPSTF found adequate evidence that vitamin D supplementation has no benefit in preventing falls in older adults. The USPSTF found adequate evidence to bound the harms of exercise and multifactorial interventions as no greater than small. The USPSTF found adequate evidence that the overall harms of vitamin D supplementation are small to moderate.

CONCLUSIONS AND RECOMMENDATION The USPSTF recommends exercise interventions to prevent falls in community-dwelling adults 65 years or older who are at increased risk for falls. (B recommendation) The USPSTF recommends that clinicians selectively offer multifactorial interventions to prevent falls in community-dwelling adults 65 years or older who are at increased risk for falls. Existing evidence indicates that the overall net benefit of routinely offering multifactorial interventions to prevent falls is small. When determining whether this service is appropriate for an individual, patients and clinicians should consider the balance of benefits and harms based on the circumstances of prior falls, presence of comorbid medical conditions, and the patient's values and preferences. (C recommendation) The USPSTF recommends against vitamin D supplementation to prevent falls in community-dwelling adults 65 years or older. (D recommendation) These recommendations apply to community-dwelling adults who are not known to have osteoporosis or vitamin D deficiency.

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Author Audio Interview

Related article

Author/Group Information: The US Preventive Services Task Force (USPSTF) members are listed at the end of this article.

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Section 7.0

New Discussion Items

Indications for Intestinal Transplantation

Questions:

1) Should intestinal transplantation on the Prioritized List be expanded beyond children over the age of 5?
2) Should living donor intestinal transplantation be covered?

Question source: Moxie Loeffler, DO; OHA Ombuds Office; HERC staff

Issue: A recent case was referred to the OHA ombudsperson regarding an adult with short gut syndrome from intestinal resection due to complications from Crohn's disease who was failing total parenteral nutrition (TPN) therapy. The patient and his provider were requesting intestinal transplantation.

Currently, intestinal transplant is on line 230 SHORT BOWEL SYNDROME - AGE 5 OR UNDER, limited to children age 5 and under. Diagnoses on this line include necrotizing enterocolitis (ICD-10 K55.3 and P77) and post-surgical malabsorption (ICD-10 K91.2). This topic was last reviewed in 2002 when intestinal transplants were added to the List for children 5 and under as a biennial review topic.

Short bowel syndrome or short gut syndrome is a malabsorption disorder caused by a lack of functional small intestine. Most cases are due to the surgical removal of a large portion of the small intestine. This is most often acquired due to Crohn's disease in adults and necrotizing enterocolitis in young children. Other causes include damage to the small intestine from other means and being born with an abnormally short intestine. Treatment may include a specific diet, medications, or surgery. Severe cases may require TPN or intestinal transplantation.

On last review in 2009, living donor intestinal transplant was reviewed and deemed to be experimental. The CPT codes related to living intestinal donors were removed from the intestinal transplant line.

Current Prioritized List status

Line 230 SHORT BOWEL SYNDROME - AGE 5 OR UNDER Treatment: INTESTINE AND INTESTINE/LIVER TRANSPLANT

CPT code	**Code Description**	**Current Placements**
44132	Donor enterectomy (including cold preservation), open; from cadaver donor	239 SHORT BOWEL SYNDROME - AGE 5 OR UNDER
44133	Donor enterectomy (including cold preservation), open; partial, from living donor	"Never reviewed"
44135	Intestinal allotransplantation; from cadaver donor	239
44136	Intestinal allotransplantation; from living donor	"Never reviewed"

Prior HSC/HERC action

November 2000 HOSC minutes

The latest outcomes for intestinal transplantation were just review during the last biennial review. As patient survival is not improved with the transplant, these indications do not warrant inclusion on the Prioritized List according to the transplant algorithm.

April 2001 HOSC minutes

Use of Transplant Algorithm to Evaluate Intestinal Transplantation

Kathy Weaver reminded the Subcommittee that the issue of intestinal/liver transplantation was brought up at the last meeting. Annie Terrie requested that the Commission consider its placement on the List in light of the case of a baby with necrotizing enterocolitis, where subsequent surgery resulted in short gut syndrome requiring total parenteral nutrition (TPN). The Subcommittee used the transplant algorithm to access the strength of evidence. It was concluded that combined small bowel/liver transplants appeared to be appropriate to offer to children under the age of 5 that develop short gut syndrome and suffer from liver failure due to TPN. It did not appear that this case would require an immediate decision and further work was tabled for until the next biennial review.

April 2002 HOSC minutes

Intestinal Transplant – Minutes 2/22/01 & 4/19/01

Dr. Kathy Weaver referred the Committee to the HOSC minutes from 2/22/01 page 2 said, "The subcommittee used the transplant algorithm to access the strength of evidence. It was concluded that combined small bowel/liver transplants appeared to be appropriate to offer to children under the age of 5 that develop short gut syndrome and suffer from liver failure due to TPN. It did not appear that this case would require an immediate decision and further work was tabled until the next biennial review". Darren Coffman said that this could be either a new line or added to Line 58, NNECROTIZING ENTEROCOLITIS INFETUS OR NEWBORN / MEDICAL THERAPY with CPT code 777.5 that does not appear anywhere else in the List. Dr. Glass pointed out that 777.5 only applies to necrotizing enterocolitis in the fetus or newborn, so that other codes for children up to age 5 may be needed. Dr. Glass further recommended adding ICD-9 557, which is vascular insufficiency of intestine, which includes both acute and chronic vascular insufficiency that can lead to infarction. Darren Coffman noted that 579.3 is short gut syndrome following gastrointestinal surgery. He recommended that staff come back with a new line with the three appropriate ICD-9 codes and the CPT codes for intestinal/liver transplant. This will be presented at the June meeting. Further discussion on whether this should apply to only children up to age 5 occurred. The line would be titled: SHORT BOWEL SYNDROME IN CHILDREN-INTESTINAL/LIVER TRANSPLANT.

June 2002 HOSC minutes

Biennial Review

A. Intestinal Transplant

Discussion about line placement, Line 128

June 2009 HOSC minutes

Small bowel transplant

Smits presented a summary document on small bowel transplants. Currently, DMAP is authorizing cadaveric donor transplants (approximately 2-3 in the last few years), but cannot authorize living related transplants due to the experimental nature of this treatment. Smits reviewed that the literature does indicate that this procedure is experimental. The HOSC agreed that it should not be covered, as long as patients have access to the standard cadaveric transplant.

Action:

1) Remove 44133 (Donor enterectomy from living donor) and 44136 (Intestinal allotransplantation, from living donor) from Line 253 (**SHORT BOWEL SYNDROME - AGE 5 OR UNDER Treatment: INTESTINE AND INTESTINE/LIVER TRANSPLANT).**

Evidence

1) **Ontario Health Technology Assessment 2003**, small bowel transplant
    a. N=9 case series and 1 international registry study (9-155 patients).
    b. Examined only cadaveric transplants
    c. The Intestinal Small Bowel Transplant Registry reported 1-year actuarial patient survival rates of 69% for isolated small bowel transplant, 66% for small bowel-liver transplant, and 63% for multivisceral transplant, and a graft survival rate of 55% for ISB and 63% for SB-L and MV. The range of 1-year patient survival rates reported ranged from 33%-87%. Reported 1-year graft survival rates ranged from 46-71%.
    a. There is evidence that small bowel transplant can prolong the life of some patients with irreversible intestinal failure who can no longer continue to be managed by parenteral nutrition therapy. Both patient survival and graft survival rates have improved with time. However, small bowel transplant is still associated with significant mortality and morbidity. The outcomes are inferior to those of total parenteral nutrition. Evidence suggests that this procedure should only be used when total parenteral nutrition is no longer feasible.
2) **Kesseli 20019**, review of small bowel transplantation
    a. The primary therapy for intestinal failure is total parenteral nutrition, and small bowel transplantation is reserved generally for patients who develop life-threatening complications related to total parenteral nutrition administration.
    b. Intestine allografts are more immunogenic than other solid organ allografts and, therefore, patients experience more acute rejection episodes, require higher levels/doses of immunosuppressive medications, and have a higher incidence of infectious complications related to immunosuppression than recipients of other solid organ allografts.
    c. Given the relative infrequency of IT, even the largest case series published to date comprise only a few hundred patients
    d. Review of 2699 patients
        i. overall survival rates for patients transplanted since 2000 were 77%, 58%, and 41% at 1 year, 5 years, and 10 years, respectively. At 6-month follow up, two-thirds of patients had become independent of PN therapy
    e. Patient survival in other reported studies:
        i. 1 year: 65-85%
        ii. 5 year: 49-70%
        iii. 10 year: 42-65%
    f. Complications: infection reported in up to 97% of patients, rejection (50-75% of patients), chronic kidney disease, post-transplant lymphoproliferative disease (5-23% of patients), graft vs host disease (5-10% of patients)

Other payer policies

1) **CMS 2000**, National Coverage Determination
    a. Only covers cadaveric transplants

b. March 1996 assessment, the Blue Cross Blue Shield Technology Evaluation Center found small bowel/liver combination transplants for adults and children as well as small bowel transplants alone for children to meet their criteria for coverage
c. AHRQ report (no longer available at AHRQ site)
    i. In general, transplants have only been done on patients who have failed TPN. Based on available data, patient survival rates (adults and children) at 1, 3, and 5 years following SBT or related procedures range from 46% - 80%, 48% - 60%, and 48% - 55%, respectively.
    ii. Death is the expected outcome for patients failing TPN who do not receive a transplant.
    iii. Graft survival rates (adults and children at 1, 3, and 5 years following SBT or related procedures range from 50%-90%, 36%-48%, and 40%-48%, respectively.
    iv. Survival at 1, 3, and 5 years for the general group of patients on long-term TPN are reported to be approximately 90%, 65-80%, and 60% respectively.
    v. The assessment concludes that small bowel and related transplantation appear to be potentially life-saving options for patients who have failed TPN and would therefore otherwise face certain death.
d. Coverage criteria
    i. Recurrent catheter-associated bloodstream infection
        1. Two or more line infections per year
        2. A single episode of fungal infection
        3. Development of septic shock or acute respiratory distress syndrome
    ii. IFALD
        1. Characterized by elevated liver enzymes, elevated bilirubin, splenomegaly, thrombocytopenia, gastroesophageal varices, coagulopathy
    iii. Complications of venous thrombosis
        1. Thrombosis of 2 or more major central vessels
        2. Loss of venous access
        3. Sepsis secondary to infected thrombus
        4. Pulmonary embolism
    iv. Frequent episodes of dehydration where fluid losses exceed maximum infusion rates
    v. Transplant performed at a center with annual volume greater than 10 per year
e. Aetna 2019
    i. Covers living and cadaveric donor intestine transplant
    ii. Aetna considers intestinal transplantation medically necessary for persons who have failed total parenteral nutrition (TPN) when the selection criteria below are met.
        1. Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN. Under certain medical conditions such as secretory diarrhea and non-constructible gastro-intestinal (GI) tract, the loss of the GI and pancreatobiliary secretions exceeds the maximum intravenous infusion rates that can be tolerated by the cardiopulmonary system. Frequent episodes of dehydration are detrimental to all body organs, especially the kidney and the central nervous system with the development of multiple kidney stones, renal failure, and permanent brain damage.

2. Frequent line infection and sepsis. The development of 2 or more episodes of systemic sepsis due to line infection per year that requires hospitalization indicates failure of TPN therapy. A single episode of line-related fungemia, septic shock and/or acute respiratory distress syndrome are considered indicators of TPN failure.
3. Impending or overt liver failure due to TPN-induced liver injury. The clinical signs include elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastro-esophageal varices, coagulopathy, stomal bleeding or hepatic fibrosis/cirrhosis.
4. Other complications leading to loss of vascular access. TPN failure may due to inadequate TPN access, which is an indication for intestinal transplantation.
5. Thrombosis of the major central venous channels, jugular, subclavian, and femoral veins. Thrombosis of 2 or more of these vessels is considered a life-threatening complication and failure of TPN therapy. The consequence of central venous thrombosis is a lack of access for TPN infusion, fatal sepsis as a result of infected thrombi, pulmonary embolism, superior vena cava syndrome, or chronic venous insufficiency.

f. Wellmark BCBS 2018

i. A small bowel transplant using a cadaveric intestine may be considered medically necessary in adult and pediatric patients when ALL of the following criteria is met:
   1. Intestinal failure characterized by loss of absorption and the inability to maintain protein-energy, fluid, electrolyte or micronutrient balance, AND
   2. Who have established long-term dependency on total parenteral nutrition (TPN) and are developing or have developed severe complications due to total parenteral nutrition (TPN) to include one or more of the following:
      a. Development of progressive liver failure due to TPN induced liver injury and liver disease is felt to be reversible (clinical indications of liver failure include: increased serum bilirubin or liver enzyme levels, splenomegaly, thrombocytopenia, gastroesophageal varices, coagulopathy, stomal bleeding, hepatic fibrosis or cirrhosis) (small bowel transplant may be considered a technique to avoid end-stage liver failure related to chronic TPN, thus avoiding the necessity of a small bowel/liver or multivisceral transplant); OR
      b. Thrombosis of two or more major central venous channels (subclavian, jugular, or femoral veins); OR
      c. Frequent central line related sepsis
         1) 2 or more episodes of line-induced systemic sepsis per year
         2) 1 episode of line-related fungemia, septic shock, or acute respiratory distress syndrome; OR
      d. Frequent episodes of dehydration despite total parenteral nutrition (TPN) and intravenous fluid supplement.

3. Small bowel transplant using a living donor intestine may be considered medically necessary only when a cadaveric intestine is not available for transplantation in a patient who meets the above criteria for a cadaveric small bowel transplant

g. HealthNet 2019

i. Covers small intestinal transplant from living and cadaveric donors

ii. Members must have one of the indications in **A** and none of the contraindications in **B**:

1. **A.** Indications, any one of the following:
    a. Failure of total parenteral nutrition (TPN) as indicated by one of the following:
        1) Impending or overt liver failure due to TPN, indicated by elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastro-esophageal varices, coagulopathy, peristomal bleeding, or hepatic fibrosis/cirrhosis;
        2) Thrombosis of ≥ 2 central veins, including jugular, subclavian, and femoral veins;
        3) Two or more episodes of systemic sepsis due to line infection, per year, or one episode of septic shock, acute respiratory distress syndrome, and/or line related fungemia;
        4) Frequent episodes of dehydration despite IV fluid supplementation;
        5) Other complications leading to loss of vascular access
    b. High risk of death if transplant is not performed;
    c. Severe short bowel syndrome (gastrostomy, duodenostomy, and/or residual small bowel <10 cm in infants and <20 cm in adults);
    d. Frequent hospitalizations for complications directly related to intestinal failure;
    e. Significant hepatic cirrhosis associated with diffuse post-mesenteric thrombosis;
2. **B.** Does not have ANY of the following contraindications:
    a. Malignancy in the past two years, except for non-melanoma localized skin cancer that has been treated appropriately; Untreatable significant dysfunction of another major organ system, unless combined organ transplantation can be performed
    b. Presence of other GI diseases;
    c. Acute medical instability, including, but not limited to, acute sepsis or myocardial infarction;
    d. Uncorrectable bleeding diathesis;
    e. Chronic infection with highly virulent and/or resistant microbes that are poorly controlled pre-transplant;
    f. Current non-adherence to medical therapy or a history of repeated or prolonged episodes of non-adherence to medical

therapy that are perceived to increase the risk of non-adherence after transplantation;

g. Psychiatric or psychological condition associated with the inability to cooperate or comply with medical therapy;
h. Absence of an adequate or reliable social support system;
i. Severely limited functional status with poor rehabilitation potential;
j. Substance abuse or dependence (including tobacco and alcohol) without convincing evidence of risk reduction behaviors, such as meaningful and/or long-term participation in therapy for substance abuse and/or dependence. Serial blood and urine testing may be used to verify abstinence from substances of concern

Living intestinal donor transplant

1) **Tzvetanov 2010**, review of living intestinal transplant

a. N=4 articles

b. N=13 living transplants with 10 recipients

c. No surgical complications occurred in any of the donors. In CLDILT, the patient survival at 1 and 2 years was 100%, the liver graft survival was 100% and intestinal graft survival was 80%. One patient who lost intestinal graft was successfully retransplanted. In LDIT recipients, the patient and graft survival at 1 and 3 years were 60 and 50%, respectively

Indications for Intestinal Transplantation

HERC staff summary: Small intestine transplant has reasonable evidence of effectiveness as a last line therapy for short bowel syndrome with failure of TPN. Nothing was found in the literature which would indicate that the procedure is less effective over the age of 5. The included reviews did not evaluate outcomes based on age, but both children and adults were included in the studies cited. All major private payers cover this procedure with failure of TPN in appropriate patients without limits based on age.

The literature on living donor intestinal transplant consists of small case series. Private insurers are mixed on coverage of living donor intestinal transplants. Currently CMS does not cover this.

HERC staff recommendations:

1) Expand coverage of intestinal transplantation to patients over the age of 5
    a. Change the line title for line 230 to Line 230 SHORT BOWEL SYNDROME ~~– AGE 5 OR UNDER~~ Treatment: INTESTINE AND INTESTINE/LIVER TRANSPLANT
2) Adopt the new guideline shown below for line 230
3) Add living donor intestinal transplants to line 662/GN173 due to lack of evidence of effectiveness
    a. Continues current non-coverage; lack of evidence in the literature

GUIDELINE NOTE XXX INTESTINE TRANSPLANT

Line 230

Intestine transplant is included on this line only for patients with failure of total parenteral nutrition (TPN) as indicated by one of the following, and no contraindications to transplant:

1) Impending or overt liver failure due to TPN, indicated by elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastro-esophageal varices, coagulopathy, peristomal bleeding, or hepatic fibrosis/cirrhosis;
2) Thrombosis of ≥ 2 central veins, including jugular, subclavian, and femoral veins;
3) Two or more episodes of systemic sepsis due to line infection, per year, or one episode of septic shock, acute respiratory distress syndrome, and/or line related fungemia;
4) Frequent episodes of dehydration despite IV fluid supplementation;
5) Other complications leading to loss of vascular access

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

Line 662

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

Procedure Code	Intervention Description	Rationale	Last Review
44133, 44136	Donor enterectomy and intestinal allotransplantation from living donor	Insufficient evidence of effectiveness	November 2019

Ontario Health Technology Assessment Series 2003; Vol. 3, No. 1

Small Bowel Transplant

An Evidence-Based Analysis

April 2003

Ontario

Medical Advisory Secretariat
Ministry of Health and Long-Term Care

EXECUTIVE SUMMARY

Objective

The Medical Advisory Secretariat undertook a review of the evidence on the effectiveness and cost-effectiveness of small bowel transplant in the treatment of intestinal failure.

Small Bowel Transplantation

Intestinal failure is the loss of absorptive capacity of the small intestine that results in an inability to meet the nutrient and fluid requirements of the body via the enteral route. Patients with intestinal failure usually receive nutrients intravenously, a procedure known as parenteral nutrition. However, long-term parenteral nutrition is associated with complications including liver failure and loss of venous access due to recurrent infections.

Small bowel transplant is the transplantation of a cadaveric intestinal allograft for the purpose of restoring intestinal function in patients with irreversible intestinal failure. The transplant may involve the small intestine alone (isolated small bowel ISB), the small intestine and the liver (SB-L) when there is irreversible liver failure, or multiple organs including the small bowel (multivisceral MV or cluster). Although living related donor transplant is being investigated at a limited number of centres, cadaveric donors have been used in most small bowel transplants.

The actual transplant procedure takes approximately 12-18 hours. After intestinal transplant, the patient is generally placed on prophylactic antibiotic medication and immunosuppressive regimen that, in the majority of cases, would include tacrolimus, corticosteroids and an induction agent. Close monitoring for infection and rejection are essential for early treatment.

Medical Advisory Secretariat Review

The Medical Advisory Secretariat undertook a review of 35 reports from 9 case series and 1 international registry. Sample size of the individual studies ranged from 9 to 155.

As of May 2001, 651 patients had received small bowel transplant procedures worldwide. According to information from the Canadian Organ Replacement Register, a total of 27 small bowel transplants were performed in Canada from 1988 to 2002.

Patient Outcomes

The experience in small bowel transplant is still limited. International data showed that during the last decade, patient survival and graft survival rates from SBT have improved, mainly because of improved immunosuppression therapy and earlier detection and treatment of infection and rejection. The Intestinal

Transplant Registry reported 1-year actuarial patient survival rates of 69% for isolated small bowel transplant, 66% for small bowel-liver transplant, and 63% for multivisceral transplant, and a graft survival rate of 55% for ISB and 63% for SB-L and MV. The range of 1-year patient survival rates reported ranged from 33%-87%. Reported 1-year graft survival rates ranged from 46-71%.

Regression analysis performed by the International Transplant Registry in 1997 indicated that centres that have performed at least 10 small bowel transplants had better patient and graft survival rates than centres that performed less than 10 transplants. However, analysis of the data up to May 2001 suggests that the critical mass of 10 transplants no longer holds true for transplants after 1995, and that good results can be achieved at any multiorgan transplant program with moderate patient volumes.

The largest Centre reported an overall 1-year patient and graft survival rate of 72% and 64% respectively, and 5-year patient and graft survival of 48% and 40% respectively. The overall 1-year patient survival rate reported for Ontario pediatric small bowel transplants was 61% with the highest survival rate of 83% for ISB.

The majority (70% or higher) of surviving small bowel transplant recipients was able to wean from parenteral nutrition and meet all caloric needs enterally. Some may need enteral or parenteral supplementation during periods of illness. Growth and weight gain in children after ISB were reported by two studies while two other studies reported a decrease in growth velocity with no catch-up growth.

The quality of life after SBT was reported to be comparable to that of patients on home enteral nutrition. A study found that while the parents of pediatric SBT recipients reported significant limitations in the physical and psychological well being of the children compared with normal school children, the pediatric SBT recipients themselves reported a quality of life similar to other school children.

Survival was found to be better in transplants performed since 1991. Patient survival was associated with the type of organ transplanted with better survival in isolated small bowel recipients.

Adverse Events

Despite improvement in patient and graft survival rates, small bowel transplant is still associated with significant mortality and morbidity.

Infection with subsequent sepsis is the leading cause of death (51.3%). Bacterial, fungal and viral infections have all been reported. The most common viral infections are cytomegalorvirus (18-40%) and Epstein-Barr virus. The latter often led to ß-cell post-transplant lymphoproliferative disease.

Graft rejection is the second leading cause of death after SBT (10.4%) and is responsible for 57% of graft removal. Acute rejection rates ranged from 51% to 83% in the major programs. Most of the acute rejection episodes were mild and responded to steroids and OKT3. Antilymphocyte therapy was needed in up to 27% of patients. Isolated small bowel allograft and positive lymphocytotoxic cross-match were found to be risk factors for acute rejection.

Post-transplant lymphoproliferative disease occurred in 21% of SBT recipients and accounted for 7% of post-transplant mortality. The frequency was higher in pediatric recipients (31%) and in adults receiving composite visceral allografts (25%). The allograft itself is often involved in post-transplant lymphoproliferative disease. The reported incidence of host versus graft disease varied widely among centers (0% - 14%).

Surgical complications were reported to occur in 85% of SB-L transplants and 25% of ISB transplants. Reoperations were required in 45% - 66% of patients in a large series and the most common reason for reoperation was intra-abdominal abscess.

The median cost of intestinal transplant in the US was reported to be approximately $275,000US (approximately CDN$429,000) per case. A US study concluded that based on the US cost of home parenteral nutrition, small bowel transplant could be cost-effective by the second year after the transplant.

Conclusion

There is evidence that small bowel transplant can prolong the life of some patients with irreversible intestinal failure who can no longer continue to be managed by parenteral nutrition therapy. Both patient survival and graft survival rates have improved with time. However, small bowel transplant is still associated with significant mortality and morbidity. The outcomes are inferior to those of total parenteral nutrition. Evidence suggests that this procedure should only be used when total parenteral nutrition is no longer feasible.

