Health Evidence Review Commission's Value-based Benefits Subcommittee

March 12, 2020

9:00 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
3/12/2020
9:00am - 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 **9:00 AM**

II. Staff report – staff **9:05 AM**
- **A.** Errata
- **B.** Coronavirus coding

III. Straightforward/Consent agenda – Ariel Smits **9:10 AM**
- **A.** Consent table
- **B.** Removal of Essure and related procedure codes from the Prioritized List

IV. New Discussion item – Cat Livingston **9:15 AM**
- **A.** Female genital mutilation treatment

V. Biennial Review 2022 **9:45 AM**
- **A.** Orientation to the prioritization process and proposed biennial review topic discussion
- **B.** Summary and disposition of topics proposed to date
- **C.** 2022 topics
    - A. Surgical treatment of chronic pancreatitis
    - B. Foreign body in the ear and nose
    - C. Meniere's disease

VI. Previous discussion items **11:15 AM**
- **A.** Bone marrow transplant for sickle cell disease
- **B.** Peripheral nerve ablation

VII. New discussion items **11:45 AM**
- **A.** Bone grafts
- **B.** Cranial electrical stimulation guideline entry update
- **C.** Acupuncture for cancer related pain
- **D.** Psoriasis guideline update
- **E.** Telehealth guideline
    - **A.** Edit teleconsultation guideline

VIII.	**Public comment**	**12:55 PM**
IX.	**Adjournment – Kevin Olson**	**1:00 PM**

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on January 16, 2020

For specific coding recommendations and guideline wording, please see the text of the 1/16/2020 VbBS minutes.

RECOMMENDED CODE MOVEMENT (changes to the 10/1/2020 Prioritized List unless otherwise noted)

- Add several diagnosis codes for chronic lower extremity venous disease to a covered line with a new guideline
- Delete the procedure code for intracardiac echocardiograms from an uncovered line and recommend addition to the Diagnostic Procedures File
- Move vitamin D testing codes from the Diagnostic Procedures File to specific lines
- Add the procedure code for fetal myelomeningocele repair to a covered line
- Add an additional procedure code for aqueous shunts to the covered glaucoma line
- Delete the procedure codes for spinal cord stimulators from one covered line with no appropriate diagnoses
- Make various straightforward coding and guideline changes

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- Acupuncture and yoga were not added as treatment for post-traumatic stress disorder or anxiety

RECOMMENDED GUIDELINE CHANGES (changes to the 10/1/2020 Prioritized List unless otherwise noted)

- Add a clause allowing an exception for pre-operative testing prior to epilepsy surgery to the neuropsychological testing guideline
- Add a new guideline specifying when treatment of chronic lower extremity venous disease is covered
- Delete the pharmacist prescribing guideline
- Expand the guideline note entry for TENS to apply to all similar therapies that include the same CPT code
- Edit the guideline on Yttrium 90 therapy for hepatocellular carcinoma to clarify that pre-treatment mapping is covered but not pre-treatment embolization
- Edit the fetal surgery guideline to include fetal myelomeningocele repair
- Edit the guideline regarding aqueous shunts to remove the brand name reference
- Add a new guideline specifying when spinal cord stimulators are covered

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VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
January 16, 2020
8:00 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, MBA, Vice-chair (via phone); Vern Saboe, DC (via phone); Gary Allen, DMD (via phone); Kathryn Schabel, MD; Brian Duty, MD (arrived 8:10), Adriane Irwin, PharmD.

Members Absent: None.

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

Also Attending: Michael Collins (Warm Springs Tribe); Shauna Williams (Glaukos); Billy Ray Pitt (Sirtex); Trisha Wong, MD, Eneida Nemecek MD, Rochelle Williams-Belizaire, and Stefan Sang (OHSU), Joevantae Thompson; Jennifer Batchela, Robyn Tyran, and Mary Hlady (Providence); Dawn Mautner (OHA), Andrei Sdrulla (OHSU); Laura Ocker (OCOM); Rosa Schnyer (University of Texas; via phone).

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

  The meeting was called to order at 8:00 am and roll was called. A quorum of members was present at the meeting. Minutes from the November 14, 2019 VbBS meeting were reviewed and approved.

  Smits noted the errata document was available for review; there were no questions regarding any of the errata. She also noted that the back lines review might be delayed from March as the AHRQ reviews have been delayed.

  Gingerich introduced Mike Collins as a new HERC member who will likely be added to VbBS at today's HERC meeting. He also noted that the planned discussion of conflict of interest forms has been delayed from today's HERC meeting to March, 2020.

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- **Topic: Straightforward/Consent Agenda**

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

  Recommended Actions:
  1) Add CPT 99490 (Chronic care management services) and HCPCS G2058 (Chronic care management services) to lines 346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS, 361 SCOLIOSIS, 529 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS, 661 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
  2) Remove ICD-10-CM M40.0 codes (Postural kyphosis), M40.4 (Postural lordosis) and M40.5 (Lordosis, unspecified) from lines 402 CONDITIONS OF THE BACK AND SPINE and 529 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
     a. Add ICD-10-CM M40.0, M40.4 and M40.5 to line 659 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
  3) Remove CPT 81225 (CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)) from line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS and recommend that HSD add the code to the Diagnostic Procedure File
  4) Modify the entry regarding P450 testing in section D of DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE as shown in Appendix A.
  5) Remove CPT 93792-93793 (INR) monitoring) from all current lines on the Prioritized List and advise HSD to add to the Diagnostic Procedures File
  6) Remove ICD-10-CM Z79.01 (Long term (current) use of anticoagulants) from all current lines on the Prioritized List and advise HSD to add to the Diagnostic Workup File

  MOTION: To approve the recommendations stated in the consent agenda. CARRIES 5-0. *(Absent: Duty)*

- **Topic: Bone marrow transplant for sickle cell disease**

  Discussion: Smits introduced the summary document and answered clarifying questions from members.

  Testimony was heard from:
  Eneida Nemecek MD, bone marrow transplant director at OHSU, who also works with the national bone marrow registry. She described the clinical course of sickle cell disease. She noted that as fetal hemoglobin decreases as kids age, they get more and more symptoms such as excruciating pain. They have repeat hospitalizations, and the spleen fails so they get increased infection. The many complications result in a shortened life expectancy. A new coverage recommendation for bone marrow transplant (BMT) was approved by CMS recently. If a patient has a matched sibling donor, then the recommendation is to have a BMT as early as possible. If there is no matched sibling, then organ damage criteria are used to determine when to consider transplant.

  Tricia Wong MD, director of Sickle Cell program at OSHU. This is a quality of life issue. The Arnold study used pediatric data only and did not capture cost savings of adults who can be more

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productive and have lower health costs for a long period. She agrees with the proposed requirements that the patient have severe disease and a matched sibling donor for now. She believes that data will be forthcoming about non-sibling transplants and less-symptomatic patients and will be coming back to ask for expanded coverage.

Schabel asked the experts what they felt about the HERC staff-proposed guideline criteria. Nemecek felt that the data is there for matching sibling donors at any age. She testified that she does not know of evidence for transplants after age 40, so she agrees with 40-year age limit in cases with no matched sibling. She also agreed patients should be required to meet study inclusion criteria related to organ damage (she offered to provide this criteria). No one recommends BMT for patients over the age of 40. She would not recommend limiting coverage to sibling matched donors as the research is rapidly changing. She noted that CMS has approved sibling HLA-matched transplant at any age. Wong recommended including coverage for patients with non-sibling matched donors if done as part of a registered trial. Essentially, the experts recommended requiring no complications if there is a sibling match and the patient is under age 40; they recommend requiring patients to meet the complications criteria from an ongoing study if they have a non-sibling match and the patient is under age 40. They did not recommend coverage of BMT for patients over age 40.

Irwin asked for a clarification of the CMS criteria. Nemecek stated that CMS approves all kids (under age 15) with a matched sibling so their guidance is just for ages 15 and above and sibling or non-sibling matched donor. There is also a half-matched protocol (allowing coverage for patients with strokes and adults with many symptoms).

Olson asked about gene therapy. Nemecek replied that gene therapy is experimental and must be done in a clinical trial. Wong noted that gene therapy was recently approved for thalassemia—she will bring this to HERC in the future.

Rochelle Williams-Belizaire from the OHSU Knight Cancer Institute testified. There is evidence to support BMT for sickle cell disease. She has an 18-month-old son with the condition, who has already been in the hospital twice. Her son has a matched sibling, and the family plans BMT for her toddler.

Joevantae Thompson, a sickle cell disease patient testified. He had frequent pain and hospitalizations before his transplant in August 2019. Now he has no pain. He is 17.

Nemecek summarized that she feels coverage should include patients of any age who have a matched sibling donor. If a patient does not have a matched sibling donor, then a patient should be eligible for BMT under the criteria of registered trial (she recommended not being detailed about end organ damage as criteria for trials are changing). Schabel asked whether the donor should be related or a sibling. Nemecek replied that they need to simply be related.

The VbBS generally agreed with adding coverage for BMT for sickle cell disease, and asked staff to work with experts to fine tune the guideline and bring back to the March 2020 VbBS meeting.

Recommended Actions:

1) HERC staff to work with experts on the proposed new guideline wording and bring this topic back to a future VbBS meeting

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- **Topic: Neuropsychological testing guideline**

  Discussion: Smits reviewed the summary document. There was no discussion.

  Recommended Actions:
  1) Modify Diagnostic Guideline D26 as shown in Appendix A

  MOTION: To recommend the guideline note changes as presented. CARRIES 6-0.

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

  Discussion: Smits introduced the summary document. Schabel noted that in the case of a non-healing ulcer, compression stockings can be harmful and are not indicated. She also noted that patients with various lower extremity conditions also frequently have neuropathy, and compression stockings can be dangerous in that situation.

  Testimony:
  Robyn Tyran, a physical therapist with Providence, testified that high compression stockings can be harmful, but there are medical compression devices which have Velcro wraps and better skin protection. These devices also have higher compliance.

  The members requested that the proposed guideline note replace "compression stockings" with "medical compression garments" to allow the use of these more effective devices.

  Tyran then gave a presentation, requesting that compression garments be covered for all levels of venous insufficiency to prevent downstream complications. She noted that untreated venous insufficiency leads to a downward spiral in health and function. She presented a flowchart of treatment recommendations from Eberhardt et al. She requested that compression garments be covered at the first symptom, before any imaging is done to look for venous reflux. She noted there is level 1 evidence for compression stockings for treatment of post-thrombotic syndrome, prevention of progression of occupational leg syndromes, and in management of lymphedema.

  Jennifer Batchela, also a physical therapist from Providence, testified that the biggest barrier to compliance with compression garments is the cost of the garments. Providing coverage for these garments would help to overcome this barrier. She noted that fit and skin issues can affect compliance with use.

  Tyran noted that there will be no studies of compression garments against non-treated controls, as not offering compression would be unethical. The studies that are published essentially compare compliant patients with non-compliant patients, which is not a random comparison.

  Hodges noted that gradient compression stockings are coded with an HCPCS "A" code (the series used for durable medical equipment (DME)) and covered based on criteria in Oregon Administrative Rules (OAR). Staff noted that they will need to check with the Health Systems Division regarding the OARs for DME such as compression stockings.

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It was noted that superficial thrombophlebitis, which was proposed for coverage in the new guideline, is actually on line 516 and those ICD-10-CM codes were not proposed to be moved to the covered line. The members suggested substituting "recurrent cellulitis resulting from chronic venous disease" in that portion of the new guideline. There was also a suggestion to make medical treatment of CLEVD a separate section in the guideline from the surgical treatment.

Olson noted that the discussion regarding compression garments went beyond the topic at hand, which was coverage for chronic lower extremity venous disease. The group agreed that the modified guideline and coding change recommendations were adequate for their intent to widen coverage slightly for chronic lower extremity venous disease. There was also discussion that if varicose veins resulted in significant bleeding, then surgical treatment should be covered. The members suggested changing that entry in the guideline to say "clinically significant bleeding" to reflect that it cannot be a small amount of bleeding, but something that might affect health. Massive bleeding would be covered as an exception without any other requirements.

The group requested that HERC staff work with the physical therapy group and HSD staff regarding coverage of compression garments for non-CLEVD indications, such as edema from heart disease, liver disease, obesity, or other causes. Staff was also directed to explore coverage of compression garments for less severe CLEVD.

Recommended Actions:

1) 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
    a. ICD10 I83.89 (Varicose veins of lower extremities with other complications)
    b. ICD10 I87.09 (Postthrombotic syndrome with other complications of lower extremity)
2) Adopt a new guideline note to line 379 as shown in Appendix B
3) Modify the line title of line 379 to CHRONIC ULCER OF SKIN; VARICOSE VEINS WITH MAJOR COMPLICATIONS

MOTION: To recommend the code and guideline note changes as modified. CARRIES 6-0.

- **Topic: Delete pharmacist prescribing guideline**

Discussion: Smits reviewed the summary document. There was no discussion.

Recommended Actions:

1) Delete GN64 as shown in Appendix A

MOTION: To recommend the guideline note changes as presented. CARRIES 6-0.

- **Topic: Intracardiac echocardiogram**

Discussion: Smits reviewed the summary document. There was no discussion.

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Recommended Actions:

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 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
2) Modify Guideline Note 173 as shown in Appendix A
3) Advise HSD to add CPT 93662 to the Diagnostic Procedure File

MOTION: To recommend the code and guideline note changes as presented. CARRIES 6-0.

- **Topic: Frequency specific microcurrent therapy and similar TENS-like therapies**

Discussion: Smits reviewed the summary document. There was no discussion.

Recommended Actions:

1) Modify the GN173 entry for CPT 97014 (Application of a modality to 1 or more areas; electrical stimulation (unattended)) as shown in Appendix A

MOTION: To recommend the guideline note changes as presented. CARRIES 6-0.

- **Topic: Yttrium 90 embolization mapping**

Discussion: Livingston reviewed the summary document. There was no discussion.

Recommended Actions:

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**
2. Modify Guideline Note 185 as shown in Appendix A.

MOTION: To recommend the guideline note changes as presented. CARRIES 6-0.

- **Topic: Vitamin D screening**

Discussion: Livingston reviewed the summary document. There was a brief discussion about the change in vitamin D recommendations for fall prevention.

Recommended Actions:

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:

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- 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

MOTION: To recommend the code changes as presented. CARRIES 6-0.

- **Topic: Fetal myelomeningocele repair**

Discussion: Smits reviewed the summary document. There was no discussion.

Recommended Actions:

1) Add HCPCS S2404 (Repair, myelomeningocele in the fetus, procedure performed in utero) to line 1 PREGNANCY
2) Modify GN2 as shown in Appendix A

MOTION: To recommend the code and guideline note changes as presented. CARRIES 6-0.

- **Topic: iStent Inject**

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Discussion: Smits reviewed the summary document. There was minimal discussion. Hodges requested that the CPT codes for the procedure be added to the guideline.

Recommended Actions:

1) Add CPT 0376T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; each additional device insertion) to line 139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE
2) Add HCPCS C1783 (Ocular implant, aqueous drainage assist device) and L8612 (Aqueous shunt) to line 139
3) Modify Guideline Note 184 as shown in Appendix A

MOTION: To recommend the code and guideline note changes as presented. CARRIES 6-0.

- **Topic: Spinal cord stimulators**

Discussion: Smits introduced the summary documents regarding both spinal cord stimulators for conditions of the back and spine and for complex regional pain syndrome.

Testimony was heard from Dr. Andrei Sdrulla, from the anesthesia department at OHSU. CRPS is uncommon and therefore few clinical trials. 50-100 Oregonians have this condition. Patients have severe neuropathic pain, and have no other treatment options. Patients with CRPS have significant disability and poor quality of life. Anything we can do to help would be worthwhile. Adding coverage for spinal cord stimulators would not a high budget item as small handful of patients a year would get SCS. SCS technology has developed greatly over time. Four different manufacturers make devices with different technology. There is a need to correctly maintain the device as well. Study heterogeneity is high due to different devices and different levels of maintenance. Older trials have high complications rates; newer devices and techniques have much lower complication rates. The Deere study had much lower complication compared to the Kemler study (an earlier study). In Deere—both arms did very well. Complication rate were reasonable. Do not put as much weight on the older studies. His experience in that these devices work well in certain patients and can be life changing. CRPS can often be mislabeled. He also noted that you cannot do sham control for SCS, so inherently get low quality studies.

Members asked what other treatments exist for CRPS. The answer was some medications, physical therapy.

Duty asked what percent of patients getting a test SCS qualify for permanent placement with CRPS. Sdrulla responded that 65-80% of CRPS patients qualify for permanent placement, which is higher than with failed back surgery syndrome.

Sdrulla noted that dorsal root ganglion (DRG) stimulation is very technically difficult, few surgeons in Oregon are doing this.

Olson noted that CRPS patients could access SCS through the exception process. Duty noted this process could be quite onerous. Hodges stated that she did not see problems with CRPS patients getting approved for SCS through the exceptions process at her CCO.

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Gingerich noted that 251 pts on OHP had paid claims for CRPS in 2018.
Saboe asked what is the cost of the procedure? Livingston reported that she found costs of $32,882 for Medicare (hospitalization, procedure, device, $5,000-$21,000 yearly maintenance cost) in a brief internet search.

Schabel requested that the clause stating that coverage for SCS placement would not be covered if a patient had a contraindication be struck from the proposed guideline, as no surgeon would operate on a patient with a contraindication.

Irwin asked about the diagnostic criteria for CRPS. Sdrulla answered: pain out of proportion to the stimulus or after normal healing. There are criteria that include symptoms and exam findings.

There were two votes. The vote to accept the staff coding changes and guideline note modifications excluding the sentence regarding CRPS was approved unanimously. The vote to include wording excluding CRPS from coverage was 4 ayes to 2 nays.

Recommended Actions:

1) Remove all spinal cord stimulator CPT and HCPCS codes from line 361 SCOLIOSIS
    a. CPT 63650, 63655, 63685
    b. HCPCS C1767, C1778, C1816, C1820, C1822, C1823, C1897
2) Add the new guideline shown in Appendix B to lines
    a. 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
    b. 346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS
    c. 529 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
3) Delete the coding specification regarding spinal cord stimulators from line 292 as this exclusion for CRPS will be addressed in the new guideline note.
    a. "~~Spinal cord stimulation (63650-63688) is not included on this line when paired with ICD-10-CM-CM category G90.5 Complex regional pain syndrome/reflex sympathetic dystrophy.~~"

MOTION: To recommend the code, coding specification, and guideline note changes as presented. CARRIES 4-2 (Opposed: Schabel, Irwin)

- **Topic: Yoga and acupuncture for PTSD and anxiety**

Discussion: Smits introduced the summary document.

Testimony was heard from Laura Ocker, LAc and Rosa Schnyer, LAc (via phone).

Schabel asked the experts about ongoing research efforts in this area. Schnyer replied that the Department of Defense (DOD) is actively collecting data on acupuncture for PTSD among veterans. Duty asked what the DOD protocol was. Schnyer replied that she did not know the details of that research.

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Ocker noted that acupuncture can have variable time of benefit and may improve the effectiveness of other treatments such as medications.

Schabel suggested that the CCOs could develop and use local resources rather than having the coverage required. There was consensus that this was the best approach at this time. There was no recommendation to make a change to the current lack of pairing of acupuncture and yoga with PTSD and anxiety at this time.

- **Public Comment:**

  No additional public comment was received.

- **Issues for next meeting:**
  - Bone marrow transplant for sickle cell disease

- **Next meeting:**

  March 12, 2020 at Clackamas Community College, Wilsonville Training Center, Wilsonville Oregon, Rooms 111-112.

- **Adjournment:**

  The meeting adjourned at 12:54 PM.

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Appendix A
Revised Guideline Notes

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: 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 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.
   3) 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

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Appendix A
Revised Guideline Notes

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 8122556-81227, 81230-81231 (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 medications when not required or recommended in the FDA labeling for that medication (e.g. psychiatric, anticoagulant, opioid medications, etc.).
   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

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(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.

DIAGNOSTIC GUIDELINE D26, NEUROBEHAVIORAL STATUS EXAMS AND NEUROPSYCHOLOGICAL TESTING

Neurobehavioral status exams (CPT 96116 and 96121) and neuropsychological testing services (CPT 96132 and 96133) are only covered when all of the following are met:

1) Symptoms are not explained by an existing diagnosis; AND

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Appendix A
Revised Guideline Notes

2) When the results of such testing will be used to develop a care plan.

OR when neuropsychological testing is done as part of the pre-operative evaluation prior to epilepsy surgery.

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).

~~**GUIDELINE NOTE 64, PHARMACIST MEDICATION MANAGEMENT**~~

~~*Included on all lines with evaluation & management (E&M) codes*~~

~~Pharmacy medication management services must be provided by a pharmacist who has:~~

~~1) A current and unrestricted license to practice as a pharmacist in Oregon.~~

~~2) Documentation must be provided for each consultation and must reflect communication with the patient's primary care provider. 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; and must be retained in the patient's medical record and be retrievable.~~

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~~		

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Appendix A
Revised Guideline Notes

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	January 2020

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.

Pretreatment mapping is included on this line, however, pre-treatment embolization is not included on this line due to insufficient evidence of effectiveness.

GUIDELINE NOTE 184, ANTERIOR SEGMENT AQUEOUS DRAINAGE DEVICE INSERTION

Line 139

Anterior segment aqueous drainage device ~~(e.g. iStent©)~~ insertion (e.g. CPT 0191T, O376T or HCPCS C1783, L8612) is only included on this line when done at the same time as cataract removal and when the two procedures are billed together as a bundled service.

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Appendix B
New Guideline Notes

GUIDELINE NOTE XXX, TREATMENT OF CHRONIC LOWER EXTREMITY VENOUS DISEASE

Lines 379,519,639

Medical treatment of chronic lower extremity venous disease with major complications (skin ulceration, recurrent cellulitis or clinically significant bleeding) is included on line 379, including medical compression garments.

Surgical 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) Ultrasound findings of severe axial venous reflux (>1 second in the greater or small saphenous vein or accessory saphenous vein; AND
3) 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 cellulitis associated with chronic venous disease OR
    c. Clinically significant bleeding from varicose vein(s).

Otherwise, these diagnoses are included on lines 519 or 639.

GUIDELINE NOTE XXX SPINAL CORD STIMULATOR THERAPY

Lines 292, 346, 529

A spinal cord stimulator trial is included on lines 292 and 346 only when a patient meets all of the following criteria:

1) The patient has moderate to severe (>5 on the VAS pain scale) neuropathic pain and objective neurologic impairment with documented pathology related to pain complaint (i.e. abnormal MRI). 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; AND
2) The patient has failed 12 or more months of other treatment modalities (e.g. pharmacological, surgical, physical therapy, cognitive therapy, and activity lifestyle modification); AND
3) The patient has had an evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) which revealed no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, psychosis) and the patient receives written clearance from the mental health provider for device placement.

Implantation of a spinal cord stimulator is included on lines 292 and 346 when the trial criteria above are met and the patient experienced significant pain reduction (50% or more) with a 3 to 7 day trial of percutaneous spinal stimulation.

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Appendix B
New Guideline Notes

Spinal cord stimulation (CPT 63650-63688) is not included on line 292 when paired with ICD-10-CMcategory G90.5 Complex regional pain syndrome/reflex sympathetic dystrophy.

Otherwise, spinal cord stimulation therapy is included on line 529.

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Section 2.0

Staff Report

Novel Coronavirus ICD10 Coding

Per the CDC guidelines, the following are the ICD10 codes to be used for patients with suspected or confirmed COVID19, along with their placements on the Prioritized List/other HSD lists.

ICD10 code	**Code descriptions**	**Current Placement**	**Notes**
J12.89	Other viral pneumonia	304 VIRAL PNEUMONIA	
B97.29	Other coronavirus as the cause of diseases classified elsewhere	615 OTHER VIRAL INFECTIONS	To be used as a secondary code
J20.8	Acute bronchitis due to other specified organisms	459 ACUTE BRONCHITIS AND BRONCHIOLITIS	
J40	Bronchitis, not specified as acute or chronic	635 CHRONIC BRONCHITIS	
J22	Unspecified acute lower respiratory infection	657 RESPIRATORY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	
J98.8	Other specified respiratory disorders	657	
J80	Acute respiratory distress syndrome	233 ADULT RESPIRATORY DISTRESS SYNDROME; ACUTE RESPIRATORY FAILURE; RESPIRATORY CONDITIONS DUE TO PHYSICAL AND CHEMICAL AGENTS	
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	
R05	Cough	DIAGNOSTIC WORKUP FILE (DWF)	
R06.02	Shortness of breath	DWF	
R50.9	Fever, unspecified	DWF	
CPT code			
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism	DIAGNOSTIC PROCEDURES	
99201-99215	Office visits	Covered regardless of diagnosis	
99281-99285	ER visits	Covered regardless of diagnosis	
98966-98968 99441-99443	Telephone assessments/telephone evaluation and management services	Covered on most lines	

HCPCS			
U0001	2019 Novel Coronavirus Real Time RT-PCR Diagnostic Test Panel	New code	Advise HSD to place on DIAGNOSTIC PROCEDURES

Section 3.0

Consent Agenda-

Straightforward Items

Consent Agenda Issues—March 2020

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
31090	Sinusotomy, unilateral, 3 or more paranasal sinuses (frontal, maxillary, ethmoid, sphenoid)	364 ACUTE SINUSITIS	All surgical codes were removed from line 364 in August 2017. CPT 31090 was left on the line by mistake	Remove 31090 from line 364
27709	Osteotomy; tibia and fibula	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	HSD claims reconsideration received a request for pairing of 27709 with ICD10 M92.5 (Juvenile osteochondrosis of tibia and fibula). This code is also used for Blount's disease. According to the orthopedic literature, Blount's disease is typically treated with osteotomy.	Add 27709 to line 359

Essure and Related Procedures Removal from the Prioritized List

Issue: Essure was the only FDA approved permanent contraceptive implant. It was removed from the market in 2018 by the manufacturer after reports of uterine perforations and other adverse events. There are no similar devices on the market or coming to market in the near future. Essure placement in still on the Prioritized List with a guideline regarding its placement.

A similar permanent contraceptive implant, Adiana, was removed from the market in 2012 by the manufacturer.

Current Prioritized List status:
CPT 58565 (Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants) is on line 1 PREGNANCY and 6 REPRODUCTIVE SERVICES

CPT 58340 (Catheterization and introduction of saline or contrast material for saline infusion sonohysterography (SIS) or hysterosalpingography) and CPT 74740 (Hysterosalpingography, radiological supervision and interpretation) are on line 6 solely for use after Essure placement to confirm occlusion.

Removal CPT codes
CPT 58562 Hysteroscopy, surgical; with removal of impacted foreign body) appears on line 424 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
CPT 58661 (Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)) appears on several lines including 6 REPRODUCTIVE SERVICES
CPT 58673 (Laparoscopy, surgical; with salpingostomy (salpingoneostomy)) appears on line 37 ECTOPIC PREGNANCY; HYDATIDIFORM MOLE; CHORIOCARCINOMA
CPT 58700 (Salpingectomy, complete or partial, unilateral or bilateral) appears on several lines including 6 REPRODUCTIVE SERVICES
CPT 58770 (Salpingostomy (salpingoneostomy)) appears on line 37 ECTOPIC PREGNANCY; HYDATIDIFORM MOLE; CHORIOCARCINOMA

GUIDELINE NOTE 68, HYSTEROSCOPIC BILATERAL FALLOPIAN TUBE OCCLUSION

Line 6

Placement of permanent implants in the fallopian tubes to induce bilateral occlusion (CPT code 58565) is covered only if the procedure is done in the office setting, not in the ambulatory surgical center or hospital setting.

Hysterosalpingography (58340, 74740) is covered only for the follow-up testing after placement of permanent implants in the fallopian tubes to induce bilateral occlusion.

Essure and Related Procedures Removal from the Prioritized List

HERC staff recommendations:

1) Remove CPT 58565 (Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants) from lines 1 PREGNANCY and 6 REPRODUCTIVE SERVICES
2) Remove CPT 58340 and 74740 (hysterosalpingography) from line 6 REPRODUCTIVE SERVICES
    a. Advise HSD to add to the Excluded List as an infertility procedure
3) Delete GN68
4) Monitor removal code issues. Currently, the most commonly used CPT codes would pair with complications or with sterilization ICD10 codes and should be sufficient for coverage

Section 4.0

New Discussion Items

Treatment of Female Genital Mutilation

Question: Should coverage for appropriate treatments of female genital mutilation status moved to a funded line on the Prioritized List?

Question source: Tracy Muday, CCO medical director

Issue: Currently, ICD-10 N90.81 (Female genital mutilation status) is on line 656 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY, which does not pair with vaginal repair CPT codes. A CCO recently contacted the HERC regarding several patients who had undergone female genital mutilation as children, and are now experiencing urinary issues, dyspareunia and other symptoms and are requesting repair. CPT 56800 (Plastic repair of introitus) currently appears on 5 covered lines on the Prioritized List, but does not pair with ICD-10 N90.81.

Resources: Because of its connection to issues of gender, culture, and identity, this issue can be difficult to discuss in a sensitive and accurate way. Here are two resources which may be helpful to in choosing language for discussion of this topic:

- https://www.endfgm.eu/resources/end-fgm-network/how-to-talk-about-fgm-using-respectful-and-non-stigmatising-language/?page=&writer=&document=&topic=
- https://www.humandignity.foundation/wp-content/uploads/2018/11/How_to_talk_about_FGM.pdf

Expert input:
See letter from Dr. Maria Rodriguez, OHSU.
Background on female genital mutilation
World Health Organization (WHO), 2020
https://www.who.int/news-room/fact-sheets/detail/female-genital-mutilation
Key facts:

- Female genital mutilation (FGM) involves the partial or total removal of external female genitalia or other injury to the female genital organs for non-medical reasons.
- The practice has no health benefits for girls and women.
- FGM can cause severe bleeding and problems urinating, and later cysts, infections, as well as complications in childbirth and increased risk of newborn deaths.
- More than 200 million girls and women alive today have been cut in 30 countries in Africa, the Middle East and Asia where FGM is concentrated (1).
- FGM is mostly carried out on young girls between infancy and age 15.
- FGM is a violation of the human rights of girls and women.
- WHO is opposed to all forms of FGM, and is opposed to health care providers performing FGM (medicalization of FGM).
- Treatment of health complications of FGM in 27 high prevalence countries costs 1.4 billion USD per year.

American College of Obstetricians and Gynecologists, 2019 *https://www.acog.org/-/media/Statements-of-Policy/Public/98FemaleGenitalMutilationREV.pdf?dmc=1&ts=20191204T1735324456*
Policy Statement on Female Genital Mutilation

- Female genital mutilation is internationally recognized as a human rights violation and is considered an extreme form of discrimination against women.
- According to U.S. federal law (18 U.S. Code § 116), it is illegal to perform FGM in the U.S. on anyone under the age of 18 years; it is also illegal to knowingly transport a girl out of the U.S. for the purpose of having FGM performed. Many state laws also prohibit FGM on minors, and some states prohibit the practice on adult women.
- The American College of Obstetricians and Gynecologists condemns the practice of FGM and supports all efforts to eliminate the practice of FGM in the U.S. as well as internationally. This position is aligned with those of the World Health Organization, the American Medical Association, and the American Academy of Family Physicians

Classification of female genital mutilation
https://www.who.int/reproductivehealth/topics/fgm/overview/en/

- **Type I** — Partial or total removal of the clitoris and/or the prepuce (clitoridectomy). When it is important to distinguish between the major variations of Type I mutilation, the following subdivisions are proposed:
  - **Type Ia**, removal of the clitoral hood or prepuce only;
  - **Type Ib**, removal of the clitoris with the prepuce.
- **Type II** — Partial or total removal of the clitoris and the labia minora, with or without excision of the labia majora (excision). When it is important to distinguish between the major variations that have been documented, the following subdivisions are proposed:
  - **Type IIa**, removal of the labia minora only;
  - **Type IIb**, partial or total removal of the clitoris and the labia minora;
  - **Type IIc**, partial or total removal of the clitoris, the labia minora and the labia majora.
- **Type III** — Narrowing of the vaginal orifice with creation of a covering seal by cutting and appositioning the labia minora and/or the labia majora, with or without excision of the clitoris (infibulation). When it is important to distinguish between variations in infibulations, the following subdivisions are proposed:
  - **Type IIIa**, removal and apposition of the labia minora;
  - **Type IIIb**, removal and apposition of the labia majora.
- **Type IV** — All other harmful procedures to the female genitalia for non-medical purposes, for example: pricking, piercing, incising, scraping and cauterization.