Small Bowel Transplantation

Samuel Kesseli, MD[a], Debra Sudan, MD[b,*]

KEYWORDS

• Small bowel transplantation • Intestinal transplantation • Short bowel syndrome
• Intestinal failure

KEY POINTS

- The primary therapy for intestinal failure is total parenteral nutrition, and small bowel transplantation is reserved generally for patients who develop life-threatening complications related to total parenteral nutrition administration.
- Given that small bowel transplantation is an infrequently performed procedure, individual centers have inadequate case volume to identify optimal surgical techniques and timing. Multicenter studies are crucial to advance knowledge in this field.
- Intestine allografts are more immunogenic than other solid organ allografts and, therefore, patients experience more acute rejection episodes, require higher levels/doses of immunosuppressive medications, and have a higher incidence of infectious complications related to immunosuppression than recipients of other solid organ allografts.
- The significance of antibody development (especially donor-specific antibody) in intestine transplant candidates or recipients and antibody-mediated rejection is less well defined than in kidney and heart transplantation and is the target of current investigations in the field.

INTRODUCTION: NATURE OF THE PROBLEM AND INDICATIONS

Intestinal failure (IF) is defined clinically as any cause of gastrointestinal (GI) dysfunction that results in the inability to meet nutritional demands, necessitating either temporary or indefinite dependence on parenteral nutrition (PN).[1] Most often this occurs secondary to surgical resection, leading to short bowel syndrome, although functional disorders in motility, mucosal defects, obstruction, and fistulae may also account for IF.[2,3] Quantitatively, IF can be assessed with biomarkers of functional enterocyte mass (ie, citrulline) or energy absorption studies; however, these tests may not accurately predict a patient's PN requirement and are not available in all centers and, therefore, are of limited clinical utility.[4–6] As such, IF is frequently a clinical diagnosis made in

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Decision Memo for Intestinal and Multivisceral Transplantation (CAG-00036N)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Decision Summary

In summary, Medicare will cover intestinal transplantation for the purpose of restoring intestinal function in patients with irreversible intestinal failure only when performed for patients who have failed TPN and only when performed in centers that meet approval criteria. The criteria for approval of centers will be based on an annual volume of 10 intestinal transplants per year with a 1-year actuarial survival of 65 percent.

Decision Memo

To: File: Intestinal and Multivisceral Transplantation
CAG-00036N

From: Sean R. Tunis, M.D., M.Sc.
Director, Coverage and Analysis Group

Jackie Sheridan
Technical Advisor, Coverage and Analysis Group

Kenneth Simon, M.D.
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Health Insurance Specialist, Coverage and Analysis Group

Subject: National Coverage Policy Request on Intestinal Transplantation

Date: October 4, 2000

This memorandum serves four purposes: (1) it describes small bowel and multivisceral transplantation as treatment for intestinal failure; (2) it outlines current coverage policy for organ transplantation; (3) it analyzes relevant clinical literature; and (4) it delineates Medicare's response to this request for a national coverage policy.

Description and Background of Small Bowel and Multivisceral Transplantation

Small bowel transplantation (SBT) is the transplantation of a cadaveric intestinal allograft for the purpose of restoring intestinal function in patients with irreversible intestinal failure. SBT can be performed in isolation, in combination with transplantation of liver (for patients who have liver failure, which often occurs in children on long-term total parenteral nutrition (TPN)). In addition to intestinal failure, candidates for multivisceral transplantation (MVT) have developed evidence of impending liver failure and other gastrointestinal problems such as pancreatic failure, thromboses of the celiac axis and the superior mesenteric artery, or pseudo-obstruction affecting the entire gastrointestinal tract.

Intestinal failure is defined as the loss of absorptive capacity of the small bowel secondary to severe primary gastrointestinal disease or surgically induced short bowel syndrome. The major causes of intestinal failure are

volvulus, gastroschisis, necrotizing enterocolitis, splanchnic vascular thrombosis, inflammatory bowel disease, radiation enteritis, congenital diseases and trauma. Intestinal failure prevents oral nutrition and may be associated with both mortality and profound morbidity.

Most of the non-transplant surgical options for intestinal failure (e.g., bowel lengthening) have been unsuccessful in improving absorptive capacity of residual bowel, and none are regarded as sufficiently safe and effective for routine use.[1] Total parenteral nutrition (TPN) delivers nutrients intravenously, avoiding the need for absorption through the small bowel. The majority of patients are managed on TPN.

Intestinal transplantation in humans proved clinically feasible in the late 1980's. Most of the literature acknowledges that the procedure is effective, but has considerable morbidity and mortality. Rejection episodes for intestinal transplantation are relatively frequent. For example, acute rejection for patients who were transplanted through February 1997 is reported in 79 percent of SBT, 71 percent of SB/LT and 56 percent of MVT. [2] Moreover, several patients developed lymphoproliferative disease and serious infections, such as cytomegalovirus. About half of the patients receiving intestinal transplants survive for 5 years or more.

Current Medicare Policy Related to Organ Transplantation

Medicare coverage of kidney transplantation was enacted by law in 1976. Kidney transplants may only be furnished in centers that meet specific criteria that are delineated in regulation (42 CFR part 405, subpart U). Coverage for other types of organ transplants was implemented administratively under the national coverage process.

Medicare extended coverage to heart transplants in 1987, but only in facilities that met criteria outlined in the *Federal Register* (52 FR 10935). Liver transplantation, for certain specified diagnoses, first became effective in 1992 (56 FR 15006) in facilities that meet specified criteria. The indications for liver transplantation were expanded in 1996 and 1999, and presently include all patients with end stage liver disease except those with malignancies. Medicare national coverage policy for lung transplantation became effective in February 1995 (60 FR 6537) for facilities that meet specified criteria. Coverage for pancreas transplantation first occurred in July 1999.

Medicare has established minimum 1- and 2-year actuarial survival standards for heart, liver and lung transplant centers. In order to be approved for Medicare coverage, a facility must demonstrate that its actuarial survival is equivalent to or exceeds these standards. The Medicare 1-year actuarial survival standards for heart, liver and lung facilities are 73%, 77%, and 69%, respectively. Two-year actuarial survival standards are 65%, 60% and 62%, respectively.

There is currently no national Medicare coverage policy on intestinal transplantation. In the absence of national coverage policy, Medicare contractors are charged with the responsibility for making individual determinations regarding whether a particular service can be considered reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act. To the best of our knowledge, all Medicare contractors are presently denying coverage for intestinal transplants.

Analysis of Relevant Clinical Literature

In its deliberation on the initial formal request, HCFA considered various sources. First, we considered the information submitted by the requestor, which included 11 distinct studies. Secondly, we reviewed the July 1999 technology assessment that was performed by the Blue Cross Blue Shield Association's Technology Evaluation Center. Thirdly, we requested the Center for Practice and Technology Assessment at the Agency for HealthCare

Research and Quality to perform a separate technology assessment on this subject. This was completed in April 2000.

1. Literature Submitted by Requestor

All of the 11 articles submitted with the original request were case reports or case series. Three of the articles included only one or two cases and represented early (pre-1991) experiences with the procedure. Four of the articles included the results of only pediatric patients (three reports of children under 10 years and one on children less than 18 years). We note, however, that the evidence indicates significant differences in outcomes between pediatric and adult populations, with outcomes of intestinal transplantation best in the pediatric population. Five of the 11 articles submitted by the requester included adult patients.

Three of the non-pediatric case series included progressively longer periods of case analysis at a single health care provider (i.e., results of cases from 1990 - 1995, cases from 1990 - 1996, and cases from 1990 - 1997 at University of Pittsburgh Medical Center). Consequently, the patients in these reports were duplicated. For purposes of this memorandum, we will discuss only the most recent of these articles, a similar analysis of the cumulative experiences at another facility (University of Miami), and an analysis of the intestinal transplant registry.

The article "Clinical Intestinal Transplantation: New Perspectives and Immunologic Considerations" discusses the experiences of 98 consecutive patients, both adult and children receiving intestinal transplants for a range of indications[3]. Thirty-seven received small bowel transplants alone, 50 received small bowel and liver transplants, and 17 received multivisceral transplants. Actuarial patient survival at 1-year was 72% and 5-year survival was 48%. One-year graft survival was 64% and 5-year graft survival 40%. The differences among the three types of transplants were not significant.

The primary causes of death in these patients were rejection, infection, technical and management errors and B-cell lymphoma. The use of donor bone marrow at time of transplant was not found to significantly influence rejection episodes. Ninety-one percent of the surviving patients attained full nutritional autonomy. The article states that "the morbidity and mortality is still too high for their [intestinal transplants] widespread application."

The article "Clinical Intestinal Transplantation: Experience in Miami"[4] describes the results of 19 intestinal transplants performed at the University of Miami from August 1994 through July 1996. The cases included all three intestinal transplant types for both adults and children. Median length of follow-up was 106 days. Eleven of the 19 patients survived through the follow-up period, but actuarial survival was not included in the study. Seven of the patients had survived longer than 365 days and all patient deaths occurred within the first 76 days following surgery.

David Grant, et al. reported on cumulative intestinal transplantation in an article entitled "Intestinal Transplantation: 1997 Report on the International Registry".[5] This article included data on 272 transplants in 269 patients from 33 intestinal transplant programs. Two-thirds of the recipients were children. Short gut syndrome was the most common indication for transplantation. Forty-one percent of the procedures were for small bowel transplants alone, 48% for small bowel and liver, and 11% for multivisceral grafts. One-year patient survival for transplants performed after February 1995 was 69% for small bowel alone, 66% for small bowel and liver transplants, and 63% for multivisceral. Transplants since 1991 and programs that had performed at least 10 transplants had significantly higher graft survival rates. Seventy-seven percent of the current survivors had stopped total parenteral nutrition and resumed oral nutrition. There was no association between type of donor, donor pretreatment or diagnosis and graft or patient survival. Although most intestinal transplants arise from cadaveric donors, nine patients received grafts from living donors with comparable results to cadaveric transplants (67% survival).

According to David Grant, because most children and adults function well on TPN, the risks of intestinal

transplantation are only warranted when standard therapies have failed. He states that patients who can be maintained on long-term TPN are generally not considered for transplantation at this time. He recommends an isolated small bowel graft when patients develop 1) fluid and electrolyte losses that cannot be managed with TPN, 2) severely limited venous access, and/or 3) moderate liver dysfunction secondary to TPN. Combined small bowel/liver transplants are offered to patients with 1) irreversible liver failure due to TPN, or 2) intestinal failure associated with a hypercoagulable state that can be corrected by a simultaneous liver graft. Multivisceral transplants are offered to patients with locally aggressive tumors that can only be removed by a massive evisceration of the abdominal organs.

2. Blue Cross Blue Shield Technology Evaluation Center Assessment

Blue Cross Blue Shield Technology Evaluation Center (TEC) reviews technology using a standard set of criteria. The criteria TEC uses are as follows:

1. The technology must have final approval from the appropriate governmental regulatory bodies.
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
3. The technology must improve the net health outcome.
4. The technology must be as beneficial as any established alternatives.
5. The improvement must be attainable outside the investigational settings.

In a March 1996 assessment, the Blue Cross Blue Shield Technology Evaluation Center found small bowel/liver combination transplants for adults and children as well as small bowel transplants alone for children to meet their criteria for coverage. Small bowel transplantation alone in adults did not meet their criteria. In July 1999, the Technology Evaluation Center conducted a further technology assessment of small bowel transplants in adults and multivisceral transplants in adults and children. Findings from the 1999 Technology Evaluation Center review are summarized as follows:

- The primary immunosuppressant agent for intestinal transplantation, tacrolimus, was approved by the Food and Drug Administration in April 1994 for rejection prophylaxis in liver transplantation. Thus, small bowel/liver and multivisceral transplantation is an approved use. Use of this drug for small bowel transplantation alone represents an off-label use of the drug.
- Data are available on several case series of patients undergoing intestinal transplantation. Reasonably reliable overall survival rates can be calculated by procedure; however, numbers are sufficiently small, therefore, TEC can only reliably calculate the overall survival for the total number of patients undergoing these procedures. The largest data sets analyze long-term survival of 41 adults receiving small bowel transplant alone and 30 patients receiving MVT.
- Long-term graft survival rates for adult patients undergoing small bowel transplants alone range from 13 - 30%. It is not possible to predict which patients will survive longer on TPN versus SB transplantation. Both treatments cause substantial morbidity in survivors; formal analysis of the quality of life between the treatments is not available.
- Whether small bowel transplantation in adults improves health outcomes has not been demonstrated in the investigational setting.
- Multivisceral transplantation in pediatric and adult patients has a similar 2-year survival at 33-50% at 5 years. Without this procedure, it is expected that these patients would face 100% mortality.
- The results of multivisceral transplantation are derived from specialized treatment settings, using desperately ill patients. Similar results can be expected only in specialized centers that have equivalent training, experience, and performance.

Based on the above, the Blue Cross Blue Shield Technology Evaluation Center found that small bowel transplantation in adults does not meet its criteria. However, multivisceral transplantation in adult and pediatric patients meets the criteria.

3. Center for Practice and Technology Assessment

We also requested the Center for Practice and Technology Assessment at the Agency for Healthcare Research and Quality (AHRQ) to perform an assessment of intestinal transplantation. AHRQ performed a computerized literature search and supplemented this with a review of the 11 studies submitted to HCFA by the requester and the TEC assessment described above. A total of 211 full-text articles were reviewed. Data include case series as well as reports from national and international registries. There are numerous methodological problems with the data, including the fact that individual patients appear to be represented in multiple published data sets. No controlled clinical trials were identified.

Transplantation data derive mainly from reports of patients who received transplantation after failing TPN. These patients would be expected to die without the transplantation. Reported survival rates for patients receiving intestinal transplantation range from 48% to 55% at 5 years. AHRQ could not identify studies of outcomes for patients on long-term TPN specifically for intestinal failure, or for patients with or without transplantation who are considered to be at "high risk" of TPN failure.

This assessment evaluated data on TPN from the registry of TPN in North America, Great Britain, Denmark and France, as well as a combined Belgian-French survey and a 1997 comprehensive systematic worldwide review of TPN experience. They found overall survival with TPN high (approximately 90% at 1-year and 60% 5-year survival). TPN-related deaths were approximately 10%. Complications of TPN are generally sepsis, vena cava thrombosis and hepatic failure.

A summary of the AHRQ findings is as follows:

1. The available data do not permit precise quantitative estimates of mortality rates for patients who are candidates for SBT either because of TPN failure or because of supposed high risk for TPN failure. Available data are not sufficient to determine the expected rates of other outcomes of interest.
2. In general, transplants have only been done on patients who have failed TPN. Based on available data, patient survival rates (adults and children) at 1, 3, and 5 years following SBT or related procedures range from 46% - 80%, 48% - 60%, and 48% - 55%, respectively.
3. Death is the expected outcome for patients failing TPN who do not receive a transplant.
4. Graft survival rates (adults and children at 1, 3, and 5 years following SBT or related procedures range from 50%-90%, 36%-48%, and 40%-48%, respectively.
5. Survival at 1, 3, and 5 years for the general group of patients on long-term TPN are reported to be approximately 90%, 65-80%, and 60% respectively.
6. Criteria for identifying patients at "high risk" for TPN failure are not defined. Specific outcomes for this group of patients cannot be determined.

The assessment concludes that small bowel and related transplantation appear to be potentially life-saving options for patients who have failed TPN and would therefore otherwise face certain death. The data are not sufficient to determine whether the risks and benefits of small bowel transplant and related procedures might yield a net benefit to patients who can continue TPN, but are considered at high risk to fail TPN sometime in the future. In order to make this determination, well-done studies that compare transplant with continue TPN would need to be conducted in patients who meet an agreed-upon definition of "high risk" for TPN failure.

The data are not sufficient to determine whether young patients, who are known to require TPN for the rest of their lives without chance of recovering intestinal function, should be provided the opportunity to receive a transplant prior to reaching the point of failing TPN.

4. Questions Posted on the Internet

Based on our review of the information discussed above, additional information was needed in order to develop a Medicare national coverage policy. We posted the following questions to our Internet site in an effort to solicit information that would assist us with the development of an appropriate policy.

- What clinical manifestations define "failed total parenteral nutrition (TPN)" and what literature is available to support this definition?
- Is there scientific evidence to support coverage of small bowel and multivisceral transplantation in the age 65 and older population?
- Scientific evidence considered in the assessment is based primarily on the experience in two hospitals. Is there evidence to expand Medicare coverage to this procedure in other facilities?
- Is there scientific evidence to support specific facility criteria (similar to Medicare coverage of liver, heart and lung transplants) that should be met prior to Medicare coverage of transplants in that facility?
- Is there scientific evidence to support small bowel and multivisceral transplantation in patients with malignant disease and if so, what types of malignant disorders?

In response to our web-site posting, we received one submission. The submission included 19 additional articles on small bowel transplantation and TPN. It also included the opinion of one of the most experienced surgeons in the field regarding the specific questions raised on the web site. Several of these subsequent articles were abstracts, unpublished reports, descriptions of surgical techniques and text materials (transplant symposium). Several articles focused on TPN. These items are discussed in more detail in the following section of this decision memorandum.

Medicare's Response to the National Coverage Request

There are three different types of intestinal transplantation: isolated intestinal transplant, combined liver-intestinal transplant and multivisceral transplant. In this section, we use the general term intestinal transplant to include all three types of transplant. While the literature reports small variations in the actuarial survival of patients receiving small bowel transplants due to differences in data used, number of organs transplanted, and methodologies, it is important to note that 1-year survival for all intestinal transplantation is approximately 70 percent. The surgical mortality of the procedure is high. For example, the Miami experience indicates that all their patient deaths from a 2-year study period occurred within the first 76 days.

In addition, the literature reveals that complications following surgery are common, including rejection, cytomeglovirus disease, lymphoproliferative disease and infection. For example, the rates for SBT, SB/LT, and MVT respectively reported by the intestinal registry are 79%, 71% and 56% for acute graft rejection, 13%, 3%, and 0% for chronic graft rejection, 24%, 18% and 40% for cytomegalovirus disease, and 7%, 11% and 13% for lymphoproliferative disease. The evidence consistently shows that there is a 50 percent or less chance of long-term (4 - 5 years) survival after intestinal transplantation. It is also questionable if the procedure enhances quality of life. That is, the literature on quality of life is not consistent. A study by Rovera et al.[6] found no difference in the quality of life between patients receiving intestinal transplantation and those on TPN, while a study by DiMartini et al.[7] found improvement. After transplantation, patients require lifelong immunosuppressive therapy.

The evidence on which to base a determination on Medicare coverage regarding intestinal transplantation is sparse. After reviewing two technology assessments and all of the studies contributed by the public, we have found no studies that permit us to directly compare the surgical procedure of intestinal transplantation to long-term TPN therapy for intestinal failure medically. (There are two studies that use subjective measures to compare the quality of life as perceived by the patients in the two treatment groups. One of these indicated no difference in quality of life between the treatment modalities; the other indicated improved quality of life for transplantation over TPN.) As the

AHRQ assessment points out, we could not identify studies of outcomes on patients on long-term TPN specifically for intestinal failure or for patients who are considered to be at "high risk" of TPN failure. This is an infrequently performed procedure. In fact, the international registry indicates that there have only been 273 procedures performed worldwide as of 1997. Although incidence of intestinal transplantation have increased, as of this date, the Scientific Registry of transplant procedures indicates that there have been only 439 total intestinal transplants performed in this country.

It seems clear that the various forms of intestinal transplantation (i.e., SBT, SB/LT, and MVT) may offer an alternative life-saving therapy for restoring intestinal function in patients with irreversible intestinal failure. However, the procedure is undoubtedly one of high risk. Given that there is no comparative data to alternative therapy we believe that intestinal transplantation can only be considered as reasonable and necessary when it is a procedure of last resort. Intestinal transplantation should be reserved only for patients with life-threatening complications from TPN who are expected to die without the transplantation. Therefore, we are limiting Medicare coverage of intestinal transplantation only to patients who have failed TPN (as define below). Coverage will include intestinal transplantation alone (SB), combined liver-intestinal transplantation (SB/LT), and multivisceral transplantation (stomach, duodenum, pancreas, liver and intestine).

A. Definition of Failed TPN

As pointed out in the AHRQ assessment and the David Grant intestinal registry report, the clinical indications for intestinal transplantation supported by the literature are impending liver failure due to TPN, thrombosis of major central venous channels, frequent line infection and sepsis and severe dehydration. In response to our solicitation on the web, the University of Pittsburgh has offered increased detail to permit us to further define the clinical conditions that indicate failed TPN for liver failure, thrombosis, frequency of infection and dehydration. Thus, Medicare will cover intestinal transplantation only in the following clinical situations:

- Impending or overt liver failure due to TPN induced liver injury. The clinical manifestations include elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastroesophageal varices, coagulopathy, stomal bleeding or hepatic fibrosis/cirrhosis.
- Thrombosis of the major central venous channels; jugular, subclavian, and femoral veins. Thrombosis of two or more of these vessels is considered a life threatening complication and failure of TPN therapy. The sequelae of central venous thrombosis are lack of access for TPN infusion, fatal sepsis due to infected thrombi, pulmonary embolism, superior vena cava syndrome, or chronic venous insufficiency.
- Frequent line infection and sepsis. The development of two or more episodes of systemic sepsis secondary to line infection per year that requires hospitalization indicates failure of TPN therapy. A single episode of line related fungemia, septic shock and/or Acute Respiratory Distress Syndrome are considered indicators of TPN failure.
- Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN. Under certain medical conditions such as secretory diarrhea and non-constructable gastrointestinal tract, the loss of the gastrointestinal and pancreatobiliary secretions exceeds the maximum intravenous infusion rates that can be tolerated by the cardiopulmonary system. Frequent episodes of dehydration are deleterious to all body organs particularly kidneys and central nervous system with the development of multiple kidney stones, renal failure, and permanent brain damage.

We received information also suggesting that significant bone disease, metabolic disorders, developmental insufficiency, and significant limitations on social and personal activities be considered as failed TPN. However, these are common side effects for patients on long-term TPN therapy. The literature we reviewed, including the AHRQ assessment and the intestinal transplant registry report, does not mention these conditions as indications for intestinal transplantation. Since they are not included in the literature and are common side effects of TPN, we do not consider these indications of therapy failure.

B. Contraindications

Rajendra and Pollard's article[8] states that the contraindications for small bowel transplantation include age over 60 years, cardiopulmonary insufficiency, presence of AIDS, systemic malignancy, and life-threatening infections. In response to the questions raised in the Internet posting, Dr. Abu-Elmagd, one of the most published researchers on the topic of intestinal transplantation, indicates, "There is no scientific evidence at the present time to support coverage of small bowel, combined liver-small bowel or multivisceral transplantation in the age 65 and older population." The literature is clear that all forms of intestinal transplantation are primarily pediatric procedures with two-third of the procedures occurring in children. Grant's analysis of data in the international registry of intestinal transplantation reports only 11 percent of these procedures were performed on patients over age 40. Further, the outcomes for intestinal transplantation in patients between the ages of 2 and 18 are superior to that in adult patients. In an informal query of the data maintained by the Scientific Registry of Transplant Recipients, we learned that there have been nine transplants of patients over 60 with a maximum age of 66; only five of these resulted in functioning grafts.

We believe the evidence supports the fact that aged patients generally do not survive as well as younger patients receiving intestinal transplantation. Nonetheless, some older patients who are free from other contraindications have received the procedure and are progressing well, as evidenced by the UNOS data. Thus, we do not believe it is appropriate to include specific exclusions from coverage, such as an age limitation, in the national coverage policy. We note that the facility criteria described below include an outcome measure. This outcome measure will serve to exclude facilities that fail to consider individual patient contraindications in selecting patients for the procedure.