Visual reference is available here:
https://sirc.asu.edu/sites/default/files/fgmc_poster.pdf

Abdulcadir, 2016 https://www.ncbi.nlm.nih.gov/pubmed/27741194
(full text in members packet only)

- FGM, A Visual Reference and Learning Tool for Health Care Professionals

Abdalla, 2019 *https://gh.bmj.com/content/4/4/e001553*

- Systematic review
- Studies examining adverse mental health consequences of FGM
- 16 studies included, only 10 focusing on mental health consequences, sample size 3 to 4800
- Only one received a rating of 'good' methodological quality. Further, the majority of studies reported 'high risk of bias' or 'unclear risk' in one or more of the categories used to assess risk of bias.
- Results
    - 14 out of 16 reported an association between FGM and at least 1 adverse mental health outcome
    - In comparative studies 8 out of 11 studies found a higher burden of adverse mental health outcomes among women who underwent FGM/cutting compared with the control group
    - Overview of studies examining the association between FGM/cutting and adverse mental health outcomes.
- The four studies that stratified their results by FGM/cutting type found an association between the severity of FGM/cutting and the severity adverse mental health outcomes.
- Author conclusion: This systematic review documents an association between FGM/cutting and adverse mental health outcomes. Importantly, our review demonstrates the need for more rigorous research on the topic.

Berg, 2014 *https://bmjopen.bmj.com/content/bmjopen/4/11/e006316.full.pdf*

- Systematic review and meta-analysis of physical health outcomes from FGM
- 185 studies, 3.17 million women; 57 studies had the best available evidence
- The most common immediate complications were excessive bleeding, urine retention and genital tissue swelling.
- The most valid and statistically significant associations for the physical health sequelae of FGM/cutting were seen on:
    - urinary tract infections (unadjusted RR=3.01)
    - bacterial vaginosis (adjusted OR (AOR) =1.68)
    - dyspareunia (RR=1.53)
    - prolonged labour (AOR=1.49)
    - caesarean section (AOR=1.60)
    - difficult delivery (AOR=1.88).
    - A variety of other consequences had inconclusive results such as: scarring, keloids, abscesses, fistulae, damaged tissue (perineum, anal sphincter), disfigurement, vaginal obstruction and cysts, infertility and STIs.
    - Author conclusions: While the precise estimation of the frequency and risk of immediate, gynaecological, sexual and obstetric complications is not possible, the

results weigh against the continuation of FGM/cutting and support the diagnosis and management of girls and women suffering the physical risks of FGM/cutting.

Buggio, 2019 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6386073/

- Narrative review of psychosexual consequences of FGM and reconstructive surgery
- **Results:** Women with FGM/cutting are more likely to develop psychological disorders, such as post-traumatic stress disorder, anxiety, somatization, phobia, and low self-esteem, than those without FGM/cutting. Reconstructive surgery could be beneficial, in terms of both enhanced sexual function and body image. However, prospective studies on the impact of reconstructive surgery are limited, and safety issues should be addressed.
- **Conclusion:** Although it is clear that FGM/cutting can cause devastating immediate and long-term health consequences for girls and women, high-quality data on these issues are limited.

Current Prioritized List Status:

Code	Code Description	Current Prioritized List Placement
N90.810	Female genital mutilation status, unspecified	658
N90.811	Female genital mutilation Type I status	658
N90.812	Female genital mutilation Type II status	658
N90.813	Female genital mutilation Type III status	658
N90.818	Other female genital mutilation status	658

Codes related to female genital reconstructive surgery:

Code	Code Description	Current Prioritized List Placement
Q52.3	Imperforate hymen	353 STRUCTURAL CAUSES OF AMENORRHEA
Q52.5	Fusion of labia	353
Q52.6	Congenital malformation of clitoris	353
Q52.79	Other congenital malformations of vulva	353
Q52.8	Other specified congenital malformations of female genitalia	353
Q52.9	Congenital malformation of female genitalia, unspecified	353
56441	Lysis of labial adhesions	353 563 BENIGN NEOPLASM AND CONDITIONS OF EXTERNAL FEMALE GENITAL ORGANS 629 BENIGN CERVICAL CONDITIONS

Code	Code Description	Current Prioritized List Placement
56501	Destruction of lesion(s), vulva; simple (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery)	286 CANCER OF VAGINA, VULVA, AND OTHER FEMALE GENITAL ORGANS 387 ANOGENITAL VIRAL WARTS 435 PRECANCEROUS VULVAR CONDITIONS 481 CYSTS OF BARTHOLIN'S GLAND AND VULVA 563 BENIGN NEOPLASM AND CONDITIONS OF EXTERNAL FEMALE GENITAL ORGANS
56515	Destruction of lesion(s), vulva; extensive (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery)	286 CANCER OF VAGINA, VULVA, AND OTHER FEMALE GENITAL ORGANS 387 ANOGENITAL VIRAL WARTS 435 PRECANCEROUS VULVAR CONDITIONS 481 CYSTS OF BARTHOLIN'S GLAND AND VULVA
56442	Hymenotomy, simple incision	353
56700	Partial hymenectomy or revision of hymenal ring	353
56800	Plastic repair of introitus	120 ABUSE AND NEGLECT 207 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT 312 GENDER DYSPHORIA/TRANSEXUALISM 353 STRUCTURAL CAUSES OF AMENORRHEA 425 ADRENOGENITAL DISORDERS
56805	Clitoroplasty for intersex state	312 GENDER DYSPHORIA/TRANSEXUALISM 425 ADRENOGENITAL DISORDERS 629 BENIGN CERVICAL CONDITIONS
56810	Perineoplasty, repair of perineum, nonobstetrical (separate procedure)	120 ABUSE AND NEGLECT 312 GENDER DYSPHORIA/TRANSEXUALISM 425 ADRENOGENITAL DISORDERS 466 UTERINE PROLAPSE; CYSTOCELE

Relevant lines

Line: 120
Condition: ABUSE AND NEGLECT (See Guideline Note 64)
Treatment: MEDICAL/PSYCHOTHERAPY
ICD-10: T73.0XXA-T73.0XXD,T73.1XXA-T73.1XXD,T74.01XA-T74.01XD,T74.02XA-T74.02XD, T74.11XA-T74.11XD,T74.12XA-T74.12XD,T74.21XA-T74.21XD,T74.22XA-T74.22XD, T74.31XA-T74.31XD,T74.32XA-T74.32XD,T74.4XXA-T74.4XXD,T74.51XA-T74.51XD, T74.52XA-T74.52XD,T74.61XA-T74.61XD,T74.62XA-T74.62XD,T74.91XA-T74.91XD, T74.92XA-T74.92XD,T76.01XA-T76.01XD,T76.02XA-T76.02XD,T76.11XA-T76.11XD, T76.12XA-T76.12XD,T76.21XA-T76.21XD,T76.22XA-T76.22XD,T76.31XA-T76.31XD, T76.32XA-T76.32XD,T76.51XA-T76.51XD,T76.52XA-T76.52XD,T76.61XA-T76.61XD, T76.62XA-T76.62XD,T76.91XA-T76.91XD,T76.92XA-T76.92XD,Z04.41-Z04.42, Z04.71-Z04.82,Z69.010-Z69.020,Z69.11,Z69.81
CPT: 46700,46706,46707,56800,56810,57023,57200,57210,57415,90785,90832-90840, 90846-90853,90882,90887,93792,93793,96156-96159,96164-96171,98966-98972, 99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99449,99451,99452,99468-99472,99475-99480,99487-99491,99495-99498,99605-99607
HCPCS: G0068,G0071,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427,G0463-G0467,G0490,G0508-G0511,G2010-G2012,G2058-G2065,H0038,H2014,H2027

Line: 353
Condition: STRUCTURAL CAUSES OF AMENORRHEA (See Guideline Note 176)
Treatment: SURGICAL TREATMENT
ICD-10: N85.7,N89.5-N89.7,N90.810,N92.5,N99.2,Q51.0,Q51.5,Q51.7,Q51.820-Q51.9, Q52.0,Q52.10-Q52.11,Q52.121-Q52.8,Z40.03,Z43.7
CPT: 56441,56442,56700,56800,57130,57291-57295,57400,57426,57800,58120,58700, 93792,93793,98966-98972,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99449,99451,99452,99468-99472,99475-99480,99487-99491,99495-99498,99605-99607
HCPCS: G0068,G0071,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427,G0463-G0467,G0490,G0508-G0511,G2010-G2012,G2058-G2065

Relevant part of guideline on surgery for gender dysphoria is included here:
GUIDELINE NOTE 127, GENDER DYSPHORIA (excerpt)

> Revisions to surgeries for the treatment of gender dysphoria are only covered in cases where the revision is required to address complications of the surgery (wound dehiscence, fistula, chronic pain directly related to the surgery, etc.). Revisions are not covered solely for cosmetic issues.
>
> Pelvic physical therapy (CPT 97110,97140,97161-97164, and 97530) is included on this line only for pre- and post-operative therapy related to genital surgeries also included

on this line and as limited in Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES.

Evidence Summary for surgical interventions:

Berg, 2017 *https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/1471-0528.14839*

- Systematic review
- 62 studies, 5829 women investigated the effect of defibulation, excision of cysts, and clitoral reconstruction
- 13 comparative studies with 4743 participants: four retrospective case series with two or more groups, two prospective cohort studies with two or more groups, one controlled before-and-after study, and six uncontrolled before and after studies. The remaining 49 studies were non-comparative studies
- The majority (70%) had FGM type III, whereas almost all the other women had type II (28%).
- Three types of interventions were identified, all surgical: defibulation/surgical separation of fused labia; excision of cysts (generally with some form of reconstruction of the clitoris and/or labia); and clitoral/clitorolabial reconstructive surgery.
- Defibulation/surgical separation of fused labia (Type II and III) – 32 studies. Mostly focused on obstetric outcomes.
    - Meta-analyses of defibulation versus no defibulation showed a significantly lower risk of caesarean section (relative risk, RR: 0.33; 95% confidence interval, 95% CI: 0.25–0.45) and perineal tears with defibulation: second-degree tear (RR: 0.44, 95% CI: 0.24–0.79), third-degree tear (RR: 0.21, 95% CI: 0.05–0.94), fourth-degree tear (RR: 0.06, 95% CI: 0.01–0.41). The metaanalyses detected no significant differences in obstetric outcomes of antenatal versus intrapartum defibulation.
    - 5 studies (n=436) reported on Intraoperative complications, there were none. Postoperative complications occurred among 12.4% and were minor.
    - Recovery and healing were satisfactory at 1– 3 months of follow-up, with good anatomical results (k = 13, n = 117).
    - Twelve studies (n = 191) reported on outcomes related to sexual function. Sexual function was positively impacted.
- Cyst excision – 21 studies.
    - Except for one study, none of the studies on the excision of cysts indicated any complications, and the results were deemed favourable.
- Clitoral reconstructive surgery (Type 1) – 9 studies mostly addressed sexuality related outcomes.
    - Reconstructive surgery resulted in a visible clitoris in about 77% of women. Most women self-reported improvements in their sexual life, but up to 22% experienced a worsening in sexuality-related outcomes after reconstruction.

- Author conclusions: Women with FGM/Cutting who seek therapeutic surgery should be informed about the scarcity of evidence for benefits and the potential harms of the available procedures.

Abdulcadir, 2015 [coauthor OHSU faculty Maria Rodriguez]
https://obgyn.onlinelibrary.wiley.com/doi/full/10.1016/j.ijgo.2014.11.008

- Systematic review of clitoral reconstruction for female genital mutilation/cutting
- 4 articles, fair to poor quality
- No summary measures due to high heterogeneity. Studies had significant limitations: 3 with no comparison group, use of non-validated measures, loss to follow up, using surgeon assessment as primary outcome.
- Outcomes include sexual functioning, appearance, safety
- Complication rate is 5-30%
- Author conclusions: Women who request clitoral reconstruction should be informed about the scarcity of evidence available. There is a need for more robust evidence on safety and efficacy before this surgery is widely disseminated.

Recommendations from Others

Royal College of Obstetricians and Gynecologists, 2015
https://www.rcog.org.uk/globalassets/documents/guidelines/gtg-53-fgm.pdf

- Women who are likely to benefit from de-infibulation should be counselled and offered the procedure before pregnancy, ideally before first sexual intercourse.
- Women offered de-infibulation should have the option of having the procedure performed under local anaesthetic in the clinic setting in a suitable outpatient procedures room
- All women should be offered referral for psychological assessment and treatment, testing for HIV, hepatitis B and C and sexual health screening. Where appropriate, women should be referred to gynaecological subspecialties, e.g. psychosexual services, urogynaecology, infertility.
- Clitoral reconstruction should not be performed because current evidence suggests unacceptable complication rates without conclusive evidence of benefit.

World Health Organization, 2016
https://apps.who.int/iris/bitstream/handle/10665/206437/9789241549646_eng.pdf?sequence=1

Summary of the recommendations (R) and best practice statements (BP)

DEINFIBULATION

R-1 Deinfibulation is recommended for preventing and treating obstetric complications in women living with type III FGM (strong recommendation; very low-quality evidence).

R-2 Either antepartum or intrapartum deinfibulation is recommended to facilitate childbirth in women living with type III FGM (conditional recommendation; very low-quality evidence).

R-3 Deinfibulation is recommended for preventing and treating urologic complications – specifically recurrent urinary tract infections and urinary retention – in girls and women living with type III FGM (strong recommendation; no direct evidence).

BP-1 Girls and women who are candidates for deinfibulation should receive adequate preoperative briefing (Best practice statement).

BP-2 Girls and women undergoing deinfibulation should be offered local anaesthesia (Best practice statement).

MENTAL HEALTH

R-4 Cognitive behavioural therapy (CBT) should be considered for girls and women living with FGM who are experiencing symptoms consistent with anxiety disorders, depression or post-traumatic stress disorder (PTSD) (conditional recommendation; no direct evidence).

BP-3 Psychological support should be available for girls and women who will receive or have received any surgical intervention to correct health complications of FGM (Best practice statement).

FEMALE SEXUAL HEALTH

R-5 Sexual counselling is recommended for preventing or treating female sexual dysfunction among women living with FGM (conditional recommendation; no direct evidence).

INFORMATION AND EDUCATION

BP-4 Information, education and communication (IEC)[4] interventions regarding FGM and women's health should be provided to girls and women living with any type of FGM (Best practice statement).

BP-5 Health education[5] information on deinfibulation should be provided to girls and women living with type III FGM (Best practice statement).

BP-6 Health-care providers have the responsibility to convey accurate and clear information, using language and methods that can be readily understood by clients (Best practice statement).

BP-7 Information regarding different types of FGM and the associated respective immediate and long-term health risks should be provided to health-care providers who care for girls and women living with FGM (Best practice statement).

BP-8 Information about FGM delivered to health workers should clearly convey the message that medicalization is unacceptable (Best practice statement).

HERC Staff Summary

FGM is internationally recognized as a violation of human rights. Long-term adverse health consequences of FGM appear to be psychological and physical including higher rates of urinary tract infections, dyspareunia, and obstetric complications. Currently, female genital mutilation status is an unfunded condition and therefore does not pair with behavioral or surgical treatments. Offering psychological treatment is recommended as a best practice. Limited evidence is available about the surgical repair of FGM. Evidence demonstrates improvements in obstetric outcomes from defibulation/surgical separation of fused labia after Type II or III FGM. Cyst excision (could be associated with a variety of Types of FGM) has benefit and no harms. Clitoral reconstruction for Type I FGM has insufficient evidence to understand benefits/harms.

Moving female genital mutilation status codes to the funded region requires some clarity, that the intent is for treatments to pair (e.g. surgery and psychological treatments) but not the procedures involved in performing female genital mutilation. Therefore, adding clarity that the intent is not to cover FGM may be prudent, given that there may be cases in which FGM may be requested, such as re-infibulation following vaginal delivery.

HERC staff recommendations:

1) Add the following ICD-10 codes to Line 120 Abuse and Neglect to pair with psychotherapy and surgery codes

N90.810	Female genital mutilation status, unspecified
N90.811	Female genital mutilation Type I status
N90.812	Female genital mutilation Type II status
N90.813	Female genital mutilation Type III status
N90.818	Other female genital mutilation status

These codes will also pair with surgical repair on this line:

56800	Plastic repair of introitus
56810	Perineoplasty, repair of perineum, nonobstetrical (separate procedure)

2) Add these CPT codes to Line 120

13131	Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 1.1 cm to 2.5 cm
56441	Lysis of labial adhesions

3) Add a guideline

GUIDELINE NOTE XXX SURGERIES RELATED TO FEMALE GENITAL MUTILATION
Line 120

Female genital mutilation of children or adults is not included on any line on the Prioritized List, including returning a woman to her former status after delivery.

Repair of female genital mutilation (e.g. Type II or III) with defibulation or lysis of adhesions is included on this line when causing interference in function (i.e. urinary, menstrual, or potential future vaginal childbirth) or causing recurrent complications including chronic pain related to the mutilation. Clitoral reconstruction is not included on this line due to an unclear risk/benefit ratio.

4) Delete FGM ICD-10 codes (N90.81X) from Line 658 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

5) Rename line 629

    a. BENIGN ~~CERVICAL~~ GYNECOLOGICAL CONDITIONS
    b. It has diagnoses that are not limited to the cervix but also include vulvar and vaginal diagnosis codes.

Current Commentary

Female Genital Mutilation

A Visual Reference and Learning Tool for Health Care Professionals

Jasmine Abdulcadir, MD, Lucrezia Catania, MD, Michelle Jane Hindin, PhD, Lale Say, MD, Patrick Petignat, MD, and Omar Abdulcadir, MD

Female genital mutilation comprises all procedures that involve partial or total removal of the external female genitalia or injury to the female genital organs for nonmedical reasons. Health care providers for women and girls living with female genital mutilation have reported difficulties in recognizing, classifying, and recording female genital mutilation, which can adversely affect treatment of complications and discussions of the prevention of the practice in future generations. According to the World Health Organization, female genital mutilation is classified into four types, subdivided into subtypes. An agreed-upon classification of female genital mutilation is important for clinical practice, management, recording, and reporting, as well as for research on prevalence, trends, and consequences of female genital mutilation. We provide a visual reference and learning tool for health care professionals. The tool can be consulted by caregivers when unsure on the type of female genital mutilation diagnosed and used for training and surveys for monitoring the prevalence of female genital mutilation types and subtypes.

(Obstet Gynecol 2016;128:958–63)

DOI: 10.1097/AOG.0000000000001686

From the Department of Obstetrics and Gynaecology, Geneva University Hospitals, Faculty of Medicine, University of Geneva, and the Department of Reproductive Health and Research, World Health Organization, Geneva, Switzerland; and the Regional Referral Centre for the Treatment and Prevention of FGM, Health Promotion of Immigrant Woman, Department of Maternal and Child Integrated Activity, University of Florence, Florence, Italy.

Supported by the World Health Organization.

The authors thank Svetlin Kolev for his help in making the video.

The views expressed in this document are solely the responsibility of the authors and do not necessarily represent the views of the World Health Organization or its member countries.

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Financial Disclosure

The authors did not report any potential conflicts of interest.

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ISSN: 0029-7844/16

Female genital mutilation comprises all procedures that involve partial or total removal of the external female genitalia or injury to the female genital organs for nonmedical reasons.[1] According to the World Health Organization (WHO), female genital mutilation is classified into four types, subdivided

Box 1. World Health Organization Classification of Female Genital Mutilation

Type I: Partial or total removal of the clitoris* and/or the prepuce (clitoridectomy)
- Type Ia: Removal of the clitoral hood or prepuce only
- Type Ib: Removal of the clitoris* with the prepuce

Type II: Partial or total removal of the clitoris* and the labia minora, with or without excision of the labia majora (excision)
- Type IIa: Removal of the labia minora only
- Type IIb: Partial or total removal of the clitoris* and the labia minora
- Type IIc: Partial or total removal of the clitoris,* the labia minora and the labia majora

Type III: Narrowing of the vaginal orifice with creation of a covering seal by cutting and apposition the labia minora and/or the labia majora, with or without excision of the clitoris (infibulation)
- Type IIIa: Removal and apposition of the labia minora
- Type IIIb: Removal and apposition of the labia majora

Type IV: Unclassified

All other harmful procedures to the female genitalia for nonmedical purposes, for example, pricking, piercing, incising, scraping and cauterisation

* In the World Health Organization classification, when there is reference to removal of the clitoris, only the glans or the glans with part of the body of the clitoris is removed. The body or part of the body and the crura of the clitoris remain intact as well as the bulbs, two other sexual erectile structures.[13]

Reprinted from OHCHR, UNAIDS, UNDP, UNECA, UNESCO, UNFPA, UNHCR, UNICEF, UNIFEM, WHO. Eliminating female genital mutilation: an interagency statement. Available at: http://www.un.org/womenwatch/daw/csw/csw52/statements_missions/Interagency_Statement_on_Eliminating_FGM.pdf. Retrieved July 19, 2016. Copyright 2016.

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Section 5.0

Biennial Review

Prioritization 101 and the 2022 Biennial Review of the Prioritized List

Value Based Benefits Subcommittee
March 12, 2020

Oregon Health Authority

The Prioritized List of Health Services

- List is the cornerstone of Oregon's original 1115 Medicaid Waiver in 1994
- Ranks health services from "most important to least important"
  - Sets OHP benefit package
  - Provide basis of rates developed for CCOs
- Based on "pairings" of conditions and treatments
- Funding line set by legislature, according to available resources
- Includes guideline notes

Updating the List

Biennial review

- Effective January 1st of even numbered years
- Significant changes
  - Line movement
  - Line merging/splitting
  - Changes involving significant fiscal impact

Interim modifications

- Effective every January 1st and October 1st
- Technical changes
  - Incorporation of new diagnosis/procedure codes
  - Add appropriate pairings/delete inappropriate pairings
  - Guideline note additions/revisions
  - Fix errors

Current Methodology: Categories of Care

Category	Weight
1) Maternity/Newborn Care	100
2) Primary & Secondary Prevention	95
3) Chronic Disease Management	75
4) Reproductive Services	70
5) Comfort Care	65
6) Fatal Conditions – Disease Modification/Cure	40
7) Nonfatal Conditions – Disease Modification/Cure	20
8) Self-limited Conditions	5
9) Inconsequential Care	1

Oregon Health Authority

Category examples

1) Maternity/Newborn Care: prenatal care; delivery services; postpartum care; newborn care
2) Primary & Secondary Prevention: immunizations; fluoride treatment in children; mammograms; pap smears
3) Chronic Disease Management: diabetes mellitus, asthma, and hypertension
4) Reproductive Services: contraception, vasectomy
5) Comfort Care: hospice care
6) Fatal Conditions – Disease Modification/Cure: appendectomy for appendicitis; medical & surgical treatment for treatable cancers; dialysis for end-stage renal disease
7) Nonfatal Conditions – Disease Modification/Cure: treatment of closed fractures; medical/psychotherapy for obsessive-compulsive disorder
8) Self-limited Conditions: medical therapy for diaper rash, acute conjunctivitis and acute pharyngitis
9) Inconsequential Care: medical therapy for viral warts

Oregon Health Authority

Current Methodology: Individual/Population Impact Measures

• Impact on Healthy Life	(+ 0 to 10)
• Impact on Suffering	(+ 0 to 5)
• Population Effects	(+ 0 to 5)
• Vulnerability of Population Affected	(+ 0 to 5)
• Tertiary Prevention	(+ 0 to 5)
• EFFECTIVENESS	(x 0 to 5)
• NEED FOR MEDICAL SERVICES	(x 0 to 100%)
• Net Cost	(0 to 5)

- Details available at https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Prioritization-Methodology.aspx

Oregon Health Authority

Definitions

- **Impact on Healthy Life** - Magnitude of the benefit to the patient from the treatment as compared to no treatment, after factoring in harms associated with the treatment
  - Examples: congenital heart disease (10), major depression (7), dental cleaning (5), scabies (1)
- **Impact on Suffering** - To what degree does the condition result in pain and suffering to patient, family, caregivers
  - Examples: severe burns (5), deep open wound (3), hypertension (0)
- **Population Effects** - The degree to which individuals other than the person with the illness will be affected.
  - Example: syphilis (5), food poisoning (3), heart valve disease (0)

Definitions continued

- **Vulnerability of Population Affected** - To what degree does the condition affect vulnerable populations such as those of certain racial/ethnic descent or those afflicted by certain debilitating illnesses such as HIV disease or alcohol & drug dependence
  - Examples: schizophrenia (4), substance use disorder (1), type 1 diabetes (0)
- **Tertiary Prevention** - In considering the ranking of services within new categories 6 and 7, to what degree does early treatment prevent complications of the disease (not including death)
  - Examples: DVT (5—prevents PEs), nutritional deficiencies (3), treating existing cancer (0)
- **Effectiveness** - To what degree does the treatment achieve its intended purpose?
  - Examples: vaccines (5), asthma (4), colds (1)

Still more definitions

- **Need for Medical Services** - The percentage of time in which medical services would be required after the diagnosis has been established.
  - Examples: pregnancy (1), acute sinusitis (0.8), medications for menopause (0.5), bruise (0)
- **Net Cost** - The cost of treatment for the typical case (including lifetime costs associated with chronic diseases) minus the expected costs if treatment is not provided — including costs incurred through safety net providers (e.g., emergency departments) for urgent or emergent care related to the injury/illness or resulting complications
  - Examples: leukemia (1), evaluation of abnormal pap (3), dental cleanings (5)

Current Methodology: Line Item Score

$$\text{Category Weight} \times \frac{\text{Impact on Healthy Life} + \text{Impact on Suffering} + \text{Population Effects} + \text{Vulnerability of Population Affected} + \text{Tertiary Prevention } \textit{(Cat. 6 \& 7 only)}}{\text{Sum of Five Impact Measure Scores}} \times \text{Need for Service} \times \text{Effectiveness}$$

Oregon Health Authority

Example of Scoring: Type 2 Diabetes Mellitus

- Impact on Healthy Life: 7
- Impact on Suffering: 2
- Effects on Population: 0
- Vulnerability of Population Affected: 2
- Effectiveness: 4
- Need for Service: 1
- Net Cost: 4
- Category 3 Weight: 75

Total Score: 3300 → Line: 27

Examples of Rankings in 2020-2021

Funded Lines (1-471):

22	Schizophrenia
47	Appendicitis
53	Preventive Dental Services
139	Glaucoma
191	Breast Cancer
343	Dental Caries (Fillings)
355	Closed Fracture of Extremities
368	Strep Throat
402	Nonsurgical treatment for back condition
410	Migraine Headaches

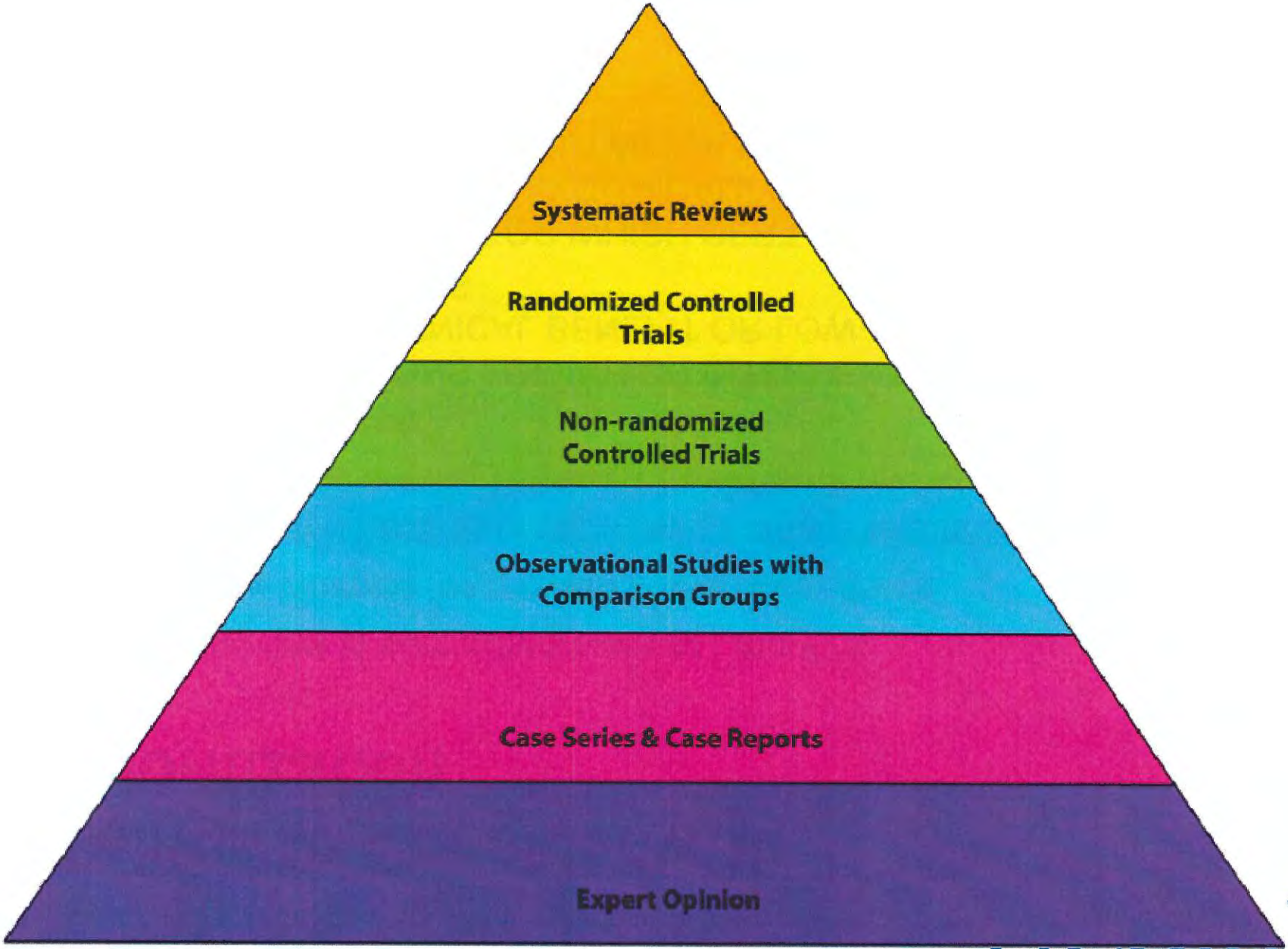
Unfunded Lines (472-662):

475	Chronic Otitis Media
513	Esophagitis and GERD (long-term medical therapy)
524	Uncomplicated Hernia
561	Nasal allergies
606	Sleep Disorders w/o Apnea
614	Common Cold
618	Orthodontia

Things to Consider with Prioritization

- Funding line is currently frozen at Line 471
- Rely on evidence for moving a line up or down
- Cost-effectiveness only considered where available when outcomes are similar between treatments on two lines
- Two special lines:
  - 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS
  - 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

Oregon Health Authority


Systematic Reviews
Randomized Controlled Trials
Non-randomized Controlled Trials
Observational Studies with Comparison Groups
Case Series & Case Reports
Expert Opinion

2022 Biennial Review
Proposed Topics

1) Back lines review
    a. Will move forward with topic when AHRQ reviews become available
    b. May or may not be biennial review—only if line movement is seen as necessary. If only procedures are added/removed, can be an interim modification
2) Surgical treatment of chronic pancreatitis
    a. See separate summary
3) Foreign body in ear/nose
    a. See separate summary
4) Meniere's disease
    a. See separate summary
5) Fecal incontinence:
    a. Fecal incontinence (ICD10 R15.9 Full incontinence of feces) is currently on line 528 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS
    b. Suggested for review by VbBS and HERC after reviewing the effectiveness of sacral nerve stimulation for fecal incontinence in August 2019.
    c. **AHRQ 2016** evidence review did not find evidence of effectiveness for any intervention beyond 6 months other than fiber supplementation.
    d. Supplies such as incontinence garments are being covered as DME
    e. *Staff recommendation:* do not consider reprioritization
6) Review prioritization and treatments for chronic sinusitis
    a. Reviewed recurrent acute rhinosinusitis (RARS) in August 2017. VBBS requested that the effectiveness of surgical treatment for sinusitis be reviewed and the chronic sinusitis lines scoring be examined based on that effectiveness
    b. Initial literature review by HERC staff finds that the evidence base for the effectiveness of surgery for chronic sinusitis consists of case series. However, this limited literature does show benefit for treatment with intranasal steroids, nasal irrigation, and endoscopic sinus procedures
    c. *Staff recommendation*: do not consider reprioritization
7) Other topics
    a. To be considered as they arise

2022 Biennial Review
Surgical Treatment of Chronic Pancreatitis

Question: Should surgical treatment of chronic pancreatitis be moved to a higher priority position on the Prioritized List?