C. Facility Criteria

As noted in the background section of this document, Medicare has historically limited organ transplantation to centers that meet specific criteria. The current criteria for heart, liver and lung transplantation consider medical criteria, (such as patient selection policies, patient management protocols, and evaluation of the transplant team), experience criteria (such as volume and outcome measures), and administrative criteria (such as laboratory services, organ procurement organizations, maintenance of data, and appropriate billing). Because of the high risk associated with intestinal transplantation, we believe coverage of this procedure should similarly be limited to carefully selected centers with demonstrated success.

There is scientific evidence that links annual volume levels of other types of high risk surgical procedures to successful outcomes. For example, a 1994 Journal of American Medical Association article by Hosenpud et al [9]and a 1999 New England Journal of Medicine article by Edwards et al[10] discuss the effect of volume on heart and liver transplantation respectively. These articles indicate significant difference in likelihood of survival in high volume centers. For heart transplantation, the Hosenpud article found risk of 1-year mortality increased 33 percent in heart transplant centers performing fewer than nine cardiac transplants per year. Edwards et al similarly found the 1-year mortality rate for centers performing fewer than 20 liver transplants per year (or lack of affiliation with a high volume center) increased eight percentage points (28.3 percent mortality for high volume compared to 20.1 percent for low volume).

The research conducted by David Grant on the intestinal transplantation registry demonstrated that transplant volume greater than 10 is a significant variable in predicting positive health outcomes of the procedure. This, coupled with the literature on volume and outcomes applicable to other organ transplants, results in a determination to limit Medicare coverage of intestinal transplantation to centers that perform 10 or more transplants per year. At this time, we know of three centers that provide intestinal transplantations at this volume.

The 1997 report of the International Intestine Transplant Registry, which includes data from 33 transplant programs,

reports on the outcomes of 273 procedures. The 1-year patient survival for procedures done after February 1995 was 69 percent for SBT, 66 percent for SB/LT, and 63 percent for MVT. Since the volume of individual types of procedures for a specific center would be so small as to be statistically meaningless, we believe centers should report aggregate survival. Thus, we are establishing the 1-year survival criterion for Medicare approval of centers for intestinal transplantation at 65 percent.

In summary, Medicare will cover intestinal transplantation for the purpose of restoring intestinal function in patients with irreversible intestinal failure only when performed for patients who have failed TPN and only when performed in centers that meet approval criteria. The criteria for approval of centers will be based on an annual volume of 10 intestinal transplants per year with a 1-year actuarial survival of 65 percent.

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Related Material

Literature Review

Current status of living donor small bowel transplantation

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Current Opinion in Organ Transplantation 2010, 15:346–348

Purpose of review

To analyze the current status of living donor intestinal transplantation (LDIT) as a treatment option for intestinal failure.

Recent findings

Long-term outcomes from LDIT and combined living donor intestinal/liver transplantation (CLDILT) are comparable with those from transplantation using deceased donors. In certain life-threatening situations, especially in pediatric patients, this strategy may offer potential advantages.

Summary

According United Network for Organ Sharing (UNOS) data children with intestinal failure affected by liver disease secondary to parenteral nutrition have the highest mortality on a waiting list compared with all candidates for solid organ transplantation. Elective nature of CLDILT offers multiple advantages for this patient population. LDIT also could be life-saving option for patients with intestinal failure who run out of venous access. Optimal timing, short ischemia time and good human leukocyte antigen (HLA) matching may contribute to lower postoperative complications. Current literature suggests that living intestinal donors experience very low morbidity and high level of satisfaction.

Keywords

intestinal transplantation, living donor, transplant outcomes

Curr Opin Organ Transplant 15:346–348

1087-2418

Introduction

The existing large gap between the number of potential recipients and available deceased donors for liver and kidney transplant has justified the significant expansion of living donor programs for those organs. This situation does not exist for adult recipients of intestinal transplant as the donor supply largely exceed the current needs. However, this is not the case for pediatric recipients, especially those with associated liver failure. UNOS data show that this subset of patients still has the highest mortality rate on the waiting list compared to all the other categories of solid organ transplantation [1,2].

Due to improved surgical technique and better immunosuppression, intestinal transplantation is now a successful treatment for patients suffering from life-threatening complications of irreversible intestinal failure and total parenteral nutrition (TPN). According to recently reported UNOS data [1] patients and graft survival is 82.76 and 77.5% at 1 year and 70.71 and 63.43% at 3 years, respectively. These encouraging results will possibly expand the indications for intestinal transplantation in the future. The outcomes from living donor intestinal transplantation (LDIT) in published literature are similar to those from deceased donors, which confirm the viability of the procedure [3••,4].

Current literature concerning intestinal transplantation shows that the experience with LDIT remains limited, with a very small number of procedures performed worldwide. The technical aspects of LDIT were standardized by Gruessner and Sharp [5] in 1997. The donor operation consists of harvesting 200 cm (150 cm for pediatric recipients) of distal ileum, preserving at least 20 cm of terminal ileum and ileocecal valve. The vascular pedicle of the graft is formed by the distal branches of the superior mesenteric artery and vein and it is anastomosed to the infrarenal aorta and cava of the recipient.

Living donor intestinal transplantation has several potential advantages such as elimination of waiting time, elective nature of the procedure, better HLA matching, and short cold ischemia time. A well timed LDIT may be critically important to rescue patients with loss of central venous access. We have also had a favorable experience in our center with young trauma victim with ultra-short bowel syndrome with excellent outcomes, complete nutritional rehabilitation and re-establishment of normal life style [6,7]. The potential for elimination of waiting time on the deceased list may be particularly important for pediatric candidates for intestinal transplantation with associated liver failure. According to UNOS data, children represent the majority (almost 70%) of the candidates on the intestinal transplantation waiting list

in USA. Most of them are listed for combined liver and bowel transplant. This subset of patients has the highest mortality on waiting list from all candidates for solid organ transplantation [1], which could be partially attributed to relatively late referral. In our experience combined living donor intestine and liver transplant may help even those children affected by failure of both organs, who are most likely to die on waiting list [3••].

Living donor intestinal transplantation tends to performed with well HLA-matched grafts. The significance of HLA matching in intestinal transplantation is still to be determined. In fact experienced programs have obtained good outcomes and low rate of rejection with poorly matched deceased intestinal transplantation [8,9]. Several cases of LDIT performed using an identical twin as the donors have been reported in the literature with uniformly excellent results [10–12]. Our data suggest that HLA-identical siblings as donors confer a significant immunological advantage to the recipient. LDIT might have a role for intestinal transplantation in highly sensitized candidates, especially pediatric patients. Significant risk of antibody-mediated graft injury in settings of positive cross-match has been demonstrated [13]. The elective conditions provided by LDIT allows highly sensitized patients to be pretreated with plasmapheresis and intravenous immunoglobulin and converted to negative cross-match before the transplant [14].

In normal physiologic condition significant amount of the energy produced in the enterocytes is used to maintain the integrity of the mucosa. Obviously, during period of ischemia decreased and even completely blocked energy production will affect the mucosal resistance leading to increased chance for bacterial translocation and septic complications in posttransplant period [15,16]. The direct correlation between the duration of ischemia and degree of mucosal injury is well known [17]. As shown in animal models, the process of mucosal damage starts even before the organ harvesting, during the brain dead state [18]. Irreversible damage has been seen after 5 h of cold ischemia and the rate of bacterial translocation increases significantly after 9 h [15].

Significant reduction of ischemia time has been achieved in the settings of LDIT. In our series of 26 cases (out of 43 performed worldwide) the average cold ischemia time was 5 min and warm ischemia time 30 min [19]. For comparison in large series of deceased bowel transplant the cold ischemia time ranged from 7 to 17 h [15]. We believe that relatively low rate of infectious complications observed in our recipients of LDIT is due to great extend to the short ischemic time. A similar low rate of infectious complications was also confirmed in pediatric patients receiving living donor liver and intestine grafts [3••]. Finally, the elective nature of LDIT allows scheduling the procedure in optimal conditions, if no emergency situation exists [20,21].

Short summary of all the relevant literature published in 2009

Only four articles in LDIT were published in 2009, reflecting the active of a very small number of transplant centers active in the field. We reported University of Illinois at Chicago's single-center experience with LDIT and combined living donor intestinal/liver transplantation (CLDILT) in pediatric patients [3••]. Between October 2002 and June 2006 we transplanted 13 living donor intestinal grafts in 10 recipients. In five cases CLDILT was performed. No surgical complications occurred in any of the donors. In CLDILT, the patient survival at 1 and 2 years was 100%, the liver graft survival was 100% and intestinal graft survival was 80%. One patient who lost intestinal graft was successfully retransplanted. In LDIT recipients, the patient and graft survival at 1 and 3 years were 60 and 50%, respectively.

We also described our experience of abdominal wound closure after CLDILT in children [22•]. We applied a staged approach to achieve a safe closure without risking abdominal compartment syndrome. We used absorbable polygalactin mesh as a first-stage closure. As soon as adequate granulation tissue was formed over the mesh, split thickness skin grafts were applied. With this relatively simple technique all five pediatric recipients included in the study were managed successfully. Ji *et al.* [23•] analyzed their experience with four donors for LDIT and outline their approach to donor selection and management. They reported no major donor complications with long term fallow up. Li *et al.* [24•] (from the same center) studied the outcome of three recipients of isolated living donor segmental intestinal graft. The authors report 7 years survival of one of their recipients, who enjoys normal life.

Conclusion

Currently, LDIT has been perfected in relation to technical details, leading to results comparable to those obtained with deceased donors. Because the availability of adequate supply of intestinal deceased grafts, LDIT should be limited to specific indications. In particular, the best indication is probably CLDILT in pediatric recipients with intestinal and hepatic failure. In this setting, the virtual elimination of waiting time may avoid the high mortality currently experienced by candidates on the deceased waiting list. Isolated LDIT may be indicated for candidates to intestinal transplantation with lack of central venous access as a rapid rescue strategy. Potentially, LDIT could be also used in highly sensitized

recipients to allow the application of de-sensitization protocols. Finally, in the specific case of available identical twins or HLA-identical sibling, LDIT has a significant immunological advantage and should be offered.

References and recommended reading

Papers of particular interest, published within the annual period of review, have been highlighted as:

- • of special interest
- •• of outstanding interest

Additional references related to this topic can also be found in the Current World Literature section in this issue (p. 399).

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Revision and Treatment of Complications of Cosmetic Breast Procedures

Question: What is the intent of the HERC regarding coverage for revisions or treatment of complications of cosmetic breast procedures?

Question source: Alison Little, CCO medical director

Issue: When a patient has had a cosmetic breast surgery (e.g. augmentation) that is not covered by OHP, it is unclear when treatment of complications of that surgery (e.g. infection, implant migration, contracture) are covered. There is currently a guideline which clarifies when breast reconstruction revision for women who have had a mastectomy with reconstruction. However, this guideline only lists line 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER, and is unclear to stakeholders whether this guideline applies to complications from cosmetic breast procedures.

Currently, ICD-10 diagnosis codes and/or CPT codes for procedures that involve breast implants or breast surgery complications appear on 4 lines.

1) Line 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER is the only line with diagnosis codes for deformity or disproportion of reconstructed breasts. It contains all breast reconstruction and revision CPT codes and is the only line attached to guideline note 79 BREAST RECONSTRUCTION.
2) Line 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT includes CPT codes for removal of implants and tissue expanders, and diagnoses codes for infection and wound complications. This allows treatment of surgical complications such as wound infection and dehiscence and is appropriate for all breast surgery complications (cosmetic and post-mastectomy).
3) Line 424 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT contains multiple ICD-10 related to breast reconstruction complications, including capsular contracture and implant rupture, as well as CPT codes for breast reconstruction and revision.
4) Line 636 GALACTORRHEA, MASTODYNIA, ATROPHY, BENIGN NEOPLASMS AND UNSPECIFIED DISORDERS OF THE BREAST is the line used for cosmetic breast augmentation. Line 636 also has all the CPT codes for revision and repair.

Breast surgeries such as reduction mammaplasty, mastectomy, mastopexy are also found on lines 312 GENDER DYSPHORIA/TRANSEXUALISM, 558 MACROMASTIA and 640 GYNECOMASTIA.

Past intent of the HSC/HERC has been that complications of a non-covered procedure, such as infection and wound dehiscence, are covered. The question to be addressed with breast surgery complications is when does a complication (like capsular contracture) rise to the level of a medical issue that needs to be addressed, and when is addressing the complication a cosmetic issue.

Surgeons generally grade capsular contracture (a hardening of the tissue around the implant) into 4 grades. Grade 4 (the highest grade) is the only one with pain in its definition.

- Grade I — the breast is normally soft and appears natural in size and shape
- Grade II — the breast is a little firm, but appears normal
- Grade III — the breast is firm and appears abnormal
- Grade IV — the breast is hard, painful to the touch, and appears abnormal

For breast cancer patients, per the Women's Health and Cancer Rights Act of 1998 (WHCRA), coverage must be provided for:

- All stages of reconstruction of the breast on which the mastectomy has been performed;
- Surgery and reconstruction of the other breast to produce a symmetrical appearance; and
- Prostheses and treatment of physical complications of all stages of the mastectomy, including lymphedema.

GUIDELINE NOTE 79, BREAST RECONSTRUCTION

Line 191

Breast reconstruction is only covered after mastectomy as a treatment for breast cancer or as prophylactic treatment for the prevention of breast cancer in a woman who qualifies under Guideline Note 3, and must be completed within 5 years of initial mastectomy. Revision of previous reconstruction is only covered in cases where the revision is required to address complications of the surgery (wound dehiscence, fistula, chronic pain directly related to the surgery, etc.). Revisions are not covered solely for cosmetic issues.

Breast reconstruction may include contralateral reduction mammoplasty (CPT 19318) or contralateral mastopexy (CPT 19316). Mastopexy is only to be covered when contralateral reduction mammaplasty is inappropriate for breast reconstruction and mastopexy will accomplish the desired reconstruction result.

ICD-10 Code	**Code Description**	**Line(s)**
L76.82	Other postprocedural complications of skin and subcutaneous tissue	424 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
N65.0	Deformity of reconstructed breast	191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
N65.1	Disproportion of reconstructed breast	191
T81.3	Disruption of wound	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
T81.4	Infection following a procedure	285
T85.41X	Breakdown (mechanical) of breast prosthesis and implant	424
T85.42X	Displacement of breast prosthesis and implant	424
T85.43X	Leakage of breast prosthesis and implant	424
T85.44X	Capsular contracture of breast implant	424
T85.49X	Other mechanical complication of breast prosthesis and implant	424
Z45.81	Encounter for adjustment or removal of breast implant	191
CPT Code	**Code Description**	**Line(s)**
11971	Removal of tissue expander(s) without insertion of prosthesis	191,285
19328	Removal of intact mammary implant	191,285,424,636
19330	Removal of mammary implant material	191,424,636
19370	Open periprosthetic capsulotomy, breast	191,636
19371	Periprosthetic capsulectomy, breast	191,424,636
19380	Revision of reconstructed breast	191,424,636

HERC staff recommendations:

1) Revise GN79 as shown below
    a. Patients with mastectomies for breast cancer or prophylactic treatment in high risk women have coverage mandated by federal law
2) Add a new guideline to multiple lines addressing revision of breast surgeries
    a. Include all lines with breast surgeries

GUIDELINE NOTE 79, BREAST RECONSTRUCTION

Line 191

Breast reconstruction is only covered after mastectomy as a treatment for breast cancer or as prophylactic treatment for the prevention of breast cancer in a woman who qualifies under Guideline Note 3, and must be completed within 5 years of initial mastectomy. ~~Revision of previous reconstruction is only covered in cases where the revision is required to address complications of the surgery (wound dehiscence, fistula, chronic pain directly related to the surgery, etc.). Revisions are not covered solely for cosmetic issues.~~

Breast reconstruction may include contralateral reduction mammoplasty (CPT 19318) or contralateral mastopexy (CPT 19316). Mastopexy is only to be covered when contralateral reduction mammaplasty is inappropriate for breast reconstruction and mastopexy will accomplish the desired reconstruction result

GUIDELINE NOTE XXX, BREAST SURGERY REVISION

Lines 191,285,312,424,560,636,642

Revision of previous breast reconstruction, augmentation, or other breast surgery is only covered in cases where the revision is required to address complications of the surgery (wound dehiscence, fistula, chronic pain directly related to the surgery, etc.). For capsular contracture, only stage 4 contractures with chronic pain are covered for revision surgery/capsulotomy. Revisions of breast reconstruction, augmentation or other breast surgery are not covered solely for cosmetic issues.

Umbilical Hernia and Other Specified Abdominal Hernias with Obstruction

Question: Should additional diagnosis codes for abdominal wall hernias which are not inguinal or femoral be added to the uncomplicated hernia line for cases when there is non-intestinal obstruction?

Question source: Holly Jo Hodges, CCO medical director

Issue: There have been several discussions in 2016 and 2018 about coverage for abdominal wall hernias with obstruction. Incisional and ventral hernias were added to line 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER OR DIAPHRAGMATIC HERNIA) earlier this year with Guideline Note 24 changes to specify that they appear on the uncovered line for chronic non-intestinal obstruction. This change was due to the fact that these types of hernias generally do not need treatment as they do not result in intestinal or other high risk obstructions. Dr. Hodges has noted an additional type of abdominal hernia, umbilical hernia, which does not appear on line 524 and should be added.

ICD-10 K42.0 (Umbilical hernia with obstruction, without gangrene) is currently only on line 168 COMPLICATED HERNIAS; UNCOMPLICATED INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER; PERSISTENT HYDROCELE. Similarly, K45.0 (Other specified abdominal hernia with obstruction, without gangrene) is only on line 168.

HERC staff recommendations:

1) Add the following ICD-10 codes to line 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER OR DIAPHRAGMATIC HERNIA) and keep on line 168
    a. K42.0 Umbilical hernia with obstruction, without gangrene
    b. K45.0 Other specified abdominal hernia with obstruction, without gangrene
2) Modify GN24 as shown below:

GUIDELINE NOTE 24, COMPLICATED HERNIAS

Lines 168,524

Complicated hernias are included on Line 168 if they cause symptoms of intestinal obstruction and/or strangulation. Incarcerated hernias (defined as non-reducible by physical manipulation) are also included on Line 168, excluding incarcerated ventral hernias. Incarcerated ventral hernias (including incarcerated abdominal incisional hernias and umbilical hernias) are included on Line 524, because the chronic incarceration of large ventral hernias does not place the patient at risk for impending strangulation. Ventral hernias are defined as anteriorly abdominal wall hernias and include primary ventral hernias (epigastric, umbilical, Spigelian), parastomal hernias, and most incisional hernias (ventral incisional hernias). ICD-10-CM K42.0, K43.0, K43.3, K43.6, K45.0 and K46.0 are included on Line 524 when used to designate incarcerated abdominal incisional and umbilical hernias without intestinal obstruction or gangrene.

Intracardiac Echocardiogram

Question: Should intracardiac echocardiogram be moved to covered line(s) on the Prioritized List or to the Ancillary List?

Question source: Holly Jo Hodges, CCO medical director

Issue: Intracardiac echocardiogram (CPT 93662 Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation (List separately in addition to code for primary procedure)) is currently on line 662/Guideline Note 173. However, this procedure is considered standard of care during certain percutaneous cardiac interventions.

Intracardiac echocardiography involves the use of a catheter-based ECHO device that replaces transesophageal echocardiography (TEE) for certain transcutaneous cardiac procedures, such as valve replacement or ablation procedures [see Enriquez 2018].

Intracardiac echocardiography was reviewed in 2001 and recommended for the Ancillary File. It was again reviewed in January, 2008. At that time, based on cardiologist consultation, intracardiac echocardiography was recommended for the Diagnostic Procedures List; however, the HOSC/HSC determined that it should be Never Covered. The HOSC/HSC minutes do not contain documentation as to the rationale for this decision.

CMS lists CPT 93662 as only billable as a secondary code to one of the following primary CPT codes:

CPT code	**CPT description**	**Current Placement**
92987	Percutaneous balloon valvuloplasty; mitral valve	39 lines
93453	Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed	Diagnostic Procedures File
93460-93462	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed	Diagnostic Procedures File
93532	Combined right heart catheterization and transseptal left heart catheterization through intact septum with or without retrograde left heart catheterization, for congenital cardiac anomalies	Diagnostic Procedures File
93580	Percutaneous transcatheter closure of congenital interatrial communication (ie, Fontan fenestration, atrial septal defect) with implant	118 ATRIAL SEPTAL DEFECT, SECUNDUM
93581	Percutaneous transcatheter closure of a congenital ventricular septal defect with implant	67 VENTRICULAR SEPTAL DEFECT
93621	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of	281 LIFE-THREATENING CARDIAC ARRHYTHMIAS 347 CARDIAC ARRHYTHMIAS

CPT code	CPT description	Current Placement
	arrhythmia; with left atrial pacing and recording from coronary sinus or left atrium (List separately in addition to code for primary procedure)	
93622	with left ventricular pacing and recording	281,347
93653	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording (when necessary), and His bundle recording (when necessary) with intracardiac catheter ablation of arrhythmogenic focus; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry	281,347
93654	Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia with right atrial pacing and recording, right ventricular pacing and recording (when necessary), and His bundle recording (when necessary) with intracardiac catheter ablation of arrhythmogenic focus; with treatment of ventricular tachycardia or focus of ventricular ectopy including intracardiac electrophysiologic 3D mapping, when performed, and left ventricular pacing and recording, when performed	281,347
93656	Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia including left or right atrial pacing/recording when necessary, right ventricular pacing/recording when necessary, and His bundle recording when necessary with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation	281,347

<u>Similar codes</u>

1) Standard transthoracic echocardiogram (CPT 93303-93314, 93320-93352) are on the Diagnostic Procedures File
2) Transesophageal ECHO for congenital diseases (CPT 93315, 93316) are on the Diagnostic Procedures File
3) CPT 93355 (Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg, TAVR, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intra-procedural), real-time image

acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D) is on 26 lines

HERC staff recommendations:

1) Remove CPT 93662 (Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation (List separately in addition to code for primary procedure) from line 662
2) Strike the entry below from Guideline Note 173
3) Add CPT 93662 to the Diagnostic Procedure File
    a. Will be secondary to appropriate procedure codes

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

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
~~93662~~	~~Intracardiac echocardiography during therapeutic/diagnostic intervention~~		

Y90 Embolization and Mapping

Question: Should the coverage of mapping and embolization for Yttrium 90 therapy for hepatocellular carcinoma be modified?

Question source: Salem Radiology Clinic, Dr. Nicholas Hanson and Dr. Yama Kharoti; Dr. Hodges MVIPA

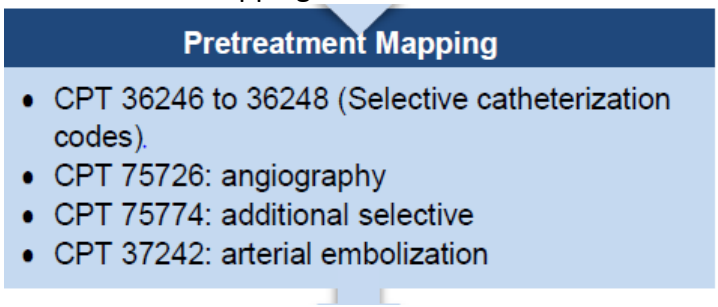
Issue: Drs. Hanson and Kharoti contacted Dr. Hodges regarding a denial for 37242 which is used in the mapping stages prior to treatment of Y90. This does not pair on the Prioritized List, rather the 37243 which is specific for tumors, pairs. Dr. Kharoti says both are necessary. The first mapping appointment is to determine if there are other nontumor areas that require embolization prior to administration of Y90. If they are identified then 37242 is used prophylactically to protect bowel and gallbladder. For example, they may embolize the right gastric branch so no Y90 beads would go there. There are sufficient collaterals that this does not cause bowel ischemia. The following appointment is when the Y90 is used for the liver cancer. Currently, only the code for liver cancer embolization (37243) pairs with liver cancer, but not this preventive embolization that is used to protect bowel and/or gallbladder (37242).