Question source: VbBS

Issue: In August 2019, VbBS and HERC reviewed islet cell transplantation for patients undergoing total pancreatectomy for chronic pancreatitis. This procedure was found to be effective. During that review, subtotal and total pancreatectomy CPT codes were added to the surgical treatment of chronic pancreatectomy line

Chronic pancreatitis is long-term inflammation of the pancreas characterized by an irreversible, permanent and progressive destruction of the pancreatic tissue. Chronic pancreatitis is a disabling condition with a number of symptoms, of which the most debilitating is severe abdominal pain. Current treatment is mainly symptom control, including opioid therapy. Some patients may benefit from surgical procedures; these may include drainage procedures in patients where there is dilatation of the main pancreatic duct and/or segmental resection of the pancreas where appropriate. Such procedures are covered on the upper chronic pancreatitis line. The primary goal of surgery is to remove the cause of the symptoms by removing the pancreas (total pancreatectomy), with an aim to control pain resistant to other therapies.

The evidence reviewed in August 2019, included a Cochrane review (Ahmed 2015) that found that surgery was superior to endoscopic procedures for providing pain relief. Similarly, a review by Hartmann et al (2016) found “strong evidence that surgical therapy for painful obstructive chronic pancreatitis leads to significantly better long-term results than endoscopic interventions and that early surgical intervention is associated with improved postoperative pain relief.”

The chronic pancreatitis surgical line was hand scored to its current position.

2022 Biennial Review
Surgical Treatment of Chronic Pancreatitis

Current Prioritized List status

1) 250 CHRONIC PANCREATITIS Treatment: MEDICAL THERAPY
    a. Included endoscopic surgical procedures
2) 599 CHRONIC PANCREATITIS Treatment: SURGICAL TREATMENT
    a. ICD-10 K86.0 and K86.1 are included on line 250

Line prioritization 250 CHRONIC PANCREATITIS Treatment: MEDICAL THERAPY
Category: 3
Healthy life years: 6
Suffering: 2
Population effects: 0
Vulnerable population: 1
Tertiary prevention: 0
Effectiveness: 2
Need for treatment: 1
Net cost: 3
Score: 1350
Line placement: 250

Line prioritization 599 CHRONIC PANCREATITIS Treatment: SURGICAL TREATMENT
Category: 7
Healthy life years: 3
Suffering: 3
Population effects: 0
Vulnerable population: 1
Tertiary prevention: 0
Effectiveness: 1
Need for treatment: 1
Net cost: 2
Score: 7
Line placement: 599

2022 Biennial Review
Surgical Treatment of Chronic Pancreatitis

HERC staff summary

Partial pancreatectomy appears, based on limited data, to result in significant pain relief and improved quality of life for patients with chronic pancreatitis, particularly that caused by chronic duct obstruction. Partial or total pancreatectomy is the end step in standard treatment algorithms for chronic pancreatitis. Meta-analyses indicate that surgery has better pain reduction outcomes than the endoscopic procedures which are currently included on the medical chronic pancreatitis line.

Based on previous VbBS discussion, surgical treatment of chronic pancreatitis should be reprioritized to a higher position on the List.

HERC staff recommendations:

1) Combine the medical and surgical lines for chronic pancreatitis and keep at prioritization line 250
    a. Endoscopic procedures on the upper line are no more effective and possibly less effective that the surgical procedures on the lower line
2) Change the treatment description to "MEDICAL AND SURGICAL THERAPY"
3) Move all CPT codes from line 599 to line 250 that do not currently appear there
    a. All ICD-10 codes on line 599 already appear on line 250

Reprioritization of CHRONIC PANCREATITIS Treatment: SURGICAL TREATMENT
(Current scores for line 599 and line 250 shown in parentheses)
Category: 3 (7; 3)
Healthy life years: 6 (3; 6)
Suffering: 2 (3; 2)
Population effects: 0
Vulnerable population: 1
Tertiary prevention: 0
Effectiveness: 2 (1; 2)
Need for treatment: 1
Net cost: 2 (2; 3)
Score: 1350 (7; 1350)
Line placement: 250 (599; 250)

Foreign Body in Nose or Ear
Biennial Review 2022

Question: Should the line for foreign bodies in the nose or ear be moved to a higher priority?

Question source: CCO, ENT provider

Issue: Currently, foreign bodies in the nose and ear (ICD-10 T16 Foreign body in ear; ICD-10 T17 Foreign body in nasal sinus or nostril) are on line 477 FOREIGN BODY IN EAR AND NOSE, which is below the funding line. If the foreign body in the nose or ear causes a laceration or puncture wound, then the diagnosis is on line 207 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT.

Foreign bodies in the nose or ear are common complaints in the primary care office or in the ER. Toys, beads, food, and other objects may be inserted. Children most commonly insert foreign bodies into ears and noses. Removal of these foreign bodies is currently not covered by OHP unless there is a comorbid condition such as hearing loss. An ENT proposed that we move this line above the funding line as removal of objects in the ear or nose is generally done at the time of the visit, and prior authorization of the removal is not possible.

Reported complications from foreign bodies in the nose and ear include sinusitis, acute otitis media, nasal septal perforation, and epistaxis.

Figueiredo 2008, case series of foreign bodies in nose and ear

1) N=1356 patients
2) most frequent age was between 1 and 4 years old.
3) FBs in the ear may lead to tympanic perforation and deafness, particularly if there is secondary infection. Severe nose bleeding associated with FBs is not uncommon
4) Complications were seen in 301 cases (22.20%), including those resulting from removal procedures. Complications were iatrogenic in 159 cases (11.70%).
5) the most frequent complications were bleeding (51.83% of complications), fetidness due to bacterial infection (28.57%) and external otitis (10.30%). There were fewer serious complications such as necrosis (1.33%) and tympanic perforation (0.99%).
6) delays in removing FBs increase the frequency of non-iatrogenic complications, which reinforces the importance of prompt treatment

Utilization:
Claims search found almost 20,000 paid claims for these diagnoses over a 1-year time (FFS and CCO), and almost 8000 denied claims

Lines with similar diagnoses on the Prioritized List
Line 116 FOREIGN BODY IN PHARYNX, LARYNX, TRACHEA, BRONCHUS AND ESOPHAGUS
Line 439 RESIDUAL FOREIGN BODY IN SOFT TISSUE Treatment: REMOVAL
Line 499 CERUMEN IMPACTION Treatment: REMOVAL OF EAR WAX

Foreign Body in Nose or Ear
Biennial Review 2022

HSC/HERC history

On the early Prioritized List, impacted cerumen and foreign body in ear where on the same line, which was below the funding line. In December 2005, foreign body in the ear was discussed. The HOSC at that time decided that foreign body in the ear should be equitably prioritized with cerumen impaction. It was noted that if hearing loss results, removal would be covered through the co-morbidity rule. After this discussion, a new line was created at the next biennial review for foreign body in the nose and year, which was prioritized very closely with cerumen impaction. The line scoring was done by hand, rather than by the usual scoring formula.

Current line scoring:

Current line scoring for line 477: not done. Hand moved to current location

Line 499 CERUMEN IMPACTION
Category: 7
Healthy life years: 1
Suffering: 0
Population effects: 0
Vulnerable population: 1
Tertiary prevention: 0
Effectiveness: 4
Need for treatment: 0.9
Net cost: 4
Score: 144
Line placement: 499

Foreign Body in Nose or Ear
Biennial Review 2022

HERC staff summary

Foreign bodies requiring removal from the ears and nose are common occurrences, and generally cannot be prior authorized as they are removed at the time of the first visit. Complications occur when foreign bodies are not removed, including infection and damage to the nose or ear. Complication rates increase if removal is delayed. OHP is currently paying for large numbers of claims for foreign bodies from these orifices; therefore, any change putting this line above the funding line should not have a large impact on overall OHP costs.

HERC staff recommendation:

1) Rescore the line for foreign bodies in the ear and nose as shown below

Line XXX FOREIGN BODY IN EAR AND NOSE

Line prioritization (no current scores—line hand placed previously. Scores proposed below are based on the scoring for line 499 CERUMEN IMPACTION with suffering changed from 0 to 1; tertiary prevention changed from 0 to 1 and need for treatment changed from 0.9 to 1)

Category: 7
Healthy life years: 1
Suffering: 1
Population effects: 0
Vulnerable population: 1
Tertiary prevention: 1
Effectiveness: 4
Need for treatment: 1
Net cost: 4
Score: 320
Line placement: 428 (current funding line 471)

Rev Bras Otorrinolaringol
2008;74(1):7-15.

ORIGINAL ARTICLE

Complications of ent foreign bodies: a retrospective study

Ricardo Rodrigues Figueiredo [1], Andréia Aparecida de Azevedo [2], Arthur Octavio de Ávila Kós [3], Shiro Tomita [4]

Keywords: complications, foreign bodies, otolaryngology.

Summary

Foreign bodies are one of the most common ENT (Ear, Nose and Throat) urgencies. Serious complications may occur, like tympanic perforations and bronchoaspiration, but they are uncommon. **Aim:** To analyze a 1356 foreign body series and establish causes for the complications, looking at prevention. **Materials and methods:** 1356 patients with ear, nose and throat foreign bodies from the ENT Department of Souza Aguiar Hospital, in Rio de Janeiro, between 1992 and 2000, were analyzed in a retrospective study for parameters like age, gender, type and localization of the foreign body, time span between introduction and removal of the foreign body and complications. **Results:** The most common foreign bodies were beans and the most frequent age was between 1 and 4 years old. Ear foreign bodies were the most common, followed by nasal foreign bodies. Complications were statistically related to time, child's age and practical experience of the physician. **Conclusion:** Most of the situations related to ENT foreign bodies are avoidable. Improvements in Public Health Assistance and otolaryngologists' training are essential to avoid serious complications.

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Paper submitted to the ABORL-CCF SGP (Management Publications System) on September 13th, 2006 and accepted for publication on November 9th, 2006. cod. 3392.

INTRODUCTION

According to the literature,[1-4] foreign bodies are responsible, on average, for 11% of otorhinolaryngological emergencies; complications ensue in 22% of cases. Most of these complications are easily resolved, but occasionally severe conditions may emerge, such as tympanic perforation and bronchoaspiration.[4,5]

Decisive factors contributing to complications[3,4] are:

removal attempts by laypersons and untrained health professionals;

•lack of medical experience in managing foreign bodies;

lack of adequate hospital infrastructure;

poor structure of the public health sector for dealing with otorhinolaryngological emergencies;

•foreign body remaining within the site for a long period, frequently due to the previous item.

Our purposes in this paper were:

to describe our 8-year experience in managing foreign bodies of the ear, nose, pharynx and larynx;

to analyze the main factors leading to complications by studying 1,356 foreign body removal cases and seeking forms of avoiding those complications.

PATIENTS, MATERIAL AND METHOD

We conducted a retrospective analysis of 1,356 foreign body cases seen at our Unit between December 1992 and December 2000. Six parameters were taken into account: age, sex, site of foreign body (FB), type of FB, complications, duration of the period between FB introduction and removal and date of removal (between 1992 and 2000). About this last parameter, its aim was to establish a relation between the otorhinolaryngologist's experience and the presence of complications, given that the same medical doctor (the author) removed all FB. We also analyzed the relation between complications and other parameters; complications were classified as iatrogenic and non-iatrogenic (the set of complications was named "complications in general"). The chi-square ($\chi 2$) test and Fisher's exact test were used for statistical analyzing the relation between complications on the one hand and sex, age, type of FB, site, duration until removal and date of FB removal on the other. The significance level was 5%, that is, there was no statistical significance when the statistical test p value was equal to or below 0.05.

The surgical materials used for FB removal included nasal and auricular speculae, Bruennings tongue retractors, rigid 4 mm diameter optic fibers (70°, 0° and 30°), Kelly and bayonet forceps, an optic fiber laryngoscope, Hartmann and alligator forceps, blunt and pointed hooks, syringes for ear lavage and an electrical ear cleaner. The Research Ethics Committee of the Souza Aguiar Municipal Hospital approved this study (protocol number 32/2003).

RESULTS

OF 1,356 FB cases, 753 (55.53%) were in the ear, 420 (30.97%) were nasal, 179 (13.21%) were pharyngeal, and 4 (0.29%) were laryngeal FBs. There were 129 pharyngeal FBs lodged in the tonsils (72.06%), of which 65 were in the right tonsil and 64 in the left tonsil. There were 31 FB cases (17.32%) in the base of the tongue, 12 (6.70%) in the vallecula, 3 (1.68%) in the right supratonsillar recess (STR), 2 (1.12%) in the hypopharynx, and 2 (1.12%) in tonsillar areas (tonsillectomized patients), of which 1 was to the right and 1 to the left.

There were 674 cases (49.70%) in females and 682 cases (51.30%) in males. The age distribution may be seen in Chart 1.

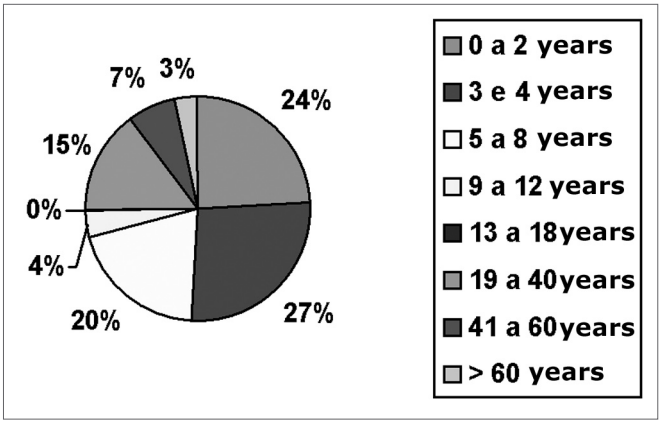

Chart 1- Distribution by age range

The type of FBs may be seen in Chart 2. The acronym SPA means "Small Plastic Artifacts." Beans and corn grains were not included in this chart and were analyzed separately.

Live FBs are described in Chart 3.

There were no complications in 1,055 cases (77.80%). Complications were seen in 301 cases (22.20%), including those resulting from removal procedures. Complications were iatrogenic in 159 cases (11.70%). The types of complications may be seen in Chart 4.

Chart 5 shows the time elapsed between FB introduction and removal. The mean duration was 9.71 hours.

Table 1 shows the frequency (n) and the percentage (%) for sex, age, type, site, duration and date related to the presence and absence of complications in general. The chi-square ($\chi 2$) test was used for the statistical analysis. After this point, bean and corn grains were included in the item "seeds".

Table 2 shows the frequency (n) and the percentage

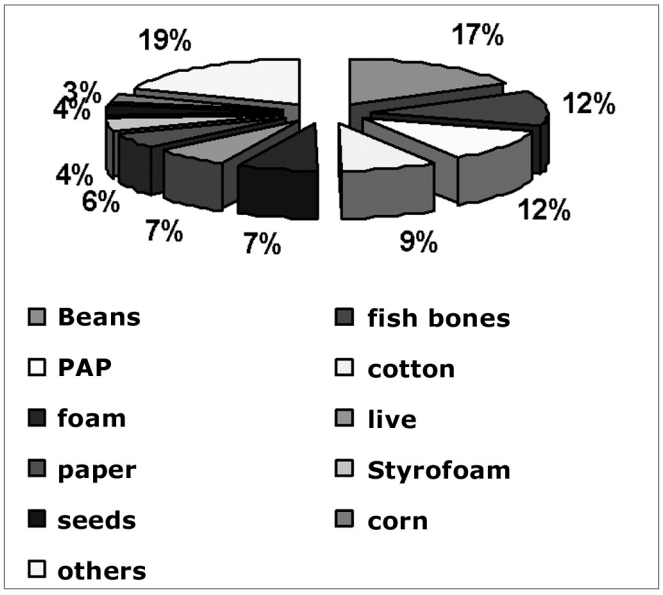

Chart 2. FB types

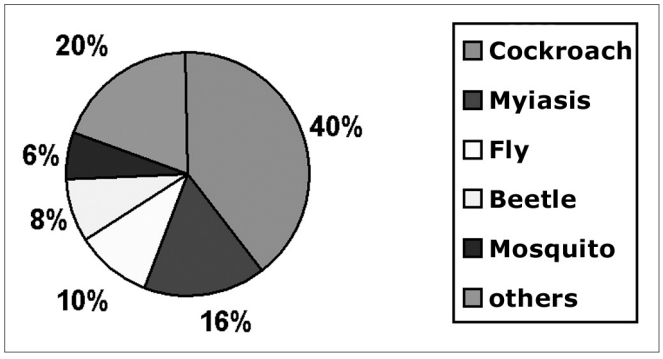

Chart 3. Live FB

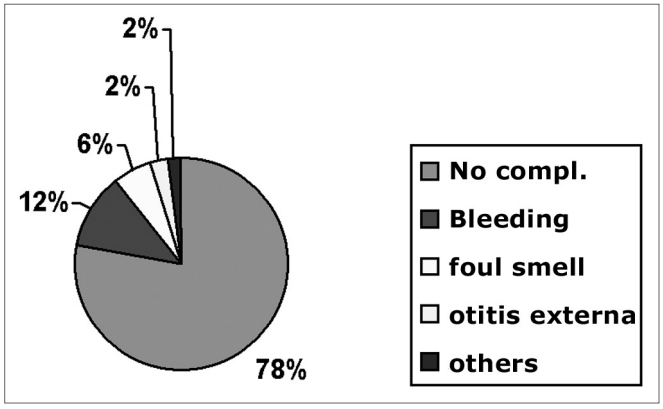

Chart 4. Complications

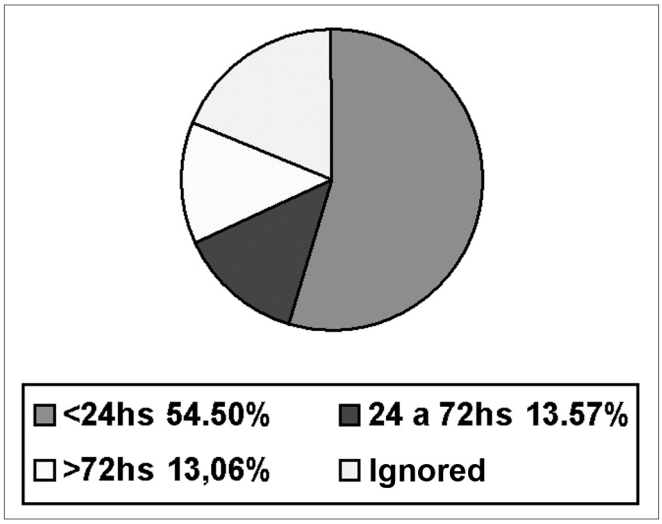

Chart 5. Time span between FB introduction and removal

(%) for sex, age, type, site, duration and date related to the presence and absence of iatrogenic complications. The chi-square ($\chi 2$) test was used for the statistical analysis.

These results up to this point showed that the non-iatrogenic complications groups had particular features. The three groups, therefore, were analyzed separately to improve characterization according to the variables we investigated.

Table 3 shows the frequency (n) and the percentage (%) for sex, age, type, site, duration and date related to the presence and absence of iatrogenic and non-iatrogenic complications, and no complications. The chi-square ($\chi 2$) test and Fisher's exact test was used for the statistical analysis.

There was no significant association ($p = 0.22$) between sex and the type of complication.

DISCUSSION

The study of FBs is fascinating, presenting many regional peculiarities. Otorhinolaryngology deals with most of the natural orifices that are habitually exposed, such as the mouth, nostrils and ears.[4] The esophagus and lower airways are affected indirectly, as FBs must first pass through the pharynx or the nasal fossae. Oropharyngeal and nasal fossae FBs are potentially esophageal and bronchial FBs.[3-5]

FBs in the ear may lead to tympanic perforation and deafness, particularly if there is secondary infection. Severe nose bleeding associated with FBs is not uncommon; fish spine may lead to peritonsillar abscesses.[4,6,7]

Our findings about the site of FBs are in agreement with the literature,[8-12] in which ear FBs predominated, followed by those in the nose and throat. In our opinion, nose and throat FBs are more easily eliminated by physio-

Table 1. Statistical analysis for complications in general.

Code	Variables	category	with complications		no complications		p value
			n	%	n	%	
x2	sex (n = 1356)	male	518	49.1	164	54.5	0.099
		Female	537	50.9	137	45.5	
x3_a	age (n = 1356)	<= 2 years	99	32.9	212	20.1	< 0.0001
		3 a 6	126	41.9	377	35.7	
		7 a 10	36	12.0	95	9.0	
		11 a 18	9	3.0	78	7.4	
		19 a 50	27	9.0	216	20.5	
		> 50	4	1.3	77	7.3	
x4_	Type (n = 411)	Live	22	35.5	74	21.2	< 0.0001
		Fish spine	6	9.7	159	45.6	
		SPA	22	35.5	76	21.8	
		Seeds	12	19.4	40	11.5	
x6_a	Site (n = 1352)	ear	157	52.3	596	56.7	< 0.0001
		Nose	137	45.7	283	26.9	
		Pharynx	6	2.0	173	16.4	
x8_a	Duration (n = 1103)	<= 24 h	109	52.9	709	79.0	< 0.0001
		24 a 72 h	35	17.0	106	11.8	
		> 72 h	62	30.1	82	9.1	
x9	Date (n = 1356)	92 a 94	103	34.2	349	33.1	0.004
		94 a 96	63	20.9	323	30.6	
		96 a 98	88	29.2	266	25.2	
		98 a 00	47	15.6	117	11.1	

A significant association was found between:

• child age and presence of complications in general (p = 0.0001).

• the type of FB (live and SPA) and presence of complications in general (p = 0,0001).

• the site of the FB (nose) and presence of complications in general (p < 0.0001).

• the time until removal and presence of complications in general (p < 0.0001). This means that there was a significant relation between complications in general and duration > 24 hours. On the other hand, there was also a time < 24 hours relation in the group with no complications.

• the date and presence of complications in general (p = 0.004). This means that there was a significant relation between complications in general and time from 1996 to 2000. No significant association was found between sex and complications in general (p=0.099).

Table 2. Statistical analysis of iatrogenic complications.

Cod.	Variables	category	Iatrogenic complication		Non-iatrogenic complication or no complication		p value
			n	%	n	%	
x2	Sex (n = 1356)	Male	89	56.0	593	49.5	0.12
		Female	70	44.0	604	50.5	
x3_a	Age (n = 1356)	<= 2 years	41	25.8	270	22.6	< 0.0001
		3 a 6	83	52.2	420	35.1	
		7 a 10	21	13.2	110	9.2	
		11 a 18	3	1.9	84	7.0	
		19 a 50	9	5.7	234	19.6	
		> 50	2	1.3	79	6.6	
x4_	Type (n = 411)	Live	5	11.9	91	24.7	< 0.0001
		Fish spine	6	14.3	159	43.1	
		SPA	21	50.0	77	20.9	
		Seeds	10	23.8	42	11.4	
x6_a	Site (n = 1352)	ear	98	62.0	655	54.9	0.001
		Nose	54	34.2	366	30.7	
		Pharynx	6	3.8	173	14.5	
x8_a	Duration (n = 1103)	<= 24 h	100	80.7	718	73.3	0.20
		24 a 72 h	11	8.9	130	13.3	
		> 72 h	13	10.5	131	13.4	
x9	Date (n = 1356)	92 a 94	68	42.8	384	32.1	< 0.0001
		94 a 96	27	17.0	359	30.0	
		96 a 98	35	22.0	319	26.7	
		98 a 00	29	18.2	135	11.3	

A significant association was found between:

• child age and presence of iatrogenic complications (p = 0.0001).

• the type (SPA and seeds) and presence of iatrogenic complications (p = 0.0001).

• the site (ear) and presence of iatrogenic complications (p = 0.001).

• the date and presence of iatrogenic complications (p = 0.0001). This means that there was a significant relation between iatrogenic complications and the date from 1992 to 1992-1994.

• There was no significant association between sex (p = 0.12) and duration (p = 0.20), and presence of iatrogenic complications.

Table 3. Statistical analysis of complications (iatrogenic, non-iatrogenic) and no complications.

Cód.	Variables	category	iatrogenic compl		non-iatrogenic compl		no complication		p value
			n	%	n	%	n	%	
x2	Sex (n = 1356)	male	89	56,0	75	52,8	518	49,1	0,22
		female	70	44,0	67	47,2	537	50,9	
x3_a	Age (n = 1356)	<= 2 years	41	25,8	58	40,9	212	20,1	< 0,0001
		3 a 6	83	52,2	43	30,3	377	35,7	
		7 a 10	21	13,2	15	10,6	95	9,0	
		11 a 18	3	1,9	6	4,2	78	7,4	
		19 a 50	9	5,7	18	12,7	216	20,5	
		> 50	2	1,3	2	1,4	77	7,3	
x4_	Type (n = 411)	Live	5	11,9	17	85,0	74	21,2	< 0,0001
		Fish spine	6	14,3	0	0,0	159	45,6	
		SPA	21	50,0	1	5,0	76	21,8	
		Seeds	10	23,8	2	10,0	40	11,5	
x6_a	Site (n = 1352)	ear	98	62,0	59	41,6	596	56,7	< 0,0001
		Nose	54	34,2	83	58,5	283	26,9	
		Pharynx	6	3,8	0	0,0	173	16,4	
x8_a	Duration (n = 1103)	<= 24 h	100	80,7	9	11,0	709	79,0	< 0,0001
		24 a 72 h	11	8,9	24	29,3	106	11,8	
		> 72 h	13	10,5	49	59,8	82	9,1	
x9	Date (n = 1356)	92 a 94	68	42,8	35	24,7	349	33,1	< 0,0001
		94 a 96	27	17,0	36	25,4	323	30,6	
		96 a 98	35	22,0	53	37,3	266	25,2	
		98 a 00	29	18,2	18	12,7	117	11,1	

A significant association was found between:

• child age and presence of complications ($p < 0.0001$). This means that there was a significant relation between age (until age 10 years) and complications (iatrogenic and non-iatrogenic). On the other hand, the group with no complications was related with adults.

• the type and presence of complications ($p < 0.0001$). This means that there was a significant relation between iatrogenic complications and SPA and seeds, and that there was a significant relation between non-iatrogenic complications and insects. On the other hand, the group with no complications was related with fish spine.

• the site and presence of complications ($p < 0.0001$). This means that there was a significant relation between iatrogenic complications and the ear, and that there was a significant relation between non-iatrogenic complications and nose. On the other hand, the group with no complications was related with the pharynx.

• the duration and presence of complications ($p < 0.0001$). This means that there was a significant relation between non-iatrogenic complications and duration > 24 hours. On the other hand, the groups with no complications and with iatrogenic complications were related with duration < 24 hours.

• the date and presence of complications ($p < 0.0001$). This means that there was a significant relation between iatrogenic complications and the date (1992-1994), and that there was a significant relation between non-iatrogenic complications and the date (1996-1998). On the other hand, the group with no complications was related with the date (1994-1996).

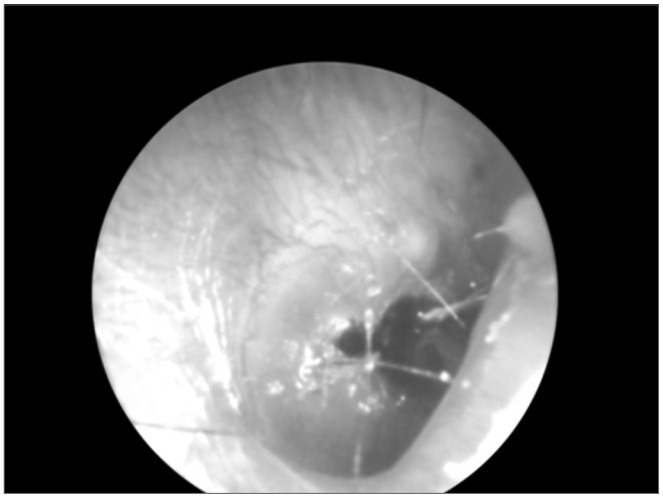

Figure 1. Tympanic perforation by a foreign body (bamboo fragment).

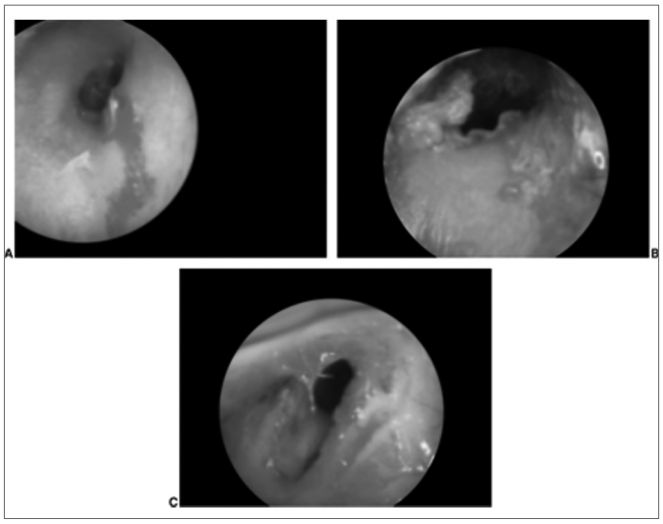

Figure 2. External auditory canal skin laceration.

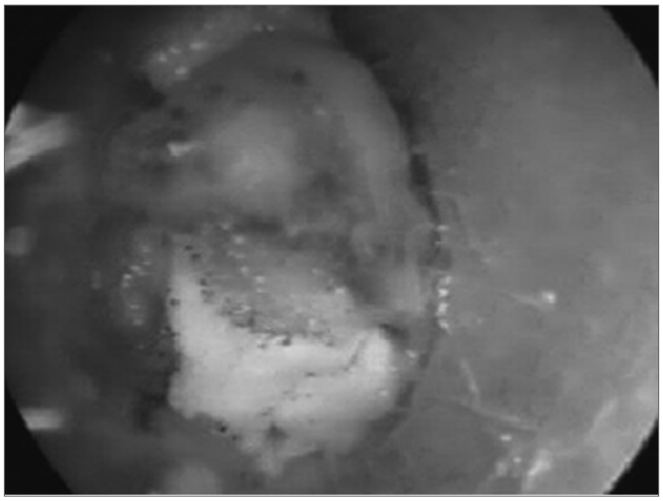

Figure 3. Foreign body associated otomycosis (cotton fragment).