"The y90 treatment (37243) can NOT be done without the Y90 mapping (37242). It would be medical malpractice to do treatment without mapping."

Background for expectations around pre-treatment planning from manufacturer

Manufacturer coding guide https://www.sirtex.com/media/168654/2019-sirtex-coding-guide-final-approved-085-u-0119-0101019docx.pdf

Pre-treatment mapping includes



Phase II: SIR-Spheres Y-90 resin microspheres DAY OF TREATMENT

- CPT 36247 to 36248 (Selective catheterization codes)
- CPT 75726: angiography
- CPT 75774: addl selective
- CPT 37243: tumor embolization
- **Authorized User (AU) dose administration:**
- CPT 79445: Radiopharmaceutical therapy, intra-arterial particulate admin **(1 doctor model (IR/AU)**
- CPT 77778: Interstitial radiation source: complex (**2 doctor model (IR with AU)**

Background from Borggreve 2016

Nontarget embolization might subsequently result in complications, including gastrointestinal ulceration (0.7–28.6 %) and cholecystitis (0.6–6.0 %). Non-target embolization can be prevented through prophylactic embolization of hepaticoenteric arteries during a pretreatment angiography after which technetium-99m-labeled macroaggregated albumin (99mTc-MAA) can be injected as an additional screening procedure.

Experienced centers increasingly omit the occlusion of the vessels originating proximal to the microsphere injection site. Several studies have shown that collateralization and recanalization of arteries can occur after occlusion of hepaticoenteric arteries, opposing the initial purpose of this procedure and bringing its benefit into question.

Current Prioritized List Status

Line: 315

Condition: CANCER OF LIVER (See Guideline Notes 7,11,12,64,65,78,185)

Treatment: MEDICAL AND SURGICAL TREATMENT, WHICH INCLUDES CHEMOTHERAPY AND RADIATION THERAPY

ICD-10: C22.0-C22.9,C49.A9,C78.7,D37.6,D61.810,G89.3,Z51.0,Z51.11-Z51.12, Z85.05

CPT: 32553,36260-36262,37243,37617,43260-43265,43274-43277,47120-47130, 47370,47371,47380-47382,47533-47540,47542,47562,47600-47620,47711, 47712,48150,49411,77014,77261-77295,77300-77370,77385-77387,77402-77417,77424-77432,77469,77470,79005-79403,79445,93792,93793,96150-96155,96377,96405,96406,96420-96450,96542,96549,98966-98969,99051, 99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99449,99451,99452,99468-99480,99487-99491,99495-99498,99605-99607

HCPCS: C2616,C9725,G0068,G0070,G0071,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427,G0463-G0467,G0490,G0508-G0511,G0513,G0514, G2010-G6017,S2095,S9537

Code	Code Description	Current Prioritized List Status
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, **other than hemorrhage or tumor** (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)	305 DISORDERS OF ARTERIES, OTHER THAN CAROTID OR CORONARY 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION 547 SUBLINGUAL, SCROTAL, AND PELVIC VARICES 627 BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; **for tumors, organ ischemia, or infarction**	315 CANCER OF LIVER 403 UTERINE LEIOMYOMA AND POLYPS
75726	Angiography, visceral, selective or supraselective (with or without flush aortogram), radiological supervision and interpretation	Diagnostic Procedures File
78205	Liver imaging (SPECT)	Diagnostic Procedures File

GUIDELINE NOTE 185, YTTRIUM 90 THERAPY

Line 315

Yttrium 90 therapy is only included on this line for treatment of hepatocellular carcinoma (HCC) and only when recommended by a multidisciplinary tumor board or team in the following circumstances:

A) Downsizing tumors in patients who could become eligible for curative treatment (transplant, ablation, or resection), OR
B) Palliative treatment of incurable patients with unresectable or inoperable tumors that are not amenable to ablation therapy and
    1) who have good liver function (Child-Pugh class A or B) and
    2) good performance status (ECOG performance status 0-2), and
    3) who have intermediate stage disease with tumors > 5 cm OR advanced stage HCC with unilateral (not main) portal vein tumor thrombus.

Evidence

Borggreve, 2016
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4821864/pdf/270_2016_Article_1310.pdf

- Systematic review of prophylactic embolization
- Authors with conflicts of interest
- 8 studies, 1237 patients, 456 received embolization of one or more arteries.
- No difference was seen in the incidence of gastrointestinal complications in patients with prophylactic embolization of the gastroduodenal artery (GDA), right gastric artery (RGA), cystic artery (CA) or hepatic falciform artery (HFA) compared to patients without embolization. The risk differences between patients in the embolized group and patients in the non-embolized group varied from 0 to 12%. None of the included studies showed evidence in favor of routine performance of prophylactic embolization.
- Few complications were reported when microspheres were injected distal to the origin of these arteries or when reversed flow of the GDA was present.
- A high risk of confounding by indication was present because of the nonrandomized nature of the included studies.
- Conclusion: It is advisable to restrict embolization to those hepaticoenteric arteries that originate distally or close to the injection site of microspheres. There is no conclusive evidence that embolization of hepaticoenteric arteries influences the risk of complications.
- Recommendation: According to the best available evidence, refraining from embolization of the GDA, RGA and CA is justified when the catheter tip can be placed distal to the origin of these arteries or when reversed flow is present in the GDA. The hepatic falciform artery can be embolized if a large uptake in the abdominal wall is seen.

Ward, 2017
https://www.jvir.org/article/S1051-0443(16)30519-X/fulltext

- Consecutive case series of 62 patients undergoing 69 treatments
- Planning angiography was performed and embolization most commonly performed of the right gastric and supradudoenal arteries. Only 2 patients received gastroduodenal artery prophylactic embolization.

Table 2. Procedural Details of Planning Angiography

Vessel Embolized	Mean or Percent	SD or Count
Right gastric artery	68%	42
Supraduodenal artery	10%	6
Left gastric artery	5%	3
Gastroduodenal artery	3%*	2*
Number of vessels embolized		
0	32%	20
1	54%	34
2	10%	6
3	2%	1
4	2%	1

*1 patient underwent gastroduodenal artery embolization at time of administration.

- Conclusions: Radioembolization without prophylactic embolization of the gastroduodenal artery can be performed safely

Other payers
Aetna, 2018 http://www.aetna.com/cpb/medical/data/200_299/0268.html

1. Intra-Hepatic Microspheres

Aetna considers intra-hepatic microspheres (e.g., TheraSphere, MDS Nordion Inc.; SIR-Spheres, Sirtex Medical Inc.) medically necessary for any of the following:

1. For treatment of neuroendocrine cancers (i.e., carcinoid tumors and pancreatic endocrine tumors) involving the liver. For carcinoid tumors, intra-hepatic microspheres are considered medically necessary only in persons who have failed systemic therapy with octreotide to control carcinoid syndrome (e.g., debilitating flushing, wheezing and diarrhea); *or*
2. For unresectable, primary HCC; *or*
3. For unresectable liver tumors from primary colorectal cancer; *or*
4. For unresectable and chemo-refractory intra-hepatic cholangiocarcinoma if member exhibits liver metastases only and has an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or better with adequate liver function (serum total bilirubin of less than 2 mg/dL); *or*
5. Pre-operative use as a bridge to orthotopic liver transplantation for HCC.

Aetna considers intra-hepatic microspheres experimental and investigational for metastases from esophageal cancer and gallbladder cancer and other indications because of insufficient evidence in the peer-reviewed literature.

Selective Internal Radiation Therapy (SIRT), also known as radioembolization, is a procedure in which tiny radiation filled beads, called microspheres, are delivered directly to the tumor. The microspheres are delivered through a catheter placed in the femoral artery and threaded through the hepatic artery to the tumor site. The microspheres contain yttrium-90. Examples of this type of treatment include: SIR-Spheres, which are resin spheres that are indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer; and Theraspheres, which are spheres made of glass, and are indicated for primary unresectable hepatocellular carcinoma (HCC).

Dancey et al (2000) indicated that the following criteria be used to select appropriate patients for administration of intra-hepatic microspheres as an adjuvant to chemotherapy, surgery or transplantation for persons with unresectable HCC. These criteria are based on the selection criteria for clinical studies of the TheraSphere submitted for FDA approval, and contraindications to use of TheraSphere in the FDA-approved product labeling. These criteria may also be applied to persons with metastatic liver tumors from primary CRC (see discussion of SIR-Spheres below):

1. Histologically confirmed non-resectable lesion confined to the liver and at least 1 measurable lesion; *and*

    - Absolute granulocyte count greater than or equal to 2.0 x 10 9/L
    - Aspartate aminotransferase (AST), alanine aminotransferase (ALT), and alkaline phosphatase (ALP) less than 5 x upper normal limit [AST = 5 to 40 IU/L, ALT = 5 to 35 IU/L, ALP = 42 to 128 U/L]
    - Bilirubin less than 1.5 x upper normal limit [total bilirubin = 0.1 to 1.0 mg/dL or 5.1 to 17.0 mmol/L]
    - Estimated life expectancy greater than or equal to 12 weeks
    - Normal pulmonary function defined as within 30 % of the expected values for each parameter (e.g., forced vital capacity, forced expiratory volume in 1 second, maximal mid-expiratory flow, maximal voluntary ventilation, and arterial blood gases);
    - Platelet count greater than or equal to 100 x 109/L
    - Prothrombin time (PT) and activated partial prothrombin time (APTT) within normal limits [PT = 11.0 to 12.5 seconds; APTT = 30 to 40 seconds]; *and*
    - Eastern Cooperative Oncology Group (ECOG) performance status score less than or equal to 3

2. Adequate bone marrow and hepatic function; *and*

3. No contraindications to hepatic artery catheterization (e.g., vascular abnormalities, bleeding diathesis, allergy to contrast dye, or portal vein thrombosis); *and*
4. No other concurrently planned oncotherapy; *and*
5. At least 1 month post other chemotherapy or surgery.

The following exclusion criteria apply:

1. Previous chemotherapy or radiation therapy for hepatoma; *or*
2. Potential absorbed dose to lungs greater than 30 Gy; *or*
3. Any uncorrectable angiographic flow to the gastrointestinal tract; *or*
4. Co-morbid disease that would preclude safe delivery of intra-hepatic microspheres treatment and place the member at undue risk.

Diagnostic work-up prior to the use of intra-hepatic microspheres includes:

1. Hepatic angiogram which entails placement of intra-hepatic catheter to assess vasculature and TheraSphere delivery route, and
2. Technetium-99 macroaggregated albumin (Tc-99 MAA) study to evaluate hepatic flow to gastrointestinal tract and/or pulmonary shunting.

These studies are medically necessary and thus are eligible for coverage.

In the United States, SIR-Spheres are indicated for the treatment of unresectable metastatic liver tumors from primary CRC with adjuvant intra-hepatic artery chemotherapy (IHAC) of FUDR (floxuridine). The Food and Drug Administration (FDA) approval of SIR-Spheres was based on the results of a RCT involving 70 persons with CRC metastatic to the liver, 34 of whom received FUDR chemotherapy (control group), and 36 of whom received FUDR plus SIR-Spheres. Two of the patients receiving FUDR plus SIR-Spheres had a CR, and 16 had a partial response (PR). By comparison, 1 patient receiving FUDR alone achieved a CR and 7 had a PR. There is a statistically significant delay of time to progression of the disease in the group treated with FUDR plus SIR-Spheres, when compared with the group treated with FUDR only.

The FDA-approved product labeling for SIR-Spheres states that treatment with SIR-Spheres may be indicated when the metastatic CRC in the liver is considered unresectable. According to the FDA-approved labeling, metastatic CRC may be considered non-resectable in any of the following circumstances:

1. Multiple liver metastases together with involvement of both lobes; *or*
2. Tumor invasion of the hepatic confluence where the 3 hepatic veins enter the inferior vena cava (IVC) such that none of the hepatic veins could be preserved if the metastases were resected; *or*

3. Tumor invasion of the porta hepatis such that neither origin of the right or left portal veins could be preserved if resection were undertaken; *or*
4. Widespread metastases such that resection would require removal of more liver than is necessary to maintain life.

The FDA-approved product labeling for SIR-Sphere's states that resectability may be evaluated via imaging with a triple phase contrast angio-portal CT scan or magnetic resonance imaging (MRI).

The FDA-approved labeling for SIR-Sphere states that the following tests are recommended before treatment.

1. A hepatic angiogram should be performed to establish arterial anatomy of the liver.
2. A nuclear medicine break-through scan (intra-hepatic technetium MAA Scan) to determine the percent lung shunting. If a port has been inserted, this test can be performed through the port.
3. Serologic tests of liver function should be performed to determine the extent of liver function/damage.

The FDA-approved product labeling for SIR-Spheres states that appropriate imaging studies are recommended to determine the extent of disease. These may include chest x-ray, CT scan of chest and abdomen, abdominal ultrasound and a bone scan.

The product labeling states that SIR-Spheres are contraindicated in patients who have:

- Ascites or are in clinical liver failure, *or*
- Been treated with capecitabine within the 2 previous months, or who will be treated with capecitabine at any time following treatment with SIR-Spheres, *or*
- Disseminated extra-hepatic malignant disease, *or*
- Greater than 20 % lung shunting of the hepatic artery blood flow determined by technetium MAA scan, *or*
- Had previous external beam radiation therapy to the liver, *or*
- Markedly abnormal synthetic and excretory liver function tests (LTFs), *or*
- Portal vein thrombosis; *or*
- Pre-assessment angiogram that demonstrates abnormal vascular anatomy that would result in significant reflux of hepatic arterial blood to the stomach, pancreas or bowel.

The manufacturer of SIR-Spheres recommends a SPECT scan of the upper abdomen be performed immediately after implantation of SIR-Spheres to confirm placement of the microspheres in the liver.

Both 37242 and 37243 are covered.

National Institute for Clinical Excellence, 2013. Excerpt from
https://www.nice.org.uk/guidance/ipg460/chapter/2-The-procedure

2.2 Outline of the procedure

2.2.1 Selective internal radiation therapy (SIRT) for primary hepatocellular carcinoma involves infusion of microspheres loaded with yttrium-90, which aims to deliver radiation directly into the tumour, minimising the risk of radiation damage to healthy surrounding tissues.

2.2.2 Before undertaking the treatment, a nuclear medicine liver-to-lung shunt study is carried out to assess the risk of radioactive microspheres causing lung damage. Radiographic imaging and selective coil embolisation of arteries to the stomach and duodenum are also commonly carried out.

United Health Care, 2019
https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/implantable-beta-emitting-microspheres-treatment-malignant-tumors.pdf

Transarterial radioembolization (TARE) using yttrium-90 (90Y) microspheres is proven and medically necessary for the following indications:

- Unresectable metastatic liver tumors from primary colorectal cancer (CRC)
- Unresectable metastatic liver tumors from neuroendocrine tumors
- Unresectable primary hepatocellular carcinoma (HCC)
- Unresectable intrahepatic cholangiocarcinoma

Transarterial radioembolization (TARE) using yttrium-90 (90Y) microspheres is unproven and not medically necessary for all other indications due to insufficient evidence of efficacy.

There is no menton of CPT code 37242.

CPT Code	Description
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
79445	Radiopharmaceutical therapy, by intra-arterial particulate administration

CPT® is a registered trademark of the American Medical Association

HCPCS Code	Description
S2095	Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres

Professional Society Guidelines
https://www.acr.org/-/media/ACR/Files/Practice-Parameters/RMBD.pdf
Consensus Practice Parameter, 2019 - American College of Radiology (ACR), the American Brachytherapy Society (ABS), the American College of Nuclear Medicine (ACNM), the American Society for Radiation Oncology (ASTRO), the Society of Interventional Radiology (SIR), and the Society of Nuclear Medicine and Molecular Imaging (SNMMI)

II. INDICATIONS AND CONTRAINDICATIONS

A. Indications for both agents include, but are not limited to, the following:

1. The presence of unresectable or inoperable primary or secondary liver malignancies (particularly CRC and NET metastases). The tumor burden should be liver dominant, not necessarily exclusive to the liver. Patients should also have a performance status that will allow them to benefit from such therapy.
2. A life expectancy of at least 3 months

B. Absolute contraindications include the following:

1. Inability to catheterize the hepatic artery
2. Fulminant liver failure
3. Initial mapping angiography and/or technetium-99m macroaggregated albumin (MAA) hepatic arterial perfusion scintigraphy demonstrating nontarget deposition to the gastrointestinal organs that cannot be corrected by angiographic techniques.
4. Pretreatment hepatic arterial administration with technetium-99m MAA demonstrative of unfavorable (or unacceptable) shunt fraction between the liver and the pulmonary parenchyma. This shunt fraction must not be greater than acceptable limits specific to each brachytherapy device.
5. Active hepatic infection
6. Therapy during pregnancy may possibly be an option in extraordinary circumstances and with multidisciplinary consult and considerations.

Article on costs
Steele, 2016 https://ascopubs.org/doi/pdfdirect/10.1200/JOP.2014.001523
Article on costs discussing different methods of intervention (balloon versus coil). Argues that pretreatment diagnostic visit is still necessary but balloon occlusion technique would be less expensive than coil embolization.

Gabr, 2019
https://www.techvir.com/article/S1089-2516(19)30016-2/fulltext

- Institutional description of same day preplanning and Y90 administration
- Possible model for decreased costs

HERC Staff Summary

Pre-treatment mapping appears to be commonly performed and may involve prophylactic embolization of vasculature to the bowel to avoid Y90 going to bowel, gallbladder, and abdominal wall. Evidence supporting embolization is limited, however, and emerging evidence suggests less embolization than has been done previously is likely indicated. However, uncorrectable angiographic flow is considered a contraindication to Y90.

HERC Staff Recommendations:

Discuss options

Option 1: Do not add CPT 37242 *Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)* **to Line 315**

Option 2: Add CPT 37242 to line 315 CANCER OF LIVER.

Cardiovasc Intervent Radiol (2016) 39:696–704
DOI 10.1007/s00270-016-1310-9

Radioembolization: Is Prophylactic Embolization of Hepaticoenteric Arteries Necessary? A Systematic Review

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Received: 23 October 2015 / Accepted: 6 February 2016 / Published online: 2 March 2016

Abstract
Purpose To study the effectiveness of prophylactic embolization of hepaticoenteric arteries to prevent gastrointestinal complications during radioembolization.
Methods A PubMed, Embase and Cochrane literature search was performed. We included studies assessing both a group of patients with and without embolization.
Results Our search revealed 1401 articles of which title and abstract were screened. Finally, eight studies were included investigating 1237 patients. Of these patients, 456 received embolization of one or more arteries. No difference was seen in the incidence of gastrointestinal complications in patients with prophylactic embolization of the gastroduodenal artery (GDA), right gastric artery (RGA), cystic artery (CA) or hepatic falciform artery (HFA) compared to patients without embolization. Few complications were reported when microspheres were injected distal to the origin of these arteries or when reversed flow of the GDA was present. A high risk of confounding by indication was present because of the non-randomized nature of the included studies.
Conclusion It is advisable to restrict embolization to those hepaticoenteric arteries that originate distally or close to the injection site of microspheres. There is no conclusive evidence that embolization of hepaticoenteric arteries influences the risk of complications.

Keywords Radioembolization · Yttrium · Embolization · Gastroduodenal artery · Right gastric artery · Cystic artery · Hepatic falciform artery · Complications

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Introduction

Radioembolization has gained widespread usage for the management of both primary and secondary, unresectable and chemotherapy refractory liver malignancies. Because healthy liver parenchyma is mostly supplied by the portal vein, hepatic tumors can be selectively targeted by injection of yttrium-90 (^{90}Y) microspheres in the hepatic arteries. Particles of resin or glass, containing millions of the radioactive ^{90}Y microspheres, are injected into the liver via the hepatic artery. These microspheres might disperse to surrounding organs through hepaticoenteric arteries, such as the gastroduodenal artery (GDA), right gastric artery (RGA),

USPSTF Recommendation Update for GN106

Question: How should Guideline Note 106, Preventive services, be updated?

Question source: HERC staff

Issue:

Guideline Note 106 includes coverage of USPSTF A and B recommendations on Line 3 of the Prioritized List through CY 2017. (The delay is per rules under the Affordable Care Act (ACA), to allow new preventive services to be incorporated into rates). There are annual additional updates to USPSTF A and B services that requires an update of the Prioritized List. The recommendations approved in 2018 are required for coverage in 2020 under the ACA; the 2019 recommendations either will require no change to the List or are separately recommended for coverage.

Current Prioritized List Status

Line:	**3**
Condition:	PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS (See Coding Specification Below) (See Guideline Notes 1,17,64,65,106,122,140,179,181)
Treatment:	MEDICAL THERAPY
ICD-10:	R73.03,R78.71,Z00.00-Z00.01,Z00.110-Z00.5,Z00.70-Z00.8,Z01.00-Z01.01,Z01.020-Z01.118, Z01.411-Z01.42,Z08,Z11.1-Z11.4,Z11.51,Z11.7,Z12.11,Z12.2,Z12.31,Z12.4,Z13.1,Z13.220, Z13.31-Z13.39,Z13.41-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,Z86.32,Z87.891,Z91.81
CPT:	0403T,0488T,44392,44394,45333,45338,45384,45385,76706,77067,90378,90460-90472, 90620,90621,90630-90689,90696-90716,90723-90736,90739-90748,90750,90756,92002-92014,92551,93792,93793,96110,96127,96150-96161,98962-98969,99051,99060,99070, 99078,99173,99188,99201-99215,99281-99285,99341-99378,99381-99404,99408-99449, 99451,99452,99487-99491,99495-99498,99605-99607
HCPCS:	D0191,D1206,G0008-G0010,G0068,G0071,G0104,G0105,G0121,G0248-G0250,G0296, G0297,G0396,G0397,G0438-G0445,G0463-G0468,G0490,G0511,G0513,G0514,G2010-G2012,G9873-G9891,H0049,H0050,S0285,S0610-S0613,S9443,T1029
	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:	**619**
Condition:	PREVENTION SERVICES WITH LIMITED OR NO EVIDENCE OF EFFECTIVENESS (See Guideline Notes 64,65,106)
Treatment:	MEDICAL THERAPY
ICD-10:	Q92.61,Q95.0-Q95.1,Q95.9,Z12.12,Z12.39,Z12.5,Z12.81,Z12.83,Z13.6,Z22.0-Z22.2,Z22.31, Z22.321-Z22.322,Z22.338-Z22.6,Z22.8-Z22.9,Z71.3,Z71.42,Z71.52,Z71.82,Z79.810
CPT:	58940,76706,90749,93792,93793,96110,98966-98969,99051,99060,99070,99078,99201-99215,99281-99285,99341-99378,99381-99404,99408-99449,99451,99452,99487-99491, 99495-99498,99605-99607
HCPCS:	G0068,G0071,G0117,G0118,G0248-G0250,G0396,G0397,G0446,G0451,G0463-G0467, G0490,G0511,G2010-G2012

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Lines 3,619

Included on Line 3 are the following preventive services:

A) US Preventive Services Task Force (USPSTF) "A" and "B" Recommendations in effect and issued prior to January 1, 2018.
   1) http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/
   2) USPSTF "D" recommendations are not included on this line or any other line of the Prioritized List.