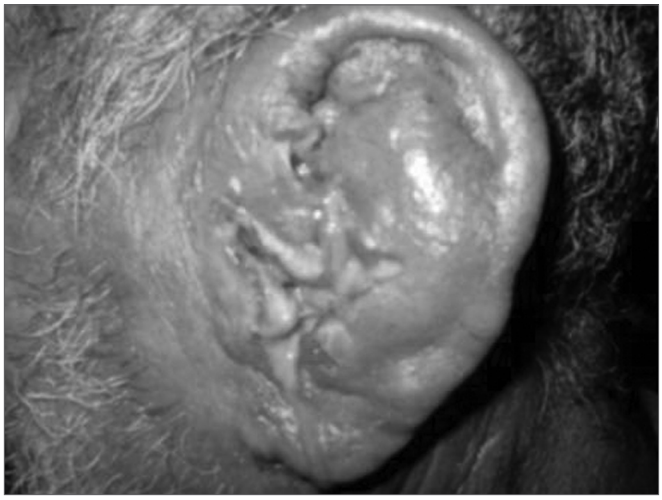

Figure 4. Perichondritis secondary to myiasis.

logical mechanisms, such as sneezing, coughing and the nausea reflex. The natural projection of tonsils into the oral cavity explains its position as the most common site for impacted pharyngeal FBs. There were no statistically significant differences in the sex distribution, which is in agreement with the literature.[2-4,11,13]

The age distribution showed a clear predominance of children aged between 1 and 4 years (47.64% of cases). Nasal FBs are almost exclusively found in children; pharyngeal FBs are more commonly found in adults; the distribution of ear FBs is more balanced, with a slight predominance in children. These findings are also in agreement with the literature[8,9,13]

Beans were the most common FB (17.18%), the most frequent FB in the ear (23.11%) and the third most frequent FB in the nose (14.76%). A high rate of fish spine as pharyngeal FBs usually reflects lack of care in preparing meals, specifically small fish, which are usually the least expensive. SPA are parts of toys and various other objects, such as buttons and food package seals. Toys and other objects bought from street vendors are especially dangerous; most of them contain no recommendations about age. Cotton fragments reflect popular cleaning habits and methods for relieving otological pruritus. Foam fragments, usually from ruptured pillows and mattresses, were the most common nasal FBs found.

Live FBs require specific comments. At our unit, the most common live FBs were cockroaches, followed by myiasis, mosquitoes and beetles.[4,15] Cockroaches generally enter the external auditory canal from the ground, particularly in people who habitually (or for lack of choice) sleep on the floor.[15,16] The clinical picture is dramatic and painful; the recommended approach is to first kill the insect by instilling oily substances, alcohol or ether into the external auditory canal. Live FBs are generally related to poor hygiene.[4,15] The most frequently found fly associated with

myiasis in Brazil is the Cochliomya hominivorax, found in ear and nasal fossae infestations.[15,16] Complications of myiasis in the nose are common, such as septal perforation, necrosis of the turbinates and orbitary complications. Larvae should be surgically removed as much as possible and parenteral antibiotics (clyndamicin or crystalline penicillin associated with ceftriaxone) should be given.[4,15] Some studies have suggested using ivermectine.[17]

Complications were found in 22.20% of cases. Marques et al. noted a higher rate of complications in cases that had been previously manipulated by non-otorhinolaryngologists, other health professionals, the patients themselves and other laypersons.[8,9,14]

In our data, the most frequent complications were bleeding (51.83% of complications), fetidness (28.57%) and external otitis (10.30%). There were fewer serious complications such as necrosis (1.33%) and tympanic perforation (0.99%). Bleeding usually is mild; in our series there was no need for contention measures. Fetidness occurs due to secondary bacterial infection, more commonly in nasal FBs, especially with hygroscopic materials such as foam fragments, paper and cotton.[2-4] Some types of complications are shown below:

There was no statistically significant difference between sexes relative to complications. The statistically significant difference between complications and age below 10 years is probably due to agitation of the child during removal. A relation between the presence of iatrogenic complications and certain types of FBs (such as SPA and seeds) has led us to conclude that these FBs are technically more difficult to remove. Non-iatrogenic complications showed a statistically significant with live FBs, possibly due to an association with inflammation and infection.

Our data reveal a statistically significant relation between non-iatrogenic complications and nasal FBs, probably due to a higher incidence of secondary infection, which results in fetidness. Ear FBs were associated with iatrogenic complications, probably due to the tortuous anatomy of the external auditory canal, which makes removal more troublesome.

On the time period between FB insertion and removal, there was a statistically significant relation between non-iatrogenic complications and longer permanence FBs (over 72 hours); we conclude that delays in removing FBs increase the frequency of non-iatrogenic complications, which reinforces the importance of prompt treatment. There was a statistically significant relation between iatrogenic complications and FBs in place for less than 24 hours. We believe that this occurs because patients are more agitated soon after FB insertion. The incidence of FBs removed with no complications is also related to early treatment.

Finally, there was a higher incidence of iatrogenic complications in the first two years of our series, from 1992 to 1994. These findings indicate that professional experience in managing FBs is important; two reasons are given: improved manual dexterity with experience, and better decision-making about using sedation or general anesthesia. These findings reinforce the need for higher-quality teaching about urgencies in graduation courses.

Data on the time between FB insertion and removal show that removal takes place within the first 24 hours in 54.50% of cases, between 24 and 48 hours in 13.57% of cases, and after 72 hours in 13.06% of cases. This time period could not be established in 18.95% of cases, particularly in children that are wary of explaining their acts to caretakers.

CONCLUSION

Our data describes the series in one of the major South American ENT urgency service. Findings in general are in agreement with the literature; there are local peculiarities, such as a predominance of beans as the most frequent FB. Iatrogenic complications were related to ear FBs, children, SPA, seeds, less than 24 hours elapsed between FB insertion and removal, and lack of professional experience in managing FBs. Non-iatrogenic complications were related with live FBs and long duration.

Based on the abovementioned conclusions, certain measures are suggested that might avoid complications, as follows:

1) Informing patients to immediately seek an otorhinolaryngologist in FB cases, especially for the treatment of live FBs.

2) Increased care by otorhinolaryngologists with technically difficult to remove FBs, such as seeds and SPA, especially in ears and in children, in whom removal under sedation or general anesthesia should be considered.

3) Improved teaching about urgencies in ENT graduation courses.

ACKNOWLEDGMENTS

We would like to dedicate this paper to our colleagues, nurse assistants and patients of the Souza Aguiar hospital.

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Meniere's Disease
Biennial Review 2022

Question: Should Meniere's disease be given a lower priority on the List?

Question source: HERC staff

Issue: Meniere's disease is currently on a funded line but does not have any effective therapies. HERC staff have identified this line as a possible line which should be reprioritized. A review of HSC and HERC minutes could not find any previous discussion regarding the prioritization of Meniere's disease.

Meniere's disease is a disorder of the inner ear that is characterized by episodes of vertigo, tinnitus, hearing loss, and a fullness in the ear. Typically, only one ear is affected initially; however, over time both ears may become involved. Episodes generally last from 20 minutes to a few hours. The time between episodes varies. The hearing loss and ringing in the ears can become constant over time. The cause of Meniere's disease is unclear but likely involves both genetic and environmental factors. A cure does not exist. Attacks are often treated with medications to help with the nausea and anxiety. Measures to prevent attacks are overall poorly supported by the evidence. A low-salt diet, diuretics, and corticosteroids may be tried. Physical therapy may help with balance and counselling may help with anxiety. Injections into the ear or surgery may also be tried if other measures are not effective but are associated with risks.

Current Prioritized List status
Line 417 MENIERE'S DISEASE Treatment: MEDICAL AND SURGICAL TREATMENT
ICD-10: H81.0 (Meniere's disease)
CPT: multiple diagnostic and treatment procedures

Evidence

1) **Von Sonsbeek 2015,** Cochrane review of positive pressure therapy for Meniere's disease
    a. N=5 RCTs (265 patients)
    b. Positive pressure therapy uses a device (such as the Meniett®) placed in the external ear to generate a sequence of low-pressure (micro-pressure) pulses
    c. Overall, the risk of bias varied: three out of five studies were at low risk, one was at unclear risk and one was at high risk of bias.
    d. ***Control of vertigo:*** For the primary outcome, control of vertigo, it was not possible to pool data due to heterogeneity in the measurement of the outcome measures. In most studies, no significant difference was found between the positive pressure therapy group and the placebo group in vertigo scores or vertigo days. Only one study, at low risk of bias, showed a significant difference in one measure of vertigo control in favour of positive pressure therapy. In this study, the mean visual analogue scale (VAS) score for vertigo after eight weeks of treatment was 25.5 in the positive pressure therapy group and 46.6 in the placebo group (mean difference (MD) -21.10, 95% CI -35.47 to -6.73; scale not stated - presumed to be 0 to 100).
    e. ***Secondary outcomes:*** We found statistically significant results for loss or gain of hearing. Hearing was 7.38 decibels better in the placebo group compared to the positive pressure therapy group (MD) (95% CI 2.51 to 12.25; two studies, 123 participants). The severity of tinnitus and perception of aural fullness were either not measured or

inadequate data were provided in the included studies. For the secondary outcome functional level, it was not possible to perform a pooled analysis. One included study showed less functional impairment in the positive pressure group than the placebo group (AAO-HNS criteria, one- to six-point scale: MD -1.10, 95% CI -1.81 to -0.39, 40 participants); another study did not show any significant results. In addition to the predefined secondary outcome measures, we included sick days as an additional outcome measure, as two studies used this outcome measure and it is a complementary measurement of impairment due to Ménière's disease. We did not find a statistically significant difference in sick days. No complications or adverse effects were noted by any study.

f. **Authors' conclusions** There is no evidence, from five included studies, to show that positive pressure therapy is effective for the symptoms of Ménière's disease. There is some moderate quality evidence, from two studies, that hearing levels are worse in patients who use this therapy. The positive pressure therapy device itself is minimally invasive. However, in order to use it, a tympanostomy tube (grommet) needs to be inserted, with the associated risks. These include the risks of anaesthesia, the general risks of any surgery and the specific risks of otorrhoea and tympanosclerosis associated with the insertion of a tympanostomy tube.

2) **Pullens 2013**, Cochrane review of surgery for Meniere's disease
   a. The only surgical intervention which has been evaluated in randomised controlled trials and met the inclusion criteria was endolymphatic sac surgery. We identified two randomised trials, involving a total of 59 patients; one comparing endolymphatic sac surgery with ventilation tubes and one with simple mastoidectomy. Neither study reported any beneficial effect of surgery either in comparison to placebo surgery or grommet insertion.
   b. **Authors' conclusions** The two trials included in this review provide insufficient evidence of the beneficial effect of endolymphatic sac surgery in Ménière's disease.
3) **Phillips 2011**, Cochrane review of steroid injections for Meniere's disease
   a. Single RCT of intratympanic dexamethasone versus placebo in patients with Ménière's disease
   b. N=22 patients
   c. Low risk of bias
   d. This trial found that after 24 months, compared with placebo, the use of intratympanic dexamethasone demonstrated a statistically significant improvement in vertigo as defined by a respective improvement in functional level (90% versus 42%), class (82% versus 57%), change in Dizziness Handicap Inventory scores (60.4versus 41.3) and mean vertigo subjective improvement (90% versus 57%). The treatment regime described by the authors involved daily injections of dexamethasone solution 4mg/ml for five consecutive days. These results were clinically significant. No complications were reported.
   e. **Authors' conclusions** The results of a single trial provide limited evidence to support the effectiveness of intratympanic steroids in patients with Ménière'sdisease. This trial demonstrated a statistically and clinically significant improvement of the frequency and severity of vertigo measured 24 months after the treatment was administered.
2) **Pullens 2011,** Cochrane review of intratympanic gentamicin for Meniere's disease
   a. N=2 RCTs (50 patients)

   b. Both of these trials found a significant reduction in vertigo complaints in the gentamicin group when compared to the placebo group. Due to clinical heterogeneity we could not perform a meta-analysis. One study described an increase in hearing loss in four patients (25%) treated with gentamicin while the other described no increase in hearing loss. No other adverse effects were noted by either study.
   c. **Authors' conclusions** Based on the results of the two included studies, intratympanic gentamicin seems to be an effective treatment for vertigo complaints in Ménière's disease, but carries a risk of hearing loss.
3) **Burgess 2010**, Cochrane review of diuretics for Meniere's disease
   a. There were no trials of high enough quality to meet the standard set for this review.
   b. There is insufficient good evidence of the effect of diuretics on vertigo, hearing loss, tinnitus or aural fullness in clearly defined Ménière's disease.

Other guidelines

1) European Academy of of Otology & Neurotology (**Magnan 2018**)
   a. First line therapy: diet changes, betahistine, diuretics
      i. Low level of evidence to support any of these approaches
   b. Second line therapy: intratympanic steroids
      i. Limited evidence of effectiveness
   c. Third line therapy: endolymphatic sac surgery
      i. Low level of evidence of effectiveness
   d. Fourth line therapy: gentamicin injection.
      i. Limited evidence of effectiveness, evidence of harm (hearing loss)
   e. Fifth line therapy: vestibular neurectomy, labyrinthectomy
      i. No level of evidence given

Utilization:

1-year claims review (CCO and FFS):

CPT	**CPT Description**	**Claims with Meniere's disease as diagnosis**
69801	Labyrinthotomy, with perfusion of vestibuloactive drug(s), transcanal	21
69805	Endolymphatic sac operation; without shunt	0
69806	Endolymphatic sac operation; with shunt	2
69915	Vestibular nerve section, translabyrinthine approach	0
69950	Vestibular nerve section, transcranial approach	0

Meniere's Disease
Biennial Review 2022

HERC staff summary

There is low to no evidence of effectiveness of any therapy for Meniere's disease, including diuretics, intratympanic steroids, or surgery. If this line was moved to a lower priority position, medications such as diuretics would still likely be available to patients as these medications are rarely prior authorized.

HERC staff recommendation:

1) Rescore the Meniere's line as shown below
    a. Reduce effectiveness of treatment from 3 to 1

Reprioritization of MENIERE'S DISEASE Treatment: MEDICAL AND SURGICAL TREATMENT
(Current scores for line 419 shown in parentheses)
Category: 7 (7)
Healthy life years: 4 (4)
Suffering: 2 (2)
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 0
Effectiveness: 1 (3)
Need for treatment: 1 (1)
Net cost: 3 (3)
Score: 120 (360)
Line placement: 520 (417)

Positive pressure therapy for Ménière's disease or syndrome (Review)

van Sonsbeek S, Pullens B, van Benthem PP

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2015, Issue 3

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[Intervention Review]

Positive pressure therapy for Ménière's disease or syndrome

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Editorial group: Cochrane ENT Group.
Publication status and date: New, published in Issue 3, 2015.
Review content assessed as up-to-date: 6 June 2014.

Citation: van Sonsbeek S, Pullens B, van Benthem PP. Positive pressure therapy for Ménière's disease or syndrome. *Cochrane Database of Systematic Reviews* 2015, Issue 3. Art. No.: CD008419. DOI: 10.1002/14651858.CD008419.pub2.

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ABSTRACT

Background

Ménière's disease is an incapacitating disease in which recurrent attacks of vertigo are accompanied by hearing loss, tinnitus and/or aural fullness, all of which are discontinuous and variable in intensity. A number of different therapies have been identified for patients with this disease, ranging from dietary measures (e.g. a low-salt diet) and medication (e.g. betahistine (Serc®), diuretics) to extensive surgery (e.g. endolymphatic sac surgery). The Meniett® low-pressure pulse generator (Medtronic ENT, 1999) is a device that is designed to generate a computer-controlled sequence of low-pressure (micro-pressure) pulses, which are thought to be transmitted to the vestibular system of the inner ear. The pressure pulse passes via a tympanostomy tube (grommet) to the middle ear, and hence to the inner ear via the round and/or oval window. The hypothesis is that these low-pressure pulses reduce endolymphatic hydrops.

Objectives

To assess the effects of positive pressure therapy (e.g. the Meniett device) on the symptoms of Ménière's disease or syndrome.

Search methods

We searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL); PubMed; EMBASE; CINAHL; Web of Science; Cambridge Scientific Abstracts; ICTRP and additional sources for published and unpublished trials. The date of the search was 6 June 2014.

Selection criteria

Randomised controlled trials (RCTs) comparing positive pressure therapy (using the Meniett or a similar device) with placebo in patients with Ménière's disease. The primary outcome was control of vertigo; secondary outcomes were loss or gain of hearing, severity of tinnitus, perception of aural fullness, functional level, complications or adverse effects, and sick days.