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

C) Health Resources **and Services Administration (HRSA) Women's Preventive Services-Required Health Plan Coverage Guidelines a**s as updated by HRSA on December 20, 2016. Available at https://www.hrsa.gov/womens-guidelines-2016/index.html as of 3/19/2019.

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

Colorectal cancer screening is included on Line 3 for average-risk adults aged 50 to 75, using one of the following screening programs:

A) Colonoscopy every 10 years
B) Flexible sigmoidoscopy every 5 years
C) Fecal immunochemical test (FIT) every year
D) Guaiac-based fecal occult blood test (gFOBT) every year

Colorectal cancer screening for average-risk adults aged 76 to 85 is covered only for those who

A) Are healthy enough to undergo treatment if colorectal cancer is detected, and
B) Do not have comorbid conditions that would significantly limit their life expectancy.

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

USPSTF A and B updates since 2018:

https://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/

Topic	Description	Grade	Date	Prioritized List Changes?
Bacteriuria screening: pregnant women	The USPSTF recommends screening for asymptomatic bacteriuria using urine culture in pregnant persons.	B	September 2019	Diagnostic, no change needed.
BRCA risk assessment and genetic counseling/testing	The USPSTF recommends that primary care clinicians assess women with a personal or family history of breast, ovarian, tubal, or peritoneal cancer or who have an ancestry associated with breast cancer susceptibility 1 and 2 (*BRCA1/2)* gene mutations with an appropriate brief familial risk assessment tool. Women with a positive result on the risk assessment tool should receive genetic counseling and, if indicated after counseling, genetic testing.	B	August 2019	Current guidance: Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81212, 81215-81217) for patients without a personal history of breast, ovarian and other associated cancers should be provided to high-risk patients as defined by the US Preventive Services Task Force or according to the NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast and ovarian. V2.2019 (7/30/18). www.nccn.org. Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81212, 81215-81217)) for women with a personal history of breast, ovarian, or other associated cancers and for men with breast or other associated cancers should be provided according to the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovarian. V2.2019 (7/30/18). www.nccn.org. No change needed.

USPSTF Recommendation Update for GN106

Topic	Description	Grade	Date	Prioritized List Changes?
Breast cancer preventive medications	The USPSTF recommends that clinicians offer to prescribe risk-reducing medications, such as tamoxifen, raloxifene, or aromatase inhibitors, to women who are at increased risk for breast cancer and at low risk for adverse medication effects.	B	September	Outside of HERC purview.
Cervical cancer screening	The USPSTF recommends screening for cervical cancer every 3 years with cervical cytology alone in women aged 21 to 29 years. For women aged 30 to 65 years, the USPSTF recommends screening every 3 years with cervical cytology alone, every 5 years with high-risk human papillomavirus (hrHPV) testing alone, or every 5 years with hrHPV testing in combination with cytology (cotesting).	A	August 2018	**Requires modification of Prioritized List guideline. See recommendation below.**
Falls prevention: older adults	The USPSTF recommends exercise interventions to prevent falls in community-dwelling adults 65 years or older who are at increased risk for falls.	B	April 2018	**Changes proposed in separate issue summary at November 2019 VbBS/HERC meeting.**
Gonorrhea prophylactic medication: newborns	The USPSTF recommends prophylactic ocular topical medication for all newborns to prevent	A	January 2019	Covered. No change needed.

Topic	Description	Grade	Date	Prioritized List Changes?
	gonococcal ophthalmia neonatorum.			
HIV preexposure prophylaxis for the prevention of HIV infection	The USPSTF recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition.	A	June 2019	Z20.6 (contact with and suspected exposure to HIV) is on Line 3. Previously clarified intent is to cover. No change needed.
HIV screening: adolescents and adults ages 15 to 65 years	The USPSTF recommends that clinicians screen for HIV infection in adolescents and adults aged 15 to 65 years. Younger adolescents and older adults who are at increased risk of infection should also be screened.	A	June 2019	Covered diagnostic test. No change needed.
HIV screening: pregnant women	The USPSTF recommends that clinicians screen for HIV infection in all pregnant persons, including those who present in labor or at delivery whose HIV status is unknown.	A	June 2019	Covered diagnostic test. No change needed.
Perinatal depression: counseling and interventions	The USPSTF recommends that clinicians provide or refer pregnant and postpartum persons who are at increased risk of perinatal depression to counseling interventions.	B	February 2019	**See separate issue summary (BHAP reviewed).**

New USPSTF "D" recommendations

Topic	Population	Recommendation	Date	Prioritized List changes?
Screening for asymptomatic bactiuria	Nonpregnant adults	The USPSTF recommends against screening for asymptomatic bacteriuria in nonpregnant adults.	September 2019	None needed. Not coverage issue.
Risk assessment for BRCA gene mutations	Women whose personal or family history or ancestry is not associated with potential harmful BRCA1/2 gene mutations	The USPSTF recommends against routine risk assessment, genetic counseling, or genetic testing for women whose personal or family history or ancestry is not associated with potentially harmful BRCA1/2 gene mutations.	August 2019	Captured in nonprenatal genetic testing guideline. No change needed.
Risk-reducing medications for breast cancer prevention	Women not at increased risk for breast cancer	The USPSTF recommends against the routine use of risk-reducing medications, such as tamoxifen, raloxifene, or aromatase inhibitors, in women who are not at increased risk for breast cancer.	September 2019	Outside of HERC purview.
Screening for ovarian cancer	Asymptomatic women	The USPSTF recommends against screening for ovarian cancer in asymptomatic women. This recommendation applies to asymptomatic women who are not known to have a high-risk hereditary cancer syndrome.	February 2018	Cpt 86304 (CA-125) is currently on the Diagnostic File. Ultrasounds are diagnostic. No change indicated.
Screening for pancreatic cancer	Adults	The USPSTF recommends against screening for pancreatic cancer in asymptomatic adults.	August 2019	No validated screening tools (CT, MRI, endoscopic ultrasound). No change needed.
Screening for cervical cancer	Women older than 65 years	The USPSTF recommends against screening for cervical cancer in women older than 65 years who have	August 2018	**Changes proposed to**

Topic	Population	Recommendation	Date	Prioritized List changes?
		had adequate prior screening and are not otherwise at high risk for cervical cancer.		**Guideline Note 1 below**
	Women younger than 21 years	The USPSTF recommends against screening for cervical cancer in women younger than 21 years.		
	Women who have had a hysterectomy	The USPSTF recommends against screening for cervical cancer in women who have had a hysterectomy with removal of the cervix and do not have a history of a high-grade precancerous lesion (ie, cervical intraepithelial neoplasia [CIN] grade 2 or 3) or cervical cancer.		

HERC Staff Summary

Guideline note 1 on cervical cancer screening needs minor updates to be consistent with hrHPV testing alone and removing reference to a rescinded coverage guidance.

Guideline Note 106 needs the date references the USPSTF recommendations to be updated.

HERC Staff Recommendations:

1) **Modify Guideline Note 106 as follows:**

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Lines 3,622

Included on Line 3 are the following preventive services:

E) US Preventive Services Task Force (USPSTF) "A" and "B" Recommendations in effect and issued prior to January 1, 2019 ~~January 1, 2018~~.
   1) http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/
   2) USPSTF "D" recommendations are not included on this line or any other line of the Prioritized List.

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

G) Health Resources **and Services Administration (HRSA) Women's Preventive Services-Required Health Plan Coverage Guidelines a**s as updated by HRSA on December 20, 2016. Available at https://www.hrsa.gov/womens-guidelines-2016/index.html as of ~~3~~11/~~19~~5/2019.

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

Colorectal cancer screening is included on Line 3 for average-risk adults aged 50 to 75, using one of the following screening programs:

A) Colonoscopy every 10 years
B) Flexible sigmoidoscopy every 5 years
C) Fecal immunochemical test (FIT) every year
D) Guaiac-based fecal occult blood test (gFOBT) every year

Colorectal cancer screening for average-risk adults aged 76 to 85 is covered only for those who

A) Are healthy enough to undergo treatment if colorectal cancer is detected, and
B) Do not have comorbid conditions that would significantly limit their life expectancy.

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

2) Modify Guideline Note 1 as follows:

GUIDELINE NOTE 1, ROUTINE CERVICAL CANCER SCREENING

Line 3

Cervical cancer screening is covered on Line 3 for women:

Age group in years	Type of screening covered	Frequency
<21	None	Never
21-29	Cytology alone Mandatory HPV testing (87620-87621) is not covered for women age 21-29	Every 3 years
30-65	~~Co-testing* or cytology alone~~ High-risk human papillomavirus (hrHPV) testing alone, co-testing (hrHPV and cytology) or cytology alone	Co-testing every 5 years hrHPV testing alone every 5 years Cytology alone every 3 years
>65	None Unless adequate screening* has not been achieved or it is <20 years after regression or appropriate management of a high-grade precancerous lesion	Never

Age group in years	Type of screening covered	Frequency
Women who have had a hysterectomy with removal of cervix for non cervical cancer related reasons (i.e. other than high grade precancerous lesion, CIN 2 or 3, or cervical cancer)	None	Never
Women who have abnormal testing	Per ASCCP** Guideline, until indicated to resume routine screening	Per ASCCP Guideline, until indicated to resume routine screening

~~*Co-testing is defined as simultaneous cytology and mandatory HPV testing.~~

* Adequate screening is defined as 3 consecutive negative cytology results or 2 consecutive negative HPV results within 10 years of the cessation of screening, with the most recent test occurring within 5 years.

** American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology guideline (Saslow 2012)

Women who have received a diagnosis of a high-grade precancerous cervical lesion or cervical cancer, women with in utero exposure to diethylstilbestrol, or women who are immunocompromised (such as those who are HIV positive) are intended to have screening more frequently than delineated in this guideline.

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

Vitamin D

Question: How should coverage of vitamin D testing be clarified on the Prioritized List?

Question source: Oregon Health Leadership Council, OHA Staff

Issue: The Oregon Health Leadership Council http://www.orhealthleadershipcouncil.org/about/ is looking at opportunities to reduce health care waste. One of the identified areas by the Evidence-Based Best Practice Committee is on vitamin D screening. Vitamin D screening is considered broadly overused.

This is the agreed upon OHLC guideline:
25 OH Vitamin D: Screening is medically necessary and covered for patients with the following risk factors for Vitamin D Deficiency:

A. Chronic kidney disease stage III or greater
B. Cirrhosis
C. Hypocalcemia
D. Hypercalcemia
E. Hypercalciuria
F. Hypervitaminosis D
G. Parathyroid disorders
H. Malabsorption states
I. Obstructive jaundice
J. Osteomalacia
K. Osteoporosis if:
    1. T score on DEXA scan <-2/5; **or**
    2. History of fragility fractures; or
    3. FRAX >3% (any fracture) with T-score <-1.5; **or**
    4. Initiating bisphosphonate therapy (vitamin D level should be determined and managed as necessary before bisphosphonate is initiated)
L. Osteosclerosis/petrosis
M. Rickets
N. Vitamin D deficiency on replacement therapy related to a condition listed above; to monitor the efficacy of treatment.

1,25-OH Vitamin D: This is a *more expensive* test, and is only considered medically necessary and covered for patients in the setting of the following conditions:

A. Unexplained hypercalcemia (suspected granulomatous disease or lymphoma)
B. Unexplained hypercalciuria (suspected granulomatous or lymphoma)
C. Suspected genetic childhood rickets
D. Suspected tumor induced osteomalacia
E. Nephrolithiasis or hypercalciuria
F. End stage renal disease

Current Prioritized List Status:

Code	Code Description	Prioritized List Placement	Fee Schedule
82306	Vitamin D; 25 hydroxy, includes fraction(s), if performed	Diagnostic Procedures File	23.02
82652	Vitamin D; 1, 25 dihydroxy, includes fraction(s), if performed	Diagnostic Procedures File	29.95

OHP utilization. Paid CPT only

Procedure Code	Procedure Description	Claim Indicator	Cnt
82306	Vitamin D 25 Hydroxy	CCO	85,253
82306	Vitamin D 25 Hydroxy	FFS	12,212
82652	Vit D 1 25-Dihydroxy	CCO	2,219
82652	Vit D 1 25-Dihydroxy	FFS	199

At OHP fee-for-service rates:
Vitamin D 25 hydroxy expenditures = (85253 +12212)*23.02 = **$2,243,644**
Vitamin D 1,25 dihydroxy expenditures = (2219+199)*29.95 = **$72,419**

Many of the primary diagnoses with which the blood tests are paired appearing to be for screening purposes, for example:

- Encntr for general adult medical exam w/o abnormal findings
- Encntr screen for dis of the bld/bld-form org/immun mechnsm
- Encntr for routine child health exam w/o abnormal findings
- Encounter for general adult medical exam w abnormal findings
- Encounter for screening for lipoid disorders
- Essential (primary) hypertension

Evidence review

USPSTF, 2014 https://www.ncbi.nlm.nih.gov/books/NBK263419/

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for vitamin D deficiency in asymptomatic adults.

"I" recommendation

USPSTF, 2018

Vitamin D, Calcium, or Combined Supplementation for the Primary Prevention of Fractures in Community-Dwelling Adults: Preventive Medication

https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/vitamin-d-calcium-or-combined-supplementation-for-the-primary-prevention-of-fractures-in-adults-preventive-medication

Population	Recommendation	Grade
Men and premenopausal women	The USPSTF concludes that the current evidence is insufficient to assess the balance of the benefits and harms of vitamin D and calcium supplementation, alone or combined, for the primary prevention of fractures in men and premenopausal women.	I
Postmenopausal women	The USPSTF concludes that the current evidence is insufficient to assess the balance of the benefits and harms of daily supplementation with doses greater than 400 IU of vitamin D and greater than 1000 mg of calcium for the primary prevention of fractures in community-dwelling, postmenopausal women.	I
Postmenopausal women	The USPSTF recommends against daily supplementation with 400 IU or less of vitamin D and 1000 mg or less of calcium for the primary prevention of fractures in community-dwelling, postmenopausal women.	D

USPSTF, 2018
https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/falls-prevention-in-older-adults-interventions1

Population	Recommendation	Grade
Adults 65 years or older	The USPSTF recommends against vitamin D supplementation to prevent falls in community-dwelling adults 65 years or older.	D

Recommendations from professional societies

American Society of Clinical Pathology (ASCP), 2013
http://www.choosingwisely.org/clinician-lists/american-society-clinical-pathology-population-based-screening-for-vitamin-d-deficiency/

Don’t perform population based screening for 25-OH-Vitamin D deficiency.

Vitamin D deficiency is common in many populations, particularly in patients at higher latitudes, during winter months and in those with limited sun exposure. Over the counter Vitamin D supplements and increased summer sun exposure are sufficient for most otherwise healthy patients. Laboratory testing is appropriate in higher risk patients

when results will be used to institute more aggressive therapy (e.g., osteoporosis, chronic kidney disease, malabsorption, some infections, obese individuals).

Endocrine Society, 2013
https://www.choosingwisely.org/clinician-lists/endocrine-society-vitamin-d-testing/

Don't routinely measure 1,25-dihydroxyvitamin D unless the patient has hypercalcemia or decreased kidney function.

Holick, 2011, Endocrine Society clinical practice guideline.
https://academic.oup.com/jcem/article/96/7/1911/2833671

1.1 We recommend screening for vitamin D deficiency in individuals at risk for deficiency. We do not recommend population screening for vitamin D deficiency in individuals who are not at risk (1|⊕⊕⊕⊕).

1.2 We recommend using the serum circulating 25-hydroxyvitamin D [25(OH)D] level, measured by a reliable assay, to evaluate vitamin D status in patients who are at risk for vitamin D deficiency. Vitamin D deficiency is defined as a 25(OH)D below 20 ng/ml (50 nmol/liter), and vitamin D insufficiency as a 25(OH)D of 21–29 ng/ml (525–725 nmol/liter). We recommend against using the serum 1,25-dihydroxyvitamin D [$1,25(OH)_2D$] assay for this purpose and are in favor of using it only in monitoring certain conditions, such as acquired and inherited disorders of vitamin D and phosphate metabolism (1|⊕⊕⊕⊕).

4.1 We recommend prescribing vitamin D supplementation for fall prevention. We do not recommend prescribing vitamin D supplementation beyond recommended daily needs for the purpose of preventing cardiovascular disease or death or improving quality of life (2|⊕⊕⊕⊕).

Other Payer Policies
CMS LCD, 2018 Revision
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34051&ver=27&Date=&DocID=L34051&bc=iAAAABAAAAAA&
Indications:

Measurement of 25-OH Vitamin D, CPT 82306, level is indicated for patients with:

- chronic kidney disease stage III or greater
- cirrhosis
- hypocalcemia
- hypercalcemia
- hypercalciuria
- hypervitaminosis D

- parathyroid disorders
- malabsorption states
- obstructive jaundice
- osteomalacia
- osteoporosis if

  i. T score on DEXA scan <-2.5 or
  ii. History of fragility fractures or
  iii. FRAX > 3% 10-year probability of hip fracture or 20% 10-year probability of other major osteoporotic fracture or
  iv. FRAX > 3% (any fracture) with T-score <-1.5 or
  v. Initiating bisphosphanate therapy (Vit D level should be determined and managed as necessary *before* bisphosphonate is initiated)

- osteosclerosis/petrosis
- rickets
- vitamin D deficiency on replacement therapy related to a condition listed above; to monitor the efficacy of treatment.

Measurement of 1, 25-OH Vitamin D, CPT 82652, level is indicated for patients with:

- unexplained hypercalcemia (suspected granulomatous disease or lymphoma)
- unexplained hypercalciuria (suspected granulomatous disease or lymphoma)
- suspected genetic childhood rickets
- suspected tumor-induced osteomalacia
- nephrolithiasis or hypercalciuria

Limitations:

Testing may not be used for routine or other screening.

Both assays of vitamin D need not be performed for each of the above conditions. Often, one type is more appropriate for a certain disease state than another. The most common type of vitamin D deficiency is 25-OH vitamin D. A much smaller percentage of 1,25-dihydroxy vitamin D deficiency exists; mostly, in those with renal disease. Although it is not the active form of the hormone, 25-OH vitamin D is much more commonly measured because it better reflects the sum total of vitamin D produced endogenously and absorbed from the diet than does the level of the active hormone 1, 25 -dihydroxy vitamin D. Deficiency of 1,25-dihydroxy vitamin D, which is present at much lower concentrations, does not necessarily reflect deficiency of 25-OH vitamin D and its measurement should be limited to the indications listed. Documentation must justify the test(s) chosen for a particular disease entity. Various component sources of 25-OH vitamin D, such as stored D or diet-derived D, should not be billed separately.

Once a beneficiary has been shown to be vitamin D deficient, further testing may be

medically necessary only to ensure adequate replacement has been accomplished. If Vitamin D level is between 20 and 50 ng/dl and patient is clinically stable, repeat testing is often unnecessary; if performed, documentation most clearly indicate the necessity of the test. If level <20 ng/dl or > 60 ng/dl, a subsequent level(s) may be reimbursed until the level is within the normal range.

HERC Staff Summary

USPSTF has found insufficient evidence for vitamin D screening, and has recommended against vitamin D supplementation for fall prevention and for fracture prevention. The Oregon Health Leadership Council is working on a coordinated effort to improve appropriate utilization of vitamin D testing in Oregon across payers. There appears to be significant use of vitamin D testing in the OHP population, with a proportion of it for screening purposes which is not supported by the evidence.

HERC Staff Recommendations:

1) Advise HSD to remove 82306 *Vitamin D; 25 hydroxy* and **82652** *Vitamin D; 1, 25 dihydroxy***, from the Diagnostic File**

2) Add 82306 to the following lines:

- 24 ENDOCRINE AND METABOLIC DISTURBANCES SPECIFIC TO THE FETUS AND NEWBORN
- 55 COMPLICATED STONES OF THE GALLBLADDER AND BILE DUCTS; CHOLECYSTITIS
- 102 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
- 117 NUTRITIONAL DEFICIENCIES
- 151 DISORDERS OF MINERAL METABOLISM, OTHER THAN CALCIUM
- 195 ACUTE PANCREATITIS
- 224 DISORDERS OF PARATHYROID GLAND; BENIGN NEOPLASM OF PARATHYROID GLAND; DISORDERS OF CALCIUM METABOLISM
- 227 INTESTINAL MALABSORPTION
- 239 SHORT BOWEL SYNDROME - AGE 5 OR UNDER
- 248 METABOLIC BONE DISEASE
- 250 CHRONIC PANCREATITIS
- 259 CANCER OF ENDOCRINE SYSTEM, EXCLUDING THYROID; CARCINOID SYNDROME
- 288 OSTEOPETROSIS
- 293 ANOMALIES OF GALLBLADDER, BILE DUCTS, AND LIVER
- 307 CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR MALFORMATIONS; CAROLI'S DISEASE
- 334 ALCOHOLIC FATTY LIVER OR ALCOHOLIC HEPATITIS, CIRRHOSIS OF LIVER
- 339 CHRONIC KIDNEY DISEASE

- 352 URINARY SYSTEM CALCULUS

3) Add 82652 *Vitamin D; 1, 25 dihydroxy* to the following lines

- 224 DISORDERS OF PARATHYROID GLAND; BENIGN NEOPLASM OF PARATHYROID GLAND; DISORDERS OF CALCIUM METABOLISM
- 151 DISORDERS OF MINERAL METABOLISM, OTHER THAN CALCIUM
- 248 METABOLIC BONE DISEASE
- 352 URINARY SYSTEM CALCULUS

3) **Add R82.994** Hypercalciuria (currently in the Diagnostic Workup File) to Lines 224 and 352

Frequency Specific Microcurrent Therapy and Other TENS-like Therapies

Question: Should frequency specific microcurrent therapy, or similar types of therapy such as electro therapeutic point stimulation, microcurrent therapy, or microcurrent electrical nerve stimulation, be covered on the Prioritized List?

Question source: Primary Health CCO

Issue: Electrical stimulation therapy, such as TENS units, are included on line 662/GN173 which an entry that specifically mentions TENS therapy. Similar types of therapy, specifically frequency specific microcurrent therapy, have been requested for coverage. It appears that all of these types of therapy use the same CPT code, 97014 (Application of a modality to 1 or more areas; electrical stimulation (unattended)). Primary Health CCO is requesting clarification of the HERC coverage intent for these non-TENS electrical stimulation therapy.

Evidence review:
Medline was searched for microcurrent therapy, microcurrent, and frequency specific microcurrent therapy. The literature mostly consisted of case studies and small pilot studies of various types of microcurrent therapy on various soft tissue pain or dysfunction conditions.

1) **Page 2016**, Cochrane review of electrotherapy modalities for rotator cuff disease
    a. In single, small trials, no clinically important benefits of pulsed electromagnetic field therapy (PEMF), microcurrent electrical stimulation (MENS), acetic acid iontophoresis and microwave diathermy were observed (low or very low quality evidence).
    b. **Authors' conclusions:** We are uncertain whether TENS is superior to placebo, and whether any electrotherapy modality provides benefits over other active interventions (e.g. glucocorticoid injection) because of the very low quality of the evidence.
2) **Kwon 2014,** RCT of microcurrent therapy for infants with congenital muscular torticollis
    a. N=20 (10 ultrasound, 10 microcurrent therapy)
        i. All received standard PT
    b. The mean passive cervical rotational range of motion measured at three months posttreatment was significantly greater in the microtherapy group (101.1°) than that in the ultrasound group (86.4°) The mean duration of treatment was significantly shorter in the microcurrent group (2.6 months) than in the ultrasound group (6.3 months).
    c. **Conclusions:** Microcurrent therapy may increase the efficacy of therapeutic exercise with ultrasound for the treatment of congenital muscular torticollis involving the entire sternocleidomastoid muscle.

HERC staff recommendation:

1) Modify the GN173 entry for CPT 97014 (Application of a modality to 1 or more areas; electrical stimulation (unattended)) to reflect additional electrical stimulation types of therapies other than TENS
    a. No proven efficacy of any of these modalities

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

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
97014, 97032, 0278T, E0720, E0730, G0283	Transcutaneous electrical nerve stimulation (TENS), frequency specific microcurrent therapy, microcurrent electrical stimulation, and all similar therapies; 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	November 2019

Cochrane Library

Cochrane Database of Systematic Reviews

Electrotherapy modalities for rotator cuff disease (Review)

Page MJ, Green S, Mrocki MA, Surace SJ, Deitch J, McBain B, Lyttle N, Buchbinder R

Page MJ, Green S, Mrocki MA, Surace SJ, Deitch J, McBain B, Lyttle N, Buchbinder R.
Electrotherapy modalities for rotator cuff disease.
Cochrane Database of Systematic Reviews 2016, Issue 6. Art. No.: CD012225.
DOI: 10.1002/14651858.CD012225.

www.cochranelibrary.com

WILEY

[Intervention Review]

Electrotherapy modalities for rotator cuff disease

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Editorial group: Cochrane Musculoskeletal Group.
Publication status and date: New, published in Issue 6, 2016.
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Citation: Page MJ, Green S, Mrocki MA, Surace SJ, Deitch J, McBain B, Lyttle N, Buchbinder R. Electrotherapy modalities for rotator cuff disease. *Cochrane Database of Systematic Reviews* 2016, Issue 6. Art. No.: CD012225. DOI: 10.1002/14651858.CD012225.

ABSTRACT

Background

Management of rotator cuff disease may include use of electrotherapy modalities (also known as electrophysical agents), which aim to reduce pain and improve function via an increase in energy (electrical, sound, light, or thermal) into the body. Examples include therapeutic ultrasound, low-level laser therapy (LLLT), transcutaneous electrical nerve stimulation (TENS), and pulsed electromagnetic field therapy (PEMF). These modalities are usually delivered as components of a physical therapy intervention. This review is one of a series of reviews that form an update of the Cochrane review, 'Physiotherapy interventions for shoulder pain'.

Objectives

To synthesise available evidence regarding the benefits and harms of electrotherapy modalities for the treatment of people with rotator cuff disease.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL; 2015, Issue 3), Ovid MEDLINE (January 1966 to March 2015), Ovid EMBASE (January 1980 to March 2015), CINAHL Plus (EBSCOhost, January 1937 to March 2015), ClinicalTrials.gov and the WHO ICTRP clinical trials registries up to March 2015, unrestricted by language, and reviewed the reference lists of review articles and retrieved trials, to identify potentially relevant trials.

Selection criteria

We included randomised controlled trials (RCTs) and quasi-randomised trials, including adults with rotator cuff disease (e.g. subacromial impingement syndrome, rotator cuff tendinitis, calcific tendinitis), and comparing any electrotherapy modality with placebo, no intervention, a different electrotherapy modality or any other intervention (e.g. glucocorticoid injection). Trials investigating whether electrotherapy modalities were more effective than placebo or no treatment, or were an effective addition to another physical therapy intervention (e.g. manual therapy or exercise) were the main comparisons of interest. Main outcomes of interest were overall pain, function, pain on motion, patient-reported global assessment of treatment success, quality of life and the number of participants experiencing adverse events.

Data collection and analysis

Two review authors independently selected trials for inclusion, extracted the data, performed a risk of bias assessment and assessed the quality of the body of evidence for the main outcomes using the GRADE approach.

Main results

We included 47 trials (2388 participants). Most trials (n = 43) included participants with rotator cuff disease without calcification (four trials included people with calcific tendinitis). Sixteen (34%) trials investigated the effect of an electrotherapy modality delivered in isolation. Only 23% were rated at low risk of allocation bias, and 49% were rated at low risk of both performance and detection bias (for self-reported outcomes). The trials were heterogeneous in terms of population, intervention and comparator, so none of the data could be combined in a meta-analysis.

In one trial (61 participants; low quality evidence), pulsed therapeutic ultrasound (three to five times a week for six weeks) was compared with placebo (inactive ultrasound therapy) for calcific tendinitis. At six weeks, the mean reduction in overall pain with placebo was -6.3 points on a 52-point scale, and -14.9 points with ultrasound (MD -8.60 points, 95% CI -13.48 to -3.72 points; absolute risk difference 17%, 7% to 26% more). Mean improvement in function with placebo was 3.7 points on a 100-point scale, and 17.8 points with ultrasound (mean difference (MD) 14.10 points, 95% confidence interval (CI) 5.39 to 22.81 points; absolute risk difference 14%, 5% to 23% more). Ninety-one per cent (29/32) of participants reported treatment success with ultrasound compared with 52% (15/29) of participants receiving placebo (risk ratio (RR) 1.75, 95% CI 1.21 to 2.53; absolute risk difference 39%, 18% to 60% more). Mean improvement in quality of life with placebo was 0.40 points on a 10-point scale, and 2.60 points with ultrasound (MD 2.20 points, 95% CI 0.91 points to 3.49 points; absolute risk difference 22%, 9% to 35% more). Between-group differences were not important at nine months. No participant reported adverse events.

Therapeutic ultrasound produced no clinically important additional benefits when combined with other physical therapy interventions (eight clinically heterogeneous trials, low quality evidence). We are uncertain whether there are differences in patient-important outcomes between ultrasound and other active interventions (manual therapy, acupuncture, glucocorticoid injection, glucocorticoid injection plus oral tolmetin sodium, or exercise) because the quality of evidence is very low. Two placebo-controlled trials reported results favouring LLLT up to three weeks (low quality evidence), however combining LLLT with other physical therapy interventions produced few additional benefits (10 clinically heterogeneous trials, low quality evidence). We are uncertain whether transcutaneous electrical nerve stimulation (TENS) is more or less effective than glucocorticoid injection with respect to pain, function, global treatment success and active range of motion because of the very low quality evidence from a single trial. In other single, small trials, no clinically important benefits of pulsed electromagnetic field therapy (PEMF), microcurrent electrical stimulation (MENS), acetic acid iontophoresis and microwave diathermy were observed (low or very low quality evidence).

No adverse events of therapeutic ultrasound, LLLT, TENS or microwave diathermy were reported by any participants. Adverse events were not measured in any trials investigating the effects of PEMF, MENS or acetic acid iontophoresis.

Authors' conclusions

Based on low quality evidence, therapeutic ultrasound may have short-term benefits over placebo in people with calcific tendinitis, and LLLT may have short-term benefits over placebo in people with rotator cuff disease. Further high quality placebo-controlled trials are needed to confirm these results. In contrast, based on low quality evidence, PEMF may not provide clinically relevant benefits over placebo, and therapeutic ultrasound, LLLT and PEMF may not provide additional benefits when combined with other physical therapy interventions. We are uncertain whether TENS is superior to placebo, and whether any electrotherapy modality provides benefits over other active interventions (e.g. glucocorticoid injection) because of the very low quality of the evidence. Practitioners should communicate the uncertainty of these effects and consider other approaches or combinations of treatment. Further trials of electrotherapy modalities for rotator cuff disease should be based upon a strong rationale and consideration of whether or not they would alter the conclusions of this review.

PLAIN LANGUAGE SUMMARY

Electrotherapy modalities for rotator cuff disease

Background

Article

CLINICAL REHABILITATION

Clinical Rehabilitation
2014, Vol. 28(10) 983–991

DOI: 10.1177/0269215513511341
cre.sagepub.com
SAGE

Efficacy of microcurrent therapy in infants with congenital muscular torticollis involving the entire sternocleidomastoid muscle: a randomized placebo-controlled trial

Dong Rak Kwon and Gi Young Park

Abstract

Objective: To compare the effects of a combination of therapeutic exercise and ultrasound with or without additional microcurrent therapy in infants with congenital muscular torticollis involving the entire sternocleidomastoid muscle.

Design: Prospective, randomized, placebo-controlled trial.

Setting: An outpatient rehabilitation clinic in a tertiary university hospital.

Subjects: Infants (n = 20) with congenital muscular torticollis involving the entire sternocleidomastoid muscle.

Interventions: Group 1 comprised 10 infants who received therapeutic exercise with ultrasound alone and Group 2 comprised 10 infants who received the same treatment with microcurrent therapy.

Main measures: Passive cervical rotational range of motion was measured at before treatment and one, two, three, and six months after initial treatment. Thickness, cross-sectional area, and red pixel intensity on colour histograms, which were all assessed before treatment and at three months after initial treatment. Additionally, the duration of treatment was measured.

Results: The mean passive cervical rotational range of motion measured at three months posttreatment was significantly greater in Group 2 (101.1°) than that in Group 1 (86.4°), and the thickness, cross-sectional area, and red pixel intensity of the affected sternocleidomastoid muscle were all less in Group 2 (7.8 mm, 100.3 mm^2, and 126.1, respectively) than those in Group 1 (9.6 mm, 121.5 mm^2, and 140.5, respectively). The mean duration of treatment was significantly shorter in Group 2 (2.6 months) than in Group 1 (6.3 months).

Conclusions: Microcurrent therapy may increase the efficacy of therapeutic exercise with ultrasound for the treatment of congenital muscular torticollis involving the entire sternocleidomastoid muscle.

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Low Level Laser Therapy

Question: Where should low level laser therapy (LLLT) be included on the Prioritized List?

Question source: Primary Health CCO

Issue: low level laser therapy (LLLT) is the application of low-level (low-power) lasers or light-emitting diodes (LEDs) to the surface of the body. It is claimed that application of low-power lasers relieves pain or stimulates and enhances cell function. LLLT is used for a variety of applications, including low back pain, rheumatoid arthritis, neck pain, various tendinopathies, and other chronic pain conditions.

Variations of LLLT have gone by a variety of alternate names including low-power laser therapy (LPLT), soft laser therapy, low-intensity laser therapy, low-energy laser therapy, cold laser therapy, bio-stimulation laser therapy, photobiomodulation, photo-biotherapy, therapeutic laser, and monochromatic infrared light energy (MIRE) therapy. When LLLT is administered to acupuncture points, the procedure may be called laser acupuncture. When applied to the head, LLLT may be known as transcranial photobiomodulation, transcranial near-infrared laser therapy (NILT), or transcranial low level light therapy.

Primary Health has been seeing claims for LLLT, generally billed as an office visit (i.e. CPT 99214), but where the entire purpose of the office visit appears to be for the LLLT therapy. An all payer claims search found that the majority of claims submitted with HCPCS S8948 were for musculoskeletal back pain or similar diagnoses.

Current Prioritized List status:
HCPCS S8948 (Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes): never reviewed

CPT 97039 (Unlisted modality (specify type and time if constant attendance)): never reviewed
CPT 97139 (Unlisted therapeutic procedure (specify)): never reviewed
CPT 99199 (Unlisted special service, procedure or report): never reviewed

Evidence

1) **Washington State Bureau of Labor and Industry 2018,** health technology assessment of low level laser therapy for musculoskeletal disorders
    a. There are numerous RCTs conducted and published since last the review in 2004 on LLLT for various indications related to musculoskeletal conditions. Overall, the quality of the evidence for LLLT was low or very low.
    b. Safety data are sparse, especially the long-term data. Some adverse events associated with LLT or sham laser include mild pain, discomfort and tingling sensation during LLLT treatment. LLLT appears to be safe.
    c. The results on efficacy are highly inconsistent. There seems to be a small, statistically significant difference between LLLT and placebo for some indications in the short term, but the clinical meaningfulness is uncertain. Long term data are lacking.
    d. Laser wavelength, energy density, treatment duration, numbers of sessions and site of application are highly variable. Substantial uncertainty remains regarding the treatment

benefit in comparison with other treatment modalities, long-term benefits, safety, and patient selection criteria.

2) **Brosseau 2010**; Cochrane review of low level laser therapy for rheumatoid arthritis
    a. N=5 placebo controlled trials (222 patients with 130 randomized to laser therapy) to the hand
    b. Relative to a separate control group, LLLT reduced pain by 1.10 points (95% CI: 1.82, 0.39) on visual analogue scale relative to placebo, reduced morning stiffness duration by 27.5 minutes (95%CI: 2.9 to 52 minutes) and increased tip to palm flexibility by 1.3 cm (95% CI: 0.8 to 1.7).
    c. Other outcomes such as functional assessment, range of motion and local swelling did not differ between groups. There were no significant differences between subgroups based on LLLT dosage, wavelength, site of application or treatment length.
    d. **Authors' conclusions** LLLT could be considered for short-term treatment for relief of pain and morning stiffness for RA patients, particularly since it has few side-effects. Despite some positive findings, this meta-analysis lacked data on how LLLT effectiveness is affected by four important factors: wavelength, treatment duration of LLLT, dosage and site of application over nerves instead of joints.
3) **Kadhim-Saleh 2013**, systematic review and meta-analysis of low level laser therapy for neck pain
    a. N=8 RCTs (443 patients)
        i. Five trials included patients with cervical myofascial pain syndrome (CMPS), and three trials included different patient populations.
    b. A meta-analysis of five CMPS trials revealed a mean improvement of VAS score of 10.54 with LLLT (95 % CI 0.37–20.71; Heterogeneity I2 = 65 %, P = 0.02).
    c. This systematic review provides inconclusive evidence because of significant between-study heterogeneity and potential risk of bias. The benefit seen in the use of LLLT, although statistically significant, does not constitute the threshold of minimally important clinical difference.
4) **Bjordal 2008**, systematic review of low level laser therapy for tennis elbow
    a. N=13 RCTs (730 patients)
    b. The weighted mean difference (WMD) for pain relief was 10.2 mm [95% CI: 3.0 to 17.5] and the RR for global improvement was 1.36 [1.16 to 1.60]. Trials which targeted acupuncture points reported negative results, as did trials with wavelengths 820, 830 and 1064 nm. In a subgroup of five trials with 904 nm lasers and one trial with 632 nm wavelength where the lateral elbow tendon insertions were directly irradiated, WMD for pain relief was 17.2 mm [95% CI: 8.5 to 25.9] and 14.0 mm [95% CI: 7.4 to 20.6] respectively, while RR for global pain improvement was only reported for 904 nm at 1.53 [95% CI: 1.28 to 1.83]. Secondary outcome measures of pain free grip strength, pain pressure threshold, sick leave and follow-up data from 3 to 8 weeks after the end of treatment, showed consistently significant results in favor of the same LLLT subgroup ($p < 0.02$).
    c. No serious side-effects were reported.
    d. **Conclusion:** LLLT administered with optimal doses of 904 nm and possibly 632 nm wavelengths directly to the lateral elbow tendon insertions, seem to offer short-term pain relief and less disability in LET, both alone and in conjunction with an exercise regimen. This finding contradicts the conclusions of previous reviews which failed to assess treatment procedures, wavelengths and optimal doses.

Other payer policies:
Aetna, Cigna and Wellmark BCBS all consider low level laser therapy to be experimental for all indications.

HERC staff summary
Low level laser therapy as low to very low evidence of efficacy, and most studies do not show clinically significant benefit. No other payer is currently reimbursing for low level laser therapy.

HERC staff recommendations:

1) Add HCPCS S8948 (Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes) to line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
2) Add the following entry to GN173

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS
Line 662
The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
S8948	Low level laser therapy and all similar therapies	Insufficient evidence of effectiveness	November 2019

January 18, 2018

Technology Assessment Update - Low Level Laser Therapy for Musculoskeletal Disorders

Low level laser therapy (LLLT) is a noninvasive treatment that involves the application of light from a low-intensity laser at a specific wavelength. L&I reviewed the technology for various musculoskeletal (MSK) conditions in 2004 and made a non-coverage decision.

The efficacy and the mechanism(s) of action of LLLT have not been established, although there have been many trials on LLLT conducted and published since the last review. In addition, there is no standardized protocol (e.g., dose, number of treatments, duration of treatment) for performing LLLT in treating MSK conditions. The purpose of this document is to review the new evidence and assess the effectiveness and harm of LLLT for treating MSK conditions. We focused on randomized controlled trials (RCTs) by reviewing relevant systematic reviews and meta-analyses. Six systematic reviews were found and reviewed.

A. Evidence reviewed

We searched Cochrane Database of Systematic Reviews and found three relevant systematic reviews on LLLT for MSK disorders. One of them (Brosseau et al. 2007) was withdrawn due to incompleteness in evidence collection and errors in data extraction. We reviewed the other two (Rankin et al. 2017; Yousefi-Nooraie et al. 2008) in detail.

We searched Hayes' database and assessed three systematic reviews on LLLT for MSK disorders, including carpal tunnel syndrome (Hayes, Inc. 2016, updated 2017), joint pain (Hayes, Inc. 2008, update 2012) and soft tissue pain (Hayes, Inc. 2008, updated 2012).

A recent systematic review on LLLT for pain in patients with MSK disorders (Clijsen et al. 2017) found in PubMed was also reviewed.

B. Quality assessment of the systematic reviews

The quality (Good, Fair or Poor) of the systematic reviews was assessed using the quality assessment tool developed by the NIH National Heart, Lung and Blood Institute. All the systematic reviews assessed have either good or fair quality.

C. Summary of the evidence

1. LLLT on pain in patients with MSK disorders or soft tissue pain

1.1. (Clijsen et al. 2017) – Good quality

The meta-analysis includes 18 RCTs comparing the effect of LLLT on pain in patients with different MSK disorders. From the 21 head-to-head comparisons, 17 favored LLLT while four comparisons (extracted from three studies) reported no beneficial effects of LLLT on pain. The overall weighted raw mean difference (*D*) in pain between LLLT and the control groups was -0.85 [95% CI: -1.22 to -0.48] (P<0.001). Heterogeneity of the studies was high (I^2= 85.6%) and statistically significant (Cochran's *Q*=139.2; df=20; P<0.001).

The authors concluded that "LLLT appears to be an effective treatment modality to achieve pain relief in adult patients with MSK disorders". Though this is a meta-analysis of good quality, there are several limitations with the results. 1). the heterogeneity of the studies included was quite high (I^2 = 85.6%); 2). The overall weighted raw mean difference in pain was difficult to interpret, because it was derived from 18 studies with 7 different comparators for 13 different pain conditions; 3). The overall weighted raw mean difference was small and may not be meaningful clinically.

1.2. (Hayes, Inc. 2008, Updated in 2012) – Fair quality

Evidence evaluated in this report covers the years 2005 to February 2008, and was updated in 2012. The previous version of this report covered literature published between 1980 and July 2005. Only randomized placebo-controlled trials and meta-analyses of randomized placebo-controlled trials were considered for inclusion. Eighteen trials of LLLT for different indications were selected for detailed analysis, including: Achilles tendinopathy (2 trials); ankle sprain (1 trial); carpal tunnel syndrome (3 trials); lateral epicondylitis (5 trials); low back pain (2 trials); and neck and/or shoulder girdle pain (5 trials).

Authors' conclusion: the available RCTs of LLLT reported a mix of negative (no effect) and positive results for a variety of soft tissue pain conditions, which can be summarized by indication as follows: (1) Achilles tendinopathy, very positive in younger, athletic patients but otherwise negative; (2) ankle sprain, negative; (3) carpal tunnel syndrome, conflicting but on balance negative; (4) lateral epicondylitis, conflicting but best study strongly positive; (5) low back pain, small positive effect according to sparse evidence; and (6) neck/shoulder girdle pain, on balance positive with an apparent correspondence between positive results and number of spots treated. The trials addressing each indication had several limitations. Possible combinations of treatment parameters far exceed those tested in the trials that were selected, and data relevant to specific combinations of dose, wavelength, and spot number/size were sparse. LLLT appears to be safe, but no long-term assessment has been made. The authors concluded that low-quality, inconsistent evidence showing potentially improved outcomes for treatment of pain and

disability due to Achilles tendinopathy, lateral epicondylitis, low back pain, and myofascial pain syndrome or similar symptomatology in the neck and shoulder girdle region, but substantial uncertainty remains regarding the extent of treatment benefit in comparison with other treatment modalities, long-term health benefits, safety, and patient selection criteria. There is limited evidence of no benefit or no benefit beyond end of treatment for treatment of pain and disability due to ankle sprain or carpal tunnel syndrome.

We believe there are several limitations with the conclusions. 1). the quality of RCTs included was not assessed explicitly in the systematic review. The authors seemed to assume the quality of these studies was equally good because they were RCTs; 2). Some conclusions were made based on very limited number of studies. For example, there were two studies reviewed for Achilles tendinopathy, one showed positive results and the other had negative results; 3). No meta-analysis done on multiple studies for specific indications; 4). Short term follow-up for most of the studies; 5). The effect size was small if any, and it is uncertain about clinical significance.

2. LLLT on carpal tunnel syndrome

2.1. (Rankin et al. 2017) – Good quality

The authors identified 22 trials randomizing 1153 participants that were eligible for inclusion; nine trials (525 participants, 256 randomized to LLLT) compared LLLT with placebo, two (150 participants, 75 randomized to LLLT) compared LLLT with ultrasound, one compared LLLT with placebo and LLLT with ultrasound, two compared LLLT with steroid injection, and one trial each compared LLLT with other non-surgical interventions: fascialmanipulation, application of a pulsedmagnetic field, transcutaneous electrical nerve stimulation (TENS), steroid injection, tendon gliding exercises, and applying a wrist splint combined with non-steroidal anti-inflammatory drugs. Three studies compared LLLT as part of multiple interventions. Risk of bias varied across the studies, but was high or unclear in most assessed domains in most studies. Most studies were small, with few events, and effect estimates were generally imprecise and inconsistent; the combination of these factors led the authors to categorize the quality of evidence for most outcomes as very low or low.

The authors concluded that evidence is of very low quality and they found no data to support any clinical effect of LLLT in treating CTS. Only VAS pain and finger-pinch strength met previously published MCIDs but these are likely to be overestimates of effect given the small studies and significant risk of bias. There is low or very low-quality evidence to suggest that LLLT is less effective than ultrasound in the management of CTS based on short-term, clinically significant improvements in pain and finger-pinch strength. There is insufficient evidence to support LLLT being better or worse than any other type of non-surgical treatment in the management of CTS. Any further research of LLLT should be definitive, blinded, and of high quality.

2.2. (Hayes, Inc. 2017) – Fair quality

A total of 11 RCTs met predefined inclusion criteria and answered 1 or more relevant questions. Of the eligible RCTs, 6 evaluated LLLT compared with sham laser for the treatment of mild to moderate carpal tunnel syndrome (CTS) in adults. Six RCTs also evaluated LLLT compared with an active control, including ultrasound, splinting, or steroid injections either alone or in combination with another conservative treatment. All studies evaluated LLLT for the treatment of mild to moderate CTS in adults.

Results were conflicting regarding the efficacy and comparative effectiveness of LLLT compared with sham laser, ultrasound, or splinting for the treatment of mild to moderate CTS. For all outcomes, there were unexplained inconsistencies across studies when comparing LLLT with sham laser. In 3 RCTs comparing LLLT with ultrasound, inconsistencies in comparative effectiveness exist. In general, patients treated with LLLT reported improved clinical symptoms and nerve conduction compared with baseline, as did patients in control groups. Evaluations of safety were limited and were only reported in 2 RCTs. Long term follow-up was not evaluated in any study. The authors concluded that there was low-quality and inconsistent evidence showing potentially improved outcomes among patients with mild to moderate CTS receiving LLLT either alone or in combination with other conservative treatments. Substantial uncertainty remains regarding the extent of treatment benefit in comparison with other treatment modalities, long-term health benefits, safety, and patient selection criteria. The evidence for LLLT for treatment of severe CTS in adults was lacking.

3. LLLT on non-specific lower back pain

3.1. (Yousefi-Nooraie et al. 2008) – Good quality

Seven heterogeneous English language RCTs with reasonable quality were included. Three small studies (168 people) separately showed statistically significant but clinically unimportant pain relief for LLLT versus sham therapy for sub-acute and chronic low-back pain at short-term and intermediate-term follow-up (up to six months). One study (56 people) showed that LLLT was more effective than sham at reducing disability in the short term. Three studies (102 people) reported that LLLT plus exercise were not better than exercise, with or without sham in the short-term in reducing pain or disability. Two studies (90 people) reported that LLLT was not more effective than exercise, with or without sham in reducing pain or disability in the short term. Two small trials (151 people) independently found that the relapse rate in the LLLT group was significantly lower than in the control group at the six-month follow-up.

No side effects were reported.

The authors concluded that based on the heterogeneity of the populations, interventions and comparison groups, there are insufficient data to draw firm conclusions on the clinical effect of LLLT for low-back pain. There is a need for further methodologically rigorous RCTs to evaluate the effects of LLLT compared to other treatments, different lengths of treatment, wavelengths and dosages.

4. LLLT on joint pain

4.1. (Hayes, Inc. 2008, update 2012) - Fair quality

This updated report covers literature published in the years 2005 to February 2008 (the previous version of this report covered literature published between 1980 and July 2005) including eight studies: six original blinded, placebo-controlled, randomized trials and two meta-analyses of such trials. Four of the original trials and one meta-analysis applied LLLT to knee osteoarthritis. Another original trial applied LLLT to hand osteoarthritis. One meta-analysis of trials of LLLT for rheumatoid arthritis was selected. A single trial of LLLT for patellar chondromalacia was selected. Pain assessment for all indications was typically made according to a visual analog scale (VAS). Numerous tools were used for assessment of function or disability.

The authors concluded that evidence derived from several placebo-controlled, randomized trials suggests that LLLT administered above a certain dosage level can accelerate improvement in patients with osteoarthritis of the knee by bringing immediate relief of pain and disability but that the effect is temporary. Evidence from a single placebo-controlled, randomized trial demonstrated no effect from LLLT on pain or disability in patients with osteoarthritis of the hand. Evidence from a single placebo-controlled, randomized trial indicated modest, temporary pain relief from rheumatoid arthritis of the hand and foot. A single, very small trial failed to demonstrate clinically significant improvement of pain and disability associated with chondromalacia. The trials addressing each indication had a number of methodological limitations, including variation in treatment parameters, small sample size, and lack of comparison with other treatment modalities. The authors further concluded that low-quality, inconsistent evidence showing potentially improved outcomes for treatment of pain and disability due to knee osteoarthritis, but substantial uncertainty remains regarding the extent of treatment benefit in comparison with other treatment modalities, long-term health benefits, safety, and patient selection criteria; there is either limited evidence of no benefit or no evidence of LLLT for treatment of pain and disability due to hand osteoarthritis, osteoarthritis in joints other than the knee or hand, rheumatoid arthritis in the hand and foot; and chondromalacia patellae, respectively; there is no evidence for patient-administered LLLT pertaining to the efficacy and safety of LLLT used outside of healthcare settings.

D. CMS and selected private payer coverage policies on LLLT

Table 1. Other Payer's Policy on LLLT

Payer	Policy	Note
CMS	The use of infrared and/or near-infrared light and/or heat, including monochromatic infrared energy, **is non-covered** for the treatment, including the symptoms such as pain arising from these conditions, of diabetic and/or non-diabetic peripheral sensory neuropathy, wounds and/or ulcers of the skin and/or subcutaneous tissues	National Coverage Decision (NCD) for Infrared Therapy Devices (270.6). Effective date: 10/24/2006.
Blue Cross	Investigational	2017 Federal employee program
NICE	No policy or guideline was found on LLLT	
Aetna	Experimental and investigational	2017-2018
Cigna	Experimental, investigational or unproven	2017-2018
Humana	Not covered	2018
Regence	Investigational	2017

E. Conclusions

1. There are numerous RCTs conducted and published since last review in 2004 on LLLT for various indications related to MSK conditions. Overall, the quality of the evidence for LLLT was low or very low.
2. Safety data are sparse, especially the long term data. Some adverse events associated with LLT or sham laser reported include mild pain, discomfort and tingling sensation during LLLT treatment. No reported treatment-related mortality was noticed. LLLT appears to be safe.
3. The results on efficacy are highly inconsistent. There seems to be a small statistically significant difference between LLLT and placebo for some indications in short term, but the clinical meaningfulness is uncertain. Long term data are lacking.
4. Laser wavelength, energy density, treatment duration, numbers of sessions and site of application are highly variable. Substantial uncertainty remains regarding the treatment benefit in comparison with other treatment modalities, long-term benefits, safety, and patient selection criteria.
5. None of the major payers covers LLLT for MSK disorders.

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Low level laser therapy (Classes I, II and III) for treating rheumatoid arthritis (Review)

Brosseau L, Welch V, Wells GA, de Bie R, Gam A, Harman K, Morin M, Shea B, Tugwell P

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http://www.thecochranelibrary.com

WILEY

[Intervention Review]

Low level laser therapy (Classes I, II and III) for treating rheumatoid arthritis

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ABSTRACT

Background

Rheumatoid arthritis (RA) affects a large proportion of the population. Low Level Laser Therapy (LLLT) was introduced as an alternative non-invasive treatment for RA about ten years ago. LLLT is a light source that generates extremely pure light, of a single wavelength. The effect is not thermal, but rather related to photochemical reactions in the cells. The effectiveness of LLLT for rheumatoid arthritis is still controversial. This review is an update of the original review published in October 1998.

Objectives

To assess the effectiveness of LLLT in the treatment of RA.

Search methods

We initially searched MEDLINE, EMBASE (from 1998), the registries of the Cochrane Musculoskeletal Group and the field of Rehabilitation and Related Therapies as well as the Cochrane Central Register of Controlled Trials (CENTRAL) up to June 2001. This search has now been updated to include articles published up to June 2005.

Selection criteria

Following an a priori protocol, only randomized controlled trials of LLLT for the treatment of patients with a clinical diagnosis of RA were eligible. Abstracts were excluded unless further data could be obtained from the authors.

Data collection and analysis

Two reviewers independently selected trials for inclusion, then extracted data and assessed quality using predetermined forms. Heterogeneity was tested using chi-squared. A fixed effects model was used throughout for continuous variables, except where heterogeneity existed, in which case, a random effects model was used. Results were analyzed as weighted mean differences (WMD) with 95% confidence intervals (CI), where the difference between the treated and control groups was weighted by the inverse of the variance. Dichotomous outcomes were analyzed with relative risks.

Main results

A total of 222 patients were included in the five placebo-controlled trials, with 130 randomized to laser therapy. Relative to a separate control group, LLLT reduced pain by 1.10 points (95% CI: 1.82, 0.39) on visual analogue scale relative to placebo, reduced morning stiffness duration by 27.5 minutes (95%CI: 2.9 to 52 minutes) and increased tip to palm flexibility by 1.3 cm (95% CI: 0.8 to 1.7). Other outcomes such as functional assessment, range of motion and local swelling did not differ between groups. There were no significant differences between subgroups based on LLLT dosage, wavelength, site of application or treatment length. For RA, relative to a control group using the opposite hand, there was no difference observed between the control and treatment hand for morning stiffness duration, and also no significant improvement in pain relief RR 13.00 (95% CI: 0.79 to 214.06). However, only one study was included as using the contralateral limb as control. .

Authors' conclusions

LLLT could be considered for short-term treatment for relief of pain and morning stiffness for RA patients, particularly since it has few side-effects. Clinicians and researchers should consistently report the characteristics of the LLLT device and the application techniques used. New trials on LLLT should make use of standardized, validated outcomes. Despite some positive findings, this meta-analysis lacked data on how LLLT effectiveness is affected by four important factors: wavelength, treatment duration of LLLT, dosage and site of application over nerves instead of joints. There is clearly a need to investigate the effects of these factors on LLLT effectiveness for RA in randomized controlled clinical trials.

PLAIN LANGUAGE SUMMARY

Low level laser therapy for rheumatoid arthritis

Does low level laser therapy work for treating rheumatoid arthritis?

Six studies of medium quality were reviewed and provide the best evidence we have today. Collectively, these studies tested over 220 people with rheumatoid arthritis. The studies compared how well people did while receiving either laser therapy or a 'placebo' (fake) laser therapy. Laser therapy was given mostly on the hands and generally for two to three times a week for four weeks. There were also many different wavelengths and dosages given.

What is rheumatoid arthritis and low level laser therapy?

Rheumatoid arthritis (RA) is a disease in which the body's immune system attacks its own healthy tissues. The attack happens mostly in the joints of the hands and feet and causes redness, pain, swelling and heat around the joints. Drug and non-drug treatments are used to relieve pain and/or swelling. Low level laser therapy, is a non-drug treatment used to decrease swelling and pain. Without producing heat, the laser emits very pure light that causes light and chemical reactions in cells where it is targeted.

What did the studies show?

Studies showed that laser therapy decreased pain and morning stiffness more than 'placebo' laser therapy. Laser therapy also increased hand flexibility more than placebo therapy.

Pain decreased by 1.10 points on a scale of 1-10. The length of time for morning stiffness decreased by 28 minutes.

Studies also showed that laser therapy worked just as well as 'placebo' laser therapy to improve range of motion, function, swelling and grip strength.

Only two of the studies measured the effect of laser therapy three months after the end of treatment. The results from these studies indicated that laser therapy worked just as well as 'placebo' therapy after three months times.

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ORIGINAL ARTICLE

Is low-level laser therapy in relieving neck pain effective? Systematic review and meta-analysis

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Abstract The aim of this study is to determine the efficacy of low-level laser therapy (LLLT) in reducing acute and chronic neck pain as measured by the visual analog scale (VAS). A systematic search of nine electronic databases was conducted to identify original articles. For study selection, two reviewers independently assessed titles, abstracts, and full text for eligibility. Methodological quality was assessed using the Detsky scale. Data were analyzed using random-effects model in the presence of heterogeneity and fixed-effect model in its absence. Heterogeneity was assessed using Cochran's Q statistic and quantifying I^2. Risk ratios (RR) with 95 % confidence intervals (CI) were reported. Eight randomized controlled trials involving 443 patients met the strict inclusion criteria. Inter-rater reliability for study selection was 92.8 % (95 % CIs 80.9–100 %) and for methodological quality assessment was 83.9 % (95 % CIs 19.4–96.8 %). Five trials included patients with cervical myofascial pain syndrome (CMPS), and three trials included different patient populations. A meta-analysis of five CMPS trials revealed a mean improvement of VAS score of 10.54 with LLLT (95 % CI 0.37–20.71; Heterogeneity $I^2 = 65$ %, $P = 0.02$). This systematic review provides inconclusive evidence because of significant between-study heterogeneity and potential risk of bias. The benefit seen in the use of LLLT, although statistically significant, does not constitute the threshold of minimally important clinical difference.

Keywords Neck pain · Laser therapy, low-level · Myofascial pain syndrome · Meta-analysis

Abbreviations

CI	Confidence interval
CID	Clinical important difference
CMPS	Cervical myofascial pain syndrome
ICC	Intraclass correlation coefficient
LLLT	Low-level laser therapy
RCT	Randomized controlled trial
RR	Risk ratio
VAS	Visual analog scale

Background

Neck pain is one of the most common pain complaints encountered by primary care providers. There is great variation in the overall prevalence of neck pain between studies, ranging from 0.4 to 86.8 % in the general population, with a mean prevalence of 23.1 % [1]. Several mechanisms can lead to neck pain, including trauma, repetitive and forceful occupational movements, as well as pathological factors, such as inflammatory and neurological conditions [2]. The consequences of neck pain range from minor discomfort to debilitating pain that interferes with daily living activities, work conditions, and sleep [3, 4].

A number of treatment options are available for patients with neck pain, including pharmacological, surgical, behavioral, and alternative therapies [3]. Low-level laser

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Research article

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A systematic review with procedural assessments and meta-analysis of Low Level Laser Therapy in lateral elbow tendinopathy (tennis elbow)

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Abstract

Background: Recent reviews have indicated that low level level laser therapy (LLLT) is ineffective in lateral elbow tendinopathy (LET) without assessing validity of treatment procedures and doses or the influence of prior steroid injections.

Methods: Systematic review with meta-analysis, with primary outcome measures of pain relief and/or global improvement and subgroup analyses of methodological quality, wavelengths and treatment procedures.

Results: 18 randomised placebo-controlled trials (RCTs) were identified with 13 RCTs (730 patients) meeting the criteria for meta-analysis. 12 RCTs satisfied half or more of the methodological criteria. Publication bias was detected by Egger's graphical test, which showed a negative direction of bias. Ten of the trials included patients with poor prognosis caused by failed steroid injections or other treatment failures, or long symptom duration or severe baseline pain. The weighted mean difference (WMD) for pain relief was 10.2 mm [95% CI: 3.0 to 17.5] and the RR for global improvement was 1.36 [1.16 to 1.60]. Trials which targeted acupuncture points reported negative results, as did trials with wavelengths 820, 830 and 1064 nm. In a subgroup of five trials with 904 nm lasers and one trial with 632 nm wavelength where the lateral elbow tendon insertions were directly irradiated, WMD for pain relief was 17.2 mm [95% CI: 8.5 to 25.9] and 14.0 mm [95% CI: 7.4 to 20.6] respectively, while RR for global pain improvement was only reported for 904 nm at 1.53 [95% CI: 1.28 to 1.83]. LLLT doses in this subgroup ranged between 0.5 and 7.2 Joules. Secondary outcome measures of painfree grip strength, pain pressure threshold, sick leave and follow-up data from 3 to 8 weeks after the end of treatment, showed consistently

significant results in favour of the same LLLT subgroup ($p < 0.02$). No serious side-effects were reported.

Conclusion: LLLT administered with optimal doses of 904 nm and possibly 632 nm wavelengths directly to the lateral elbow tendon insertions, seem to offer short-term pain relief and less disability in LET, both alone and in conjunction with an exercise regimen. This finding contradicts the conclusions of previous reviews which failed to assess treatment procedures, wavelengths and optimal doses.

Background

Lateral elbow tendinopathy (LET) or "tennis elbow" is a common disorder with a prevalence of at least 1.7% [1], and occuring most often between the third and sixth decades of life. Physical strain may play a part in the development of LET, as the dominant arm is significantly more often affected than the non-dominant arm. The condition is largely self-limiting, and symptoms seem to resolve between 6 and 24 months in most patients [2].

A number of interventions have been suggested for LET. Steroid injections, non-steroidal anti-inflammatory drugs or a regimen of physiotherapy with various modalities, seem to be the most commonly applied treatments [3]. However, treatment effect sizes seem to be rather small, and recommendations have varied over the years. In several systematic reviews over the last decade [4,5], glucocorticoid steroid injections have been deemed effective, at least in the short-term. But in later well-designed trials evidence is found that intermediate and long-term effects of steroid injections groups yield consistently and significantly poorer outcomes than placebo injection groups, and physiotherapy or wait-and-see groups [6,7]. Nevertheless, steroid injections have been considered as the most thoroughly investigated intervention, with 13 randomized controlled trials comparing steroid injections to either placebo/local anaesthetic or another type of intervention [5]. Non-steroidal anti-inflammatory drugs (NSAIDs) have been found to achieve smaller short-term effect sizes than steroid injections [8], and topical application seems to be the best medication administration route [8] For oral administration of NSAIDs for LET, evidence is inconclusive from two heterogeneous trials only [9]. The positive short-term results of anti-inflammatory therapies in LET appear to partly contradict the recent paradigm in tendinopathy research, where LET is thought to be mainly a degenerative disorder with minimal inflammation [10,11].

Exercise therapy and stretching exercises have been used either alone or in conjunction with manipulation techniques or physical interventions. Although the sparse evidence makes it difficult to assess the separate effect of active exercises or stretching [12], four studies have found that either exercises alone [13], or in conjunction with a physiotherapy package, are more effective than placebo ultrasound therapy or wait-and-see controls. Also exercise therapy, particularly eccentric exercises, have been found effective in the intermediate term in tendinopathies of the Achilles, patellar or shoulder tendons [14-17]. There is some evidence suggesting that joint manipulation or mobilisation techniques either of the wrist, elbow or cervical spine may contribute to short-term effects in LET [18-20].

Among the physical interventions, ultrasound therapy has been considered to offer a small benefit over placebo from two small trials [12], but a well-designed and more recent trial did not find significant effects of ultrasound therapy in LET [21]. Reviewers have arrived at different conclusions for the effect of acupuncture [22,23]. In reviews of physical interventions for LET, conclusions may vary between reviews because of differences in the treatment procedures. A good example of this is the negative conclusion of the LET review for extracorporeal shockwave therapy (ESWT) by Buchbinder et al. [24], where a later review with in-depth assessments of treatment intervention protocols [25], found that a subgroup of trials with proper treatment procedures and adequate timing of outcomes gave a positive result.

Low level laser therapy (LLLT) has been available for nearly three decades, and scattered positive results have been countered by numerous negative trial results. Several systematic reviews have found no significant effects from LLLT, in musculoskeletal disorders in general [26], and in LET in particular [12,23,27]. In this perspective it may seem futile to perform yet another systematic review in this area. But none of these reviews evaluated the results separately for the different LLLT treatment procedures, laser wavelengths or doses involved. Neither did they implement evidence of the newly discovered biomodulatory mechanisms which are involved when LLLT is applied. During the last 5–6 years the annual number of published LLLT reports in Medline has increased from 25 to around 200. We recently made a review of this literature, and concluded that LLLT has an anti-inflammatory effect in 21 out of 24 controlled laboratory trials, and a biostimulatory effect on collagen production in 31 out of 36 trials [28]. Both of these effects were dose-dependent

Fetal Repair of Myelomeningocele

Question: Should fetal repair of myelomeningocele be added to the Prioritized List?

Question source: HSD Hearings Division

Issue: HSD Hearings recently had a case in which a patient with a fetus with myelomeningocele requested fetal repair. The HCPCS code S2404 (Repair, myelomeningocele in the fetus, procedure performed in utero) is not listed on the Prioritized List, and the surgery is not included in Guideline Note 2, Fetoscopic Surgery. Several other HCPCS codes for fetal repair of congenital conditions are included on line 1 PREGNANCY and in GN2.

Myelomeningocele is the most severe form of spina bifida, in which the lower portion of the spine is open and the spinal cord and spinal nerves protrude out of the opening. It is frequently accompanied by hydrocephalus and other intracranial abnormalities. It frequently results in bowel and bladder control loss, and partial or complete lower extremity paralysis. The standard treatment for myelomeningocele is to repair the defect shortly after birth.

The Management Of Myelomeningocele Study (MOMS) study, published in 2011, established fetal repair of myelomeningocele as a viable alternative option for treatment of myelomeningocele. However, this surgery is only offered at a few centers in the US and carries considerable risk for both mom and baby.

GUIDELINE NOTE 2, FETOSCOPIC SURGERY

Line 1

Fetal surgery is only covered for the following conditions: repair of urinary tract obstructions via placement of a urethral shunt, repair of congenital cystic adenomatoid malformation, repair of extralobal pulmonary sequestration, repair of sacrococcygeal teratoma, and therapy for twin-twin transfusion syndrome.

Fetoscopic repair of urinary tract obstruction (S2401) is only covered for placement of a urethral shunt. Fetal surgery for cystic adenomatoid malformation of the lung, extralobal pulmonary sequestration and sacrococcygeal teratoma must show evidence of developing hydrops fetalis.

Certification of laboratory required (76813-76814).

Evidence

1) **Grivell 2014,** Cochrane review of fetal surgery for spina bifida
    a. N=1 trial of 158 women (MOMS trial—see below)
        i. Low risk of bias
    b. For the primary infant outcome of neonatal mortality, there was no clear evidence of a difference identified for prenatal versus postnatal repair (one study, 158 infants, risk ratio (RR) 0.51, 95%confidence interval (CI) 0.05 to 5.54), however event rates were uncommon and so the analysis is likely to be underpowered to detect differences.
    c. Prenatal repair was associated with an earlier gestational age at birth (one study, 158 infants, mean difference (MD) -3.20 weeks, 95% CI -3.93 to -2.47) and a corresponding increase in both the risk of preterm birth before 37 weeks (one study, 158 infants, RR 5.30, 95% CI 3.11 to 9.04) and preterm birth before 34 weeks (one study, 158 infants, RR 9.23, 95% CI 3.45 to 24.71). Prenatal repair was associated with a reduction in shunt dependent hydrocephalus and moderate to severe hindbrain herniation. For women, prenatal repair was associated with increased preterm ruptured membranes (one study, 158 women, RR 6.15, 95% CI 2.75 to 13.78), although there was no clear evidence of difference in the risk of chorioamnionitis or blood transfusion, although again, event rates were uncommon.
    d. A number of this review's secondary infant and maternal outcomes were not reported. For the infant: days of hospital admission; survival to discharge; stillbirth; need for further surgery (e.g. skin grafting); neurogenic bladder dysfunction; childhood/infant quality of life. For the mother: admission to intensive care; women's emotional wellbeing and satisfaction with care.
    e. **Authors' conclusions:** This review is based on one small well-conducted study. There is insufficient evidence to recommend drawing firm conclusions on the benefits or harms of prenatal repair as an intervention for fetuses with spina bifida. Current evidence is limited by the small number of pregnancies that have been included in the single conducted randomized trial to date.

1) **Adzick 2011**, MOMS trial
    a. N=158 patients
        i. trial was stopped for efficacy of prenatal surgery after the recruitment of 183 of a planned 200 patients.
        ii. This paper reports on the 158 patients with a child evaluation of 12 months
        iii. Inclusion criteria: singleton gestation, myelomeningocele with an upper boundary between T1 and S1, evidence of hindbrain herniation of fetal MRI, gestation age between 19 0/7 weeks and 25 6/7 weeks at randomization, normal karyotype
        iv. Exclusion criteria: fetal anomalies unrelated to the myelomeningocele, risk of preterm birth, placental abruption, contraindication to surgery, and a maternal body mass index of 35 or more
    b. There were 2 perinatal deaths in each group
    c. Need for cerebrospinal fluid shunt by 12 months occurred in 68% of the infants in the prenatal-surgery group and in 98% of those in the postnatal surgery group (relative risk, 0.70; 97.7% confidence interval [CI], 0.58 to 0.84; P<0.001). Actual rates of shunt placement were 40% in the prenatal-surgery group and 82% in the postnatal-surgery group (relative risk, 0.48; 97.7% CI, 0.36 to 0.64; P<0.001).
    d. At 12 months of age, the proportion of infants who had no evidence of hindbrain herniation was higher in the prenatal-surgery group (36%) than in the postnatal-surgery

group (4%). Similarly, at 12 months, the prenatal-surgery group had a lower rate of moderate or severe hindbrain herniation (25%) than the postnatal-surgery group (67%), as well as lower rates of brain-stem kinking, abnormal fourth-ventricle location, and syringomyelia

e. Infants in the prenatal-surgery group underwent more procedures for delayed spinal cord tethering
f. Prenatal surgery resulted in improvement in the composite score for mental development and motor function at 30 months (P = 0.007) and in improvement in several secondary outcomes, including hindbrain herniation by 12 months and ambulation by 30 months.
g. However, prenatal surgery was associated with an increased risk of preterm delivery and uterine dehiscence at delivery.
h. Conclusions Prenatal surgery for myelomeningocele reduced the need for shunting and improved motor outcomes at 30 months but was associated with maternal and fetal risks.

2) **Johnson 2016**, MOMS study complications
    a. N=183 women (91 prenatal, 92 postnatal surgery)
    b. prenatal surgery was associated with an increased risk for membrane separation, oligohydramnios, spontaneous membrane rupture, spontaneous onset of labor, and earlier gestational age at birth.
    c. Gestational age at birth was significantly lower in the fetal surgery group (34.0 vs 37.3 weeks, P<0.001). Overall, 74 (81.3%) in the fetal surgery group were preterm vs 11 (11.9%) in the post natal surgery group.
        i. Risk of deliver at <30 weeks was significantly greater in the fetal surgery group (10 vs 0, P<0.001)
    a. CONCLUSION: Despite the confirmed benefits of prenatal surgery, considerable maternal and fetal risk exists compared with postnatal repair. Early gestational age at surgery and development of chorioamniotic membrane separation are risk factors for ruptured membranes. Oligohydramnios is a risk factor for preterm delivery and nulliparity is a risk factor for nonintact hysterotomy at delivery.
3) **Farmer 2018**, maternal and fetal/infant outcomes at 30 months for entire MOMS cohort
    a. N=183 maternal/fetal pairs
    b. prenatal repair improves the primary outcome composite score of mental development and motor function (199.4 ± 80.5 vs 166.7 ± 76.7,P=.004). Prenatal surgery also resulted in improvement in the secondary outcomes of independent ambulation (44.8% vs 23.9%, P = .004), WeeFIM self-care score (20.8 vs 19.0, P = .006), functional level at least 2 better than anatomic level (26.4% vs 11.4%, P=.02), and mean Bayley Scales of Infant Development, Second Edition, psychomotor development index (17.3% vs 15.1%, P = .03), but does not affect cognitive development at 30 months.
    c. CONCLUSION: The full cohort data of 30-month cognitive development and motor function outcomes validate in utero surgical repair as an effective treatment for fetuses with myelomeningocele. Current data suggest that outcomes related to the need for shunting should be counseled separately from the outcomes related to distal neurologic functioning.

Fetal Repair of Myelomeningocele

Expert guidelines

1) **ACOG 2017**, committee opinion on fetal surgery for myelomeningocele
    a. ACOG and the Society for Maternal-Fetal Medicine make the following recommendations:
        i. Open maternal-fetal surgery for myelomeningocele repair has been demonstrated to improve a number of important pediatric outcomes at the expense of procedure-associated maternal and fetal risks
        ii. Women with pregnancies complicated by fetal myelomeningocele who meet established criteria for in utero repair should be counseled in nondirective fashion regarding all management options, including the possibility of open maternal-fetal surgery
        iii. Interested candidates for fetal myelomeningocele repair should be referred for further assessment and consultation to a fetal therapy center that offers this intervention and possesses the expertise, multi-disciplinary team, services, and facilities to provide detailed information regarding maternal-fetal surgery and the intensive care required for patients who choose to undergo open maternal-fetal surgery

Other payer policies

1) Aetna 2019 and United Health Care 2019 cover fetal repair of myelomeningocele

Expert input

Mark Tomlinson, Maternal Fetal Medicine and Director of Obstetrics for Providence

There are fetal benefits to in utero myelomeningocele repair and I would recommend coverage. These pts require a lot of counseling though because of the maternal morbidity associated with the uterine scar. This is particularly important for young mothers who plan future children. The rate of rupture in subsequent pregnancies is significant, 10-30% depending on definitions used. There is an article presented at the annual meeting in Feb and recently published in the AJOG in the last couple of months looking at a registry of maternal outcomes suggesting a risk of rupture at the lower end of the range. There are some groups doing the surgery fetoscopically, but currently that is controversial. It decreases adverse maternal outcomes, however the fetal outcomes are uncertain at this time.

Fetal Repair of Myelomeningocele

HERC staff summary

Fetal repair of myelomeningocele improves infant outcomes, based on one good quality RCT. However, there are significant risks to both mother and baby. ACOG recommends that fetal repair be offered as one option to women with a fetus affected by myelomeningocele who meet the inclusion criteria to the MOMS trial. Cochrane cautions that the evidence base for this procedure includes only 1 trial conducted at highly specialized centers. Our expert consultant also recommends coverage for patients who have been appropriately counseled.

HERC staff recommendations

1) Add HCPCS S2404 (Repair, myelomeningocele in the fetus, procedure performed in utero) to line 1 PREGNANCY
2) Modify GN2 as shown below

GUIDELINE NOTE 2, ~~FETOSCOPIC~~ FETAL SURGERY

Line 1

Fetal surgery is only covered for the following conditions: repair of urinary tract obstructions via placement of a urethral shunt, repair of congenital cystic adenomatoid malformation, repair of extralobal pulmonary sequestration, repair of sacrococcygeal teratoma, ~~and~~ therapy for twin-twin transfusion syndrome, and repair of myelomeningocele.

Fetoscopic repair of urinary tract obstruction (S2401) is only covered for placement of a urethral shunt. Fetal surgery for cystic adenomatoid malformation of the lung, extralobal pulmonary sequestration and sacrococcygeal teratoma must show evidence of developing hydrops fetalis.

Certification of laboratory required (76813-76814).

Prenatal versus postnatal repair procedures for spina bifida for improving infant and maternal outcomes (Review)

Grivell RM, Andersen C, Dodd JM

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WILEY

[Intervention Review]

Prenatal versus postnatal repair procedures for spina bifida for improving infant and maternal outcomes

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ABSTRACT

Background

Spina bifida is a fetal neural tube defect (NTD), which may be diagnosed in utero and is compatible with life postnatally, albeit often with significant disability and morbidity. Although postnatal repair is possible, with increasing in utero diagnosis with ultrasound, the condition has been treated during pregnancy (prenatal repair) with the aim of decreased morbidity for the child. The procedure that is performed during pregnancy does have potential morbidities for the mother, as it involves maternal surgery to access the fetus.

Objectives

To compare the effects of prenatal versus postnatal repair and different types of repair of spina bifida on perinatal mortality and morbidity, longer term infant outcomes and maternal morbidity.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31 July 2014).

Selection criteria

All published, unpublished, and ongoing randomised controlled trials comparing prenatal and postnatal repair of meningomyelocele for fetuses with spina bifida and different types of prenatal repair.

Data collection and analysis

Two review authors independently evaluated trials for inclusion and methodological quality without consideration of their results according to the stated eligibility criteria and extracted data.

Main results

Our search strategy identified six reports for potential inclusion. Of those, we included one trial (four reports) involving 158 women, which was at low risk of bias.

The one included trial examined the effect of prenatal repair versus postnatal repair. For the primary infant outcome of neonatal mortality, there was no clear evidence of a difference identified for prenatal versus postnatal repair (one study, 158 infants, risk ratio (RR) 0.51, 95% confidence interval (CI) 0.05 to 5.54), however event rates were uncommon and so the analysis is likely to be underpowered to detect differences.

Prenatal repair was associated with an earlier gestational age at birth (one study, 158 infants, mean difference (MD) -3.20 weeks, 95% CI -3.93 to -2.47) and a corresponding increase in both the risk of preterm birth before 37 weeks (one study, 158 infants, RR 5.30, 95% CI 3.11 to 9.04) and preterm birth before 34 weeks (one study, 158 infants, RR 9.23, 95% CI 3.45 to 24.71). Prenatal repair was associated with a reduction in shunt dependent hydrocephalus and moderate to severe hindbrain herniation. For women, prenatal repair was associated with increased preterm ruptured membranes (one study, 158 women, RR 6.15, 95% CI 2.75 to 13.78), although there was no clear evidence of difference in the risk of chorioamnionitis or blood transfusion, although again, event rates were uncommon.

A number of this review's secondary infant and maternal outcomes were not reported. For the infant: days of hospital admission; survival to discharge; stillbirth; need for further surgery (e.g. skin grafting); neurogenic bladder dysfunction; childhood/infant quality of life. For the mother: admission to intensive care; women's emotional wellbeing and satisfaction with care.

Authors' conclusions

This review is based one small well-conducted study. There is insufficient evidence to recommend drawing firm conclusions on the benefits or harms of prenatal repair as an intervention for fetuses with spina bifida. Current evidence is limited by the small number of pregnancies that have been included in the single conducted randomised trial to date.

PLAIN LANGUAGE SUMMARY

Spina bifida repair and infant and maternal health

Spina bifida is the term used to describe a group of neural tube conditions where the fetal spinal cord does not close properly during the first month of pregnancy. With open spina bifida some of the vertebrae are not completely formed but are split or divided and the spinal cord and its coverings (the meninges) protrude through the opening. The most severe is where the spinal cord and meninges come out of the child's back (myelomeningocele). Open spina bifida is often associated with hindbrain herniation, where the cerebellum and brainstem tissue extend into the large opening in the base of the skull, and hydrocephalus (enlargement of the fluid filled cavities in the brain). Resulting disabilities include bladder and bowel incontinence, difficulties in moving about due to limb weakness, paralysis, deformity and loss of sensation. Conventional treatment of spina bifida is surgical repair within two days of birth, which may include the placement of a shunt between the ventricles of the baby's brain and the belly (peritoneum) to relieve hydrocephalus. Spina bifida can be diagnosed with prenatal ultrasound or maternal serum alpha-feto protein and in utero treatment could improve outcomes; although it involves surgical incision into the mother's abdomen and uterus to access the unborn baby.

This review aimed to compare the effects of in utero repair versus repair as a newborn. We included one randomised controlled trial involving 158 women who were from 19 to 27 weeks pregnant with a baby with severe spina bifida and evidence of hindbrain herniation. For neonatal mortality, there was no clear difference identified for prenatal versus postnatal repair. However, the numbers of neonates who died were low and so the review was likely underpowered to detect any difference. Prenatal repair was associated with reduced need for shunt placement and a reduction in the risk of moderate to severe hindbrain herniation after birth. No direct complications of the repair procedure were evident, including orthopaedic deformities. Prenatal repair was associated with an increased risk of the women experiencing preterm ruptured membranes and subsequent preterm birth (both before 34 and 37 weeks). Severe maternal illness (infection and need for blood transfusion) were not clearly different; although the review was underpowered to detect any difference in these important, less common outcomes. The included trial was of high quality (low risk of bias) but included a small number of pregnancies. There is currently insufficient evidence to recommend in utero repair for unborn babies with spina bifida.

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A Randomized Trial of Prenatal versus Postnatal Repair of Myelomeningocele

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ABSTRACT

BACKGROUND

Prenatal repair of myelomeningocele, the most common form of spina bifida, may result in better neurologic function than repair deferred until after delivery. We compared outcomes of in utero repair with standard postnatal repair.

METHODS

We randomly assigned eligible women to undergo either prenatal surgery before 26 weeks of gestation or standard postnatal repair. One primary outcome was a composite of fetal or neonatal death or the need for placement of a cerebrospinal fluid shunt by the age of 12 months. Another primary outcome at 30 months was a composite of mental development and motor function.

RESULTS

The trial was stopped for efficacy of prenatal surgery after the recruitment of 183 of a planned 200 patients. This report is based on results in 158 patients whose children were evaluated at 12 months. The first primary outcome occurred in 68% of the infants in the prenatal-surgery group and in 98% of those in the postnatal-surgery group (relative risk, 0.70; 97.7% confidence interval [CI], 0.58 to 0.84; P<0.001). Actual rates of shunt placement were 40% in the prenatal-surgery group and 82% in the postnatal-surgery group (relative risk, 0.48; 97.7% CI, 0.36 to 0.64; P<0.001). Prenatal surgery also resulted in improvement in the composite score for mental development and motor function at 30 months (P=0.007) and in improvement in several secondary outcomes, including hindbrain herniation by 12 months and ambulation by 30 months. However, prenatal surgery was associated with an increased risk of preterm delivery and uterine dehiscence at delivery.

CONCLUSIONS

Prenatal surgery for myelomeningocele reduced the need for shunting and improved motor outcomes at 30 months but was associated with maternal and fetal risks. (Funded by the National Institutes of Health; ClinicalTrials.gov number, NCT00060606.)

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* Additional investigators in the Management of Myelomeningocele Study (MOMS) are listed in the Supplementary Appendix, available at NEJM.org.

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OBSTETRICS

The Management of Myelomeningocele Study: obstetrical outcomes and risk factors for obstetrical complications following prenatal surgery

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BACKGROUND: The Management of Myelomeningocele Study was a multicenter randomized trial to compare prenatal and standard postnatal closure of myelomeningocele. The trial was stopped early at recommendation of the data and safety monitoring committee and outcome data for 158 of the 183 randomized women published.

OBJECTIVE: In this report, pregnancy outcomes for the complete trial cohort are presented. We also sought to analyze risk factors for adverse pregnancy outcome among those women who underwent prenatal myelomeningocele repair.

STUDY DESIGN: Pregnancy outcomes were compared between the 2 surgery groups. For women who underwent prenatal surgery, antecedent demographic, surgical, and pregnancy complication risk factors were evaluated for the following outcomes: premature spontaneous membrane rupture ≤34 weeks 0 days (preterm premature rupture of membranes), spontaneous membrane rupture at any gestational age, preterm delivery at ≤34 weeks 0 days, nonintact hysterotomy (minimal uterine wall tissue between fetal membranes and uterine serosa, or partial or complete dehiscence at delivery), and chorioamniotic membrane separation. Risk factors were evaluated using χ^2 and Wilcoxon tests and multivariable logistic regression.

RESULTS: A total of 183 women were randomized: 91 to prenatal and 92 to postnatal surgery groups. Analysis of the complete cohort confirmed initial findings: that prenatal surgery was associated with an increased risk for membrane separation, oligohydramnios, spontaneous membrane rupture, spontaneous onset of labor, and earlier gestational age at birth. In multivariable logistic regression of the prenatal surgery group adjusting for clinical center, earlier gestational age at surgery and chorioamniotic membrane separation were associated with increased risk of spontaneous membrane rupture (odds ratio, 1.49; 95% confidence interval, 1.01—2.22; and odds ratio, 2.96, 95% confidence interval, 1.05—8.35, respectively). Oligohydramnios was associated with an increased risk of subsequent preterm delivery (odds ratio, 9.21; 95% confidence interval, 2.19—38.78). Nulliparity was a risk factor for nonintact hysterotomy (odds ratio, 3.68; 95% confidence interval, 1.35—10.05).

CONCLUSION: Despite the confirmed benefits of prenatal surgery, considerable maternal and fetal risk exists compared with postnatal repair. Early gestational age at surgery and development of chorioamniotic membrane separation are risk factors for ruptured membranes. Oligohydramnios is a risk factor for preterm delivery and nulliparity is a risk factor for nonintact hysterotomy at delivery.

Key words: fetal myelomeningocele, fetal spina bifida, fetal therapy, prenatal surgery

Introduction

The National Institutes of Health-sponsored Management of Myelomeningocele Study (MOMS) was initiated in 2003 to compare the safety and efficacy of prenatal repair of myelomeningocele with that of standard postnatal repair. The trial was stopped in 2010 before reaching the target sample size, at the recommendation of its data and safety monitoring committee according to prespecified stopping rules for the efficacy of prenatal surgery. Results of the trial were reported[1] based on 158 women who had undergone randomization before July 1, 2009, as this was the cohort analyzed for the data and safety monitoring committee. Findings in that report demonstrated a significant improvement in the primary outcomes at 12 and 30 months of age, and in multiple secondary outcomes, including reversal of hindbrain herniation and ambulation by 30 months, in the prenatal repair group. However, prenatal surgical intervention was associated with significantly higher rates of oligohydramnios and chorioamniotic separation, as well as spontaneous membrane rupture (SROM) and preterm delivery (PTD) ($P < .001$). Moreover, of those in the prenatal surgery group, only 64% had an intact, well-healed hysterotomy site from the prenatal repair surgery observed at cesarean delivery.

The initial MOMS report summarized the pregnancy outcomes of 86% of the 183 randomized women. The primary objective of the current report is to update the final pregnancy outcome results from the MOMS trial, as well as to analyze risk factors for preterm premature rupture of membranes (PPROM), SROM at any gestation, early preterm delivery (PTD), and uterine dehiscence among those women who underwent prenatal repair. It is the authors' view that these additional components are anticipated to enhance the knowledge of benefits, risk assessment, and informed consent process for future families considering fetal myelomeningocele repair, where maternal and fetal characteristics match those set forth in the inclusion and exclusion criteria of the trial.

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0002-9378/$36.00

http://dx.doi.org/10.1016/j.ajog.2016.07.052

OBSTETRICS

The Management of Myelomeningocele Study: full cohort 30-month pediatric outcomes

Diana L. Farmer, MD; Elizabeth A. Thom, PhD; John W. Brock III, MD; Pamela K. Burrows, MS; Mark P. Johnson, MD; Lori J. Howell, DNP, MS, RN; Jody A. Farrell, RN, MSN; Nalin Gupta, MD, PhD; N. Scott Adzick, MD; for the Management of Myelomeningocele Study Investigators

BACKGROUND: Previous reports from the Management of Myelomeningocele Study demonstrated that prenatal repair of myelomeningocele reduces hindbrain herniation and the need for cerebrospinal fluid shunting, and improves motor function in children with myelomeningocele. The trial was stopped for efficacy after 183 patients were randomized, but 30-month outcomes were only available at the time of initial publication in 134 mother-child dyads. Data from the complete cohort for the 30-month outcomes are presented here. Maternal and 12-month neurodevelopmental outcomes for the full cohort were reported previously.

OBJECTIVE: The purpose of this study is to report the 30-month outcomes for the full cohort of patients randomized to either prenatal or postnatal repair of myelomeningocele in the original Management of Myelomeningocele Study.

STUDY DESIGN: Eligible women were randomly assigned to undergo standard postnatal repair or prenatal repair <26 weeks gestation. We evaluated a composite of mental development and motor function outcome at 30 months for all enrolled patients as well as independent ambulation and the Bayley Scales of Infant Development, Second Edition. We assessed whether there was a differential effect of prenatal surgery in subgroups defined by: fetal leg movements, ventricle size, presence of hindbrain herniation, gender, and location of the myelomeningocele lesion. Within the prenatal surgery group only, we evaluated these and other baseline parameters as predictors of 30-month motor and cognitive outcomes. We evaluated whether presence or absence of a shunt at 1 year was associated with 30-month motor outcomes.

RESULTS: The data for the full cohort of 183 patients corroborate the original findings of Management of Myelomeningocele Study, confirming that prenatal repair improves the primary outcome composite score of mental development and motor function (199.4 ± 80.5 vs 166.7 ± 76.7, $P = .004$). Prenatal surgery also resulted in improvement in the secondary outcomes of independent ambulation (44.8% vs 23.9%, $P = .004$), WeeFIM self-care score (20.8 vs 19.0, $P = .006$), functional level at least 2 better than anatomic level (26.4% vs 11.4%, $P = .02$), and mean Bayley Scales of Infant Development, Second Edition, psychomotor development index (17.3% vs 15.1%, $P = .03$), but does not affect cognitive development at 30 months. On subgroup analysis, there was a nominally significant interaction between gender and surgery, with boys demonstrating better improvement in functional level and psychomotor development index. For patients receiving prenatal surgery, the presence of in utero ankle, knee, and hip movement, absence of a sac over the lesion and a myelomeningocele lesion of ≤L3 were significantly associated with independent ambulation. Postnatal motor function showed no correlation with either prenatal ventricular size or postnatal shunt placement.

CONCLUSION: The full cohort data of 30-month cognitive development and motor function outcomes validate in utero surgical repair as an effective treatment for fetuses with myelomeningocele. Current data suggest that outcomes related to the need for shunting should be counseled separately from the outcomes related to distal neurologic functioning.

Key words: ankle, knee, and hip movement, fetal surgery, long-term follow-up, Management of Myelomeningocele Study, motor outcomes, myelomeningocele, postnatal motor function, shunt, ventricular size, ventriculomegaly

Introduction

Myelomeningocele (MMC) is a life-altering birth defect resulting from incomplete closure of the neural tube during the fourth week of gestation. The exposed spinal cord sustains intrauterine trauma, leaving children with lifelong paralysis, incontinence, and cognitive disabilities. MMC is a devastating disease for patients and families, not only physically and psychologically, but also financially: MMC health costs are 13 times greater than those of unaffected children.[1,2]

With the improvement of prenatal diagnostics and prenatal surgical techniques, surgeons began to repair the lesion before birth with the hope of preventing in utero spinal cord trauma. Preliminary studies indicated that prenatal intervention resulted in more desirable outcomes than postnatal repair.[3-7]

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Management of Myelomeningocele Study (MOMS) compared prenatal closure of the MMC defect with postnatal repair in a multicenter randomized trial. MOMS was stopped for efficacy after recruitment of 183 patients from a planned sample size of 200. The original article reported 30-month neurodevelopmental, self-care, and mobility outcomes from 134 of those patients.[8] Initial publication demonstrated that prenatal repair of the MMC defect decreased hindbrain herniation, decreased the need for cerebrospinal fluid (CSF) shunting, and improved distal neurologic function.[8] The full cohort data on maternal outcomes and the reduced need for CSF shunting have been previously published.[9,10] Urologic outcomes at 30

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The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

Society for Maternal-Fetal Medicine

ACOG COMMITTEE OPINION

Number 720 • September 2017

(Replaces Committee Opinion Number 550, January 2013)

Committee on Obstetric Practice
Society for Maternal–Fetal Medicine

The North American Fetal Therapy Network endorses this document. This Committee Opinion was developed by the American College of Obstetricians and Gynecologists' Committee on Obstetric Practice in collaboration with committee member Russell S. Miller, MD, and the Society for Maternal–Fetal Medicine in collaboration with member Jeffrey A. Kuller, MD.

Maternal–Fetal Surgery for Myelomeningocele

ABSTRACT: Myelomeningocele, a severe form of spina bifida, occurs in approximately 1 in 3,000 live births in the United States. The extent of disability is generally related to the level of the myelomeningocele defect, with a higher upper level of lesion generally corresponding to greater deficits. Open maternal–fetal surgery for myelomeningocele repair is a major procedure for the woman and her affected fetus. Although there is demonstrated potential for fetal and pediatric benefit, there are significant maternal implications and complications that may occur acutely, postoperatively, for the duration of the pregnancy, and in subsequent pregnancies. Women with pregnancies complicated by fetal myelomeningocele who meet established criteria for in utero repair should be counseled in a nondirective fashion regarding all management options, including the possibility of open maternal–fetal surgery. Maternal–fetal surgery for myelomeningocele repair should be offered only to carefully selected patients at facilities with an appropriate level of personnel and resources.

Recommendations

The American College of Obstetricians and Gynecologists and the Society for Maternal–Fetal Medicine make the following recommendations:

- Open maternal–fetal surgery for myelomeningocele repair has been demonstrated to improve a number of important pediatric outcomes at the expense of procedure-associated maternal and fetal risks.
- Women with pregnancies complicated by fetal myelomeningocele who meet established criteria for in utero repair should be counseled in nondirective fashion regarding all management options, including the possibility of open maternal–fetal surgery.
- Interested candidates for fetal myelomeningocele repair should be referred for further assessment and consultation to a fetal therapy center that offers this intervention and possesses the expertise, multidisciplinary team, services, and facilities to provide detailed information regarding maternal–fetal surgery and the intensive care required for patients who choose to undergo open maternal–fetal surgery.

Introduction

Myelomeningocele, a severe form of spina bifida, occurs in approximately 1 in 3,000 live births in the United States (1) and is complicated by hydrocephalus, need for ventriculoperitoneal shunt placement, motor and cognitive defects, bowel and bladder dysfunction, and social and emotional challenges. The extent of disability generally is related to the level of the myelomeningocele defect, with a higher upper level of lesion generally corresponding to greater deficits. Among newborns prenatally diagnosed with myelomeningocele, lesions are usually surgically repaired in the early neonatal period.

Fetal surgery has historically been considered a heroic intervention reserved for severe fetal presentations in which in utero therapy might favorably alter a natural history expected to result in fetal or neonatal death or severe disability. However, significant maternal and fetal risks prompted concern regarding the appropriateness of such treatments. Although open maternal–fetal surgery was originally limited to life-threatening conditions, it was considered for fetal myelomeningocele repair because results of laboratory and animal studies