Data collection and analysis

Two authors independently selected studies, assessed risk of bias and extracted data. We contacted authors for additional data. Where possible, we pooled study results using a fixed-effect, mean difference (MD) meta-analysis and tested for statistical heterogeneity using both the Chi^2 test and I^2 statistic. This was only possible for the secondary outcomes loss or gain of hearing and sick days. We presented results using forest plots with 95% confidence intervals (CI).

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Main results

We included five randomised clinical trials with 265 participants. All trials were prospective, double-blind, placebo-controlled randomised controlled trials on the effects of positive pressure therapy on vertigo complaints in Ménière's disease. Overall, the risk of bias varied: three out of five studies were at low risk, one was at unclear risk and one was at high risk of bias.

Control of vertigo

For the primary outcome, control of vertigo, it was not possible to pool data due to heterogeneity in the measurement of the outcome measures. In most studies, no significant difference was found between the positive pressure therapy group and the placebo group in vertigo scores or vertigo days. Only one study, at low risk of bias, showed a significant difference in one measure of vertigo control in favour of positive pressure therapy. In this study, the mean visual analogue scale (VAS) score for vertigo after eight weeks of treatment was 25.5 in the positive pressure therapy group and 46.6 in the placebo group (mean difference (MD) -21.10, 95% CI -35.47 to -6.73; scale not stated - presumed to be 0 to 100).

Secondary outcomes

For the secondary outcomes, we carried out two pooled analyses. We found statistically significant results for ***loss or gain of hearing*** . Hearing was 7.38 decibels better in the placebo group compared to the positive pressure therapy group (MD) (95% CI 2.51 to 12.25; two studies, 123 participants). The ***severity of tinnitus*** and ***perception of aural fullness*** were either not measured or inadequate data were provided in the included studies. For the secondary outcome ***functional level*** , it was not possible to perform a pooled analysis. One included study showed less functional impairment in the positive pressure group than the placebo group (AAO-HNS criteria, one- to six-point scale: MD -1.10, 95% CI -1.81 to -0.39, 40 participants); another study did not show any significant results. In addition to the predefined secondary outcome measures, we included ***sick days*** as an additional outcome measure, as two studies used this outcome measure and it is a complementary measurement of impairment due to Ménière's disease. We did not find a statistically significant difference in sick days. No ***complications or adverse effects*** were noted by any study.

Authors' conclusions

There is no evidence, from five included studies, to show that positive pressure therapy is effective for the symptoms of Ménière's disease. There is some moderate quality evidence, from two studies, that hearing levels are worse in patients who use this therapy. The positive pressure therapy device itself is minimally invasive. However, in order to use it, a tympanostomy tube (grommet) needs to be inserted, with the associated risks. These include the risks of anaesthesia, the general risks of any surgery and the specific risks of otorrhoea and tympanosclerosis associated with the insertion of a tympanostomy tube. Notwithstanding these comments, no complications or adverse effects were noted in any of the included studies.

PLAIN LANGUAGE SUMMARY

Positive pressure therapy for Ménière's disease or syndrome

Background

Ménière's disease is a disorder of the inner ear, which results in vertigo, hearing loss and tinnitus. When it is secondary to another known inner ear disorder, it is called Ménière's syndrome. A number of different treatments have been used for patients with this disease, ranging from dietary measures (e.g. a low-salt diet) and medication (e.g. betahistine or diuretics) to extensive surgery. However, Ménière's disease has a fluctuating natural course with remissions and exacerbations, which makes the evaluation of treatments difficult.

Positive pressure therapy uses a device (such as the Meniett®) placed in the external ear to generate a sequence of low-pressure (micropressure) pulses. These pulses are thought to be transmitted to the vestibular system of the inner ear and to influence inner ear pressure. The device has been proposed as a second-level therapy for Ménière's disease. In order to use the device a patient needs to have a tympanostomy tube (grommet) inserted through their eardrum.

Study characteristics

In this review, we included five randomised controlled trials, with a total of 265 participants. All participants had Ménière's disease and their ages ranged from 19 to 74 years. In all of the studies positive pressure therapy was compared with a placebo device.

Key results

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Surgery for Ménière's disease (Review)

Pullens B, Verschuur HP, van Benthem PP

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2013, Issue 2

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[Intervention Review]

Surgery for Ménière's disease

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Editorial group: Cochrane Ear, Nose and Throat Disorders Group.
Publication status and date: New search for studies and content updated (no change to conclusions), published in Issue 2, 2013.
Review content assessed as up-to-date: 7 November 2012.

Citation: Pullens B, Verschuur HP, van Benthem PP. Surgery for Ménière's disease. *Cochrane Database of Systematic Reviews* 2013, Issue 2. Art. No.: CD005395. DOI: 10.1002/14651858.CD005395.pub3.

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ABSTRACT

Background

This is an update of a Cochrane review first published in *The Cochrane Library* in Issue 1, 2010.

Ménière's disease is characterised by three major symptoms: vertigo, deafness, and tinnitus or aural fullness, all of which are discontinuous and variable in intensity. A number of surgical modalities, of varying levels of invasiveness, have been developed to reduce the symptoms of Ménière's disease, but it is not clear whether or not these are effective.

Objectives

To assess the effectiveness of surgical options for the treatment of Ménière's disease. All surgical interventions used in the treatment of Ménière's disease, either to alter the natural history of the disease or to abolish vestibular function, were considered for this review.

Search methods

We searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL); PubMed; EMBASE; CINAHL; Web of Science; BIOSIS Previews; Cambridge Scientific Abstracts; ICTRP and additional sources for published and unpublished trials. The date of the most recent search was 7 November 2012.

Selection criteria

Randomised or quasi-randomised controlled studies of a surgical modality versus a placebo therapy in Ménière's disease.

Data collection and analysis

Two authors independently assessed trial quality and extracted data. We contacted study authors for further information.

Main results

The only surgical intervention which has been evaluated in randomised controlled trials and met the inclusion criteria was endolymphatic sac surgery. We identified two randomised trials, involving a total of 59 patients; one comparing endolymphatic sac surgery with ventilation tubes and one with simple mastoidectomy. Neither study reported any beneficial effect of surgery either in comparison to placebo surgery or grommet insertion.

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Authors' conclusions

The two trials included in this review provide insufficient evidence of the beneficial effect of endolymphatic sac surgery in Ménière's disease.

PLAIN LANGUAGE SUMMARY

Surgery for Ménière's disease

Ménière's disease is characterised by recurrent attacks of three major symptoms: vertigo (rotational dizziness), deafness and tinnitus (ringing of the ears), and/or aural fullness, all of which are discontinuous and variable in intensity. The symptoms of Ménière's disease are thought to be caused by excess pressure in the fluids of the inner ear which leads to sudden attacks of vertigo and hearing loss. A number of surgical procedures, of varying levels of invasiveness, have been developed to reduce the symptoms of Ménière's disease, but it is not clear whether or not these are effective. The surgical interventions can be categorised as two types: one type of surgical intervention aims to affect the natural history of the disease, with conservation of vestibular function. The other type aims to relieve symptoms by abolishing vestibular function. Both types of surgical intervention are considered in this review. Despite an extensive search the review authors only found two randomised controlled trials studying surgical interventions for Ménière's disease. Both of these trials, involving a total of 59 patients, studied endolymphatic sac surgery; one comparing it to placebo surgery and the other to a different type of surgery. Neither trial detected a significant difference between the treatment and control group.

BACKGROUND

Description of the condition

This is an update of a Cochrane review first published in *The Cochrane Library* in Issue 1, 2010.

Ménière's disease is an incapacitating disease in which recurrent attacks of vertigo are accompanied by hearing loss, tinnitus and/or aural fullness. The attacks of vertigo may follow each other with intervals of days, weeks or even months. Usually, these become less severe and disappear after two to eight years in 60% to 80% of sufferers (Portmann 1980; Silverstein 1989), with profound lasting hearing loss and tinnitus, however there is great variability in the presentation and natural course of the disease. When no known cause of the disease is identified, the term Ménière's *disease* is applicable. When the symptoms are secondary to a known disease (e.g. meningitis), the term Ménière's *syndrome* is used.

Few articles have been published on the epidemiology of Ménière's disease. Great variation exists in the published reports of the incidence and prevalence of Ménière's disease, ranging from 17 cases per 100,000 population in Japan (Nakae 1984) to 46 cases per 100,000 population in Sweden (Stahle 1978). There seems to be a slight female preponderance, with up to 1.3 times more women affected than men. The disease is more common in adults in their fourth and fifth decade of life (Kotimaki 1999; Sajjadi 2008). The frequency of bilateral disease is unclear. Published reports vary greatly between 2% and 78% (Balkany 1980). In a large population study by Kitahara in Japan, bilaterality of disease was noted in 9.1% of patients in their first year of experiencing symptoms. This increased steadily to 41.5% after 20 years of disease (Kitahara 1991).

In 1861 Prosper Ménière first recognised that this disorder originated from the inner ear (the membranous labyrinth), but wrongly attributed the cause to haemorrhage (Meniere 1861). In 1938 Hallpike and Yamakawa independently described a hydrops (i.e. accumulation of fluid) of the endolymphatic system in patients with Ménière's disease (Hallpike 1938; Yamakawa 1938). In 1965 Kimura introduced an experimental model in which an endolymphatic hydrops was produced in guinea pigs after surgical obliteration of the endolymphatic sac and duct (Kimura 1967). Endolymphatic hydrops caused by an abnormality in the absorption of endolymph at the endolymphatic sac remains the most promising theory to explain the symptoms of Ménière's disease. Other explanations for the cause of an endolymphatic hydrops, such as a hypoplasia of the vestibular aqueduct (Egami 1978; Yamamoto 1992), a genetic predisposition (Morrison 1995) or a viral aetiology (Vrabec 2003), have been suggested.

Currently no 'gold standard' diagnostic test for Ménière's disease exists. Diagnostic criteria vary among practitioners, who mostly diagnose Ménière's disease based upon the patient's history, neurotologic evaluation and clinical response to medical treatment. In 1972 the American Academy of Otolaryngology - Head

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Intratympanic steroids for Ménière's disease or syndrome (Review)

Phillips JS, Westerberg B

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2011, Issue 7

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[Intervention Review]

Intratympanic steroids for Ménière's disease or syndrome

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Editorial group: Cochrane Ear, Nose and Throat Disorders Group.
Publication status and date: New, published in Issue 7, 2011.
Review content assessed as up-to-date: 12 January 2011.

Citation: Phillips JS, Westerberg B. Intratympanic steroids for Ménière's disease or syndrome. *Cochrane Database of Systematic Reviews* 2011, Issue 7. Art. No.: CD008514. DOI: 10.1002/14651858.CD008514.pub2.

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ABSTRACT

Background

Ménière's disease is a disorder characterised by hearing loss, tinnitus and disabling vertigo. The use of intratympanic steroids to reduce the severity of these symptoms has been gaining popularity.

Objectives

To assess the effectiveness of intratympanic steroids on the frequency and severity of attacks of vertigo, on chronic symptoms such as tinnitus, imbalance and hearing loss, and on the progression of these symptoms in patients with definite Ménière's disease or syndrome, as defined by the AAO-HNS Committee.

Search strategy

We searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL); PubMed; EMBASE; CINAHL; Web of Science; BIOSIS Previews; Cambridge Scientific Abstracts; ICTRP and additional sources for published and unpublished trials. The date of the most recent search was 13 January 2011.

Selection criteria

Randomised controlled trials of intratympanic dexamethasone versus placebo in patients with Ménière's disease.

Data collection and analysis

Two authors independently assessed trial risk of bias and extracted data. We contacted study authors for further information where possible.

Main results

A single trial containing 22 patients, with a low risk of bias was included. This trial found that after 24 months, compared with placebo, the use of intratympanic dexamethasone demonstrated a statistically significant improvement in vertigo as defined by a respective improvement in functional level (90% versus 42%), class (82% versus 57%), change in Dizziness Handicap Inventory scores (60.4 versus 41.3) and mean vertigo subjective improvement (90% versus 57%). The treatment regime described by the authors involved daily injections of dexamethasone solution 4 mg/ml for five consecutive days. These results were clinically significant. No complications were reported.

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Authors' conclusions

The results of a single trial provide limited evidence to support the effectiveness of intratympanic steroids in patients with Ménière's disease. This trial demonstrated a statistically and clinically significant improvement of the frequency and severity of vertigo measured 24 months after the treatment was administered. It is important to note that there were a few aspects of the study which we were unable to clarify with the study authors.

PLAIN LANGUAGE SUMMARY

Intratympanic steroids for Ménière's disease or syndrome

Ménière's disease is a disorder of the inner ear which results in a spinning form of dizziness (vertigo), hearing loss and ringing in the ear (tinnitus); this can be very disabling. The cause of Ménière's disease is unknown. There has been some support in the medical literature for a course of treatment that involves the injection of steroids through the eardrum and into the middle ear to reduce the frequency and severity of these symptoms.

We looked for studies which compared steroid injections in the ear with placebo in patients with Ménière's disease or syndrome. Only one study satisfied the prespecified inclusion criteria for this review. This study demonstrated a benefit of this treatment for patients with Ménière's disease; at 24 months the patients in the treatment group had far fewer episodes of vertigo. The results of this review are encouraging, however as it is based solely on the results of a single study, further research is required.

BACKGROUND

Description of the condition

Definition

Prosper Ménière gave his name to a disorder characterised by recurrent episodes of spontaneous vertigo, fluctuating hearing loss and tinnitus, often with a feeling of fullness in the ear. The disorder may be subdivided into two categories. It is usually idiopathic (i.e. without known cause), in which case it is referred to as Ménière's disease. It may also be secondary to a number of known inner ear disorders, in which case it is referred to as Ménière's syndrome.

Aetiology

Ménière's disease is thought to be associated with endolymphatic hydrops, i.e. raised endolymph pressure in the membranous labyrinth of the inner ear (Hallpike 1938). The cause of the hydrops is not known in most cases. Specific disorders affecting the inner ear which are also associated with hydrops include temporal bone fracture, syphilis, hypothyroidism, Cogan's syndrome and Mondini dysplasia.

Prevalence

Ménière's disease is most common between 40 and 60 years of age, although younger people can also be affected (da Costa 2002; Morales 2003; Takeda 1998; Watanabe 1995). Few articles have been published on the epidemiology of Ménière's disease. Great variation exists in the published reports of the incidence and prevalence of Ménière's disease, ranging from 17 cases per 100,000 population in Japan (Nakae 1984) to 46 cases per 100,000 population in Sweden (Stahle 1978). Acute episodes of Ménière's tend to occur in clusters with a mean frequency of between six and 11 clusters per year, although remission may last several months. Episodes have been observed to occur with increasing frequency over the first few years after presentation and then decrease in association with a sustained deterioration in hearing (Moffat 1997). In most cases vertiginous episodes eventually cease completely (Silverstein 1989). This fluctuating character of the disease is an aspect of the natural history that makes formal evaluation of any treatment effect in patients with Ménière's disease difficult.

Diagnosis

The disorder is not always easy to diagnose and there is no 'gold standard' diagnostic test. It is almost certainly over-diagnosed by non-specialists. The American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) has produced diagnostic

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Intratympanic gentamicin for Ménière's disease or syndrome (Review)

Pullens B, van Benthem PP

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2011, Issue 4

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[Intervention Review]

Intratympanic gentamicin for Ménière's disease or syndrome

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Editorial group: Cochrane Ear, Nose and Throat Disorders Group.
Publication status and date: Edited (no change to conclusions), published in Issue 4, 2011.
Review content assessed as up-to-date: 29 June 2010.

Citation: Pullens B, van Benthem PP. Intratympanic gentamicin for Ménière's disease or syndrome. *Cochrane Database of Systematic Reviews* 2011, Issue 3. Art. No.: CD008234. DOI: 10.1002/14651858.CD008234.pub2.

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ABSTRACT

Background

Ménière's disease is characterised by three major symptoms: vertigo, deafness and tinnitus, which may be accompanied by aural fullness, all of which are discontinuous and variable in intensity. While discontinuous, these symptoms are synchronous. Intratympanic application of gentamicin, an ototoxic aminoglycoside, is a relatively new ablative treatment for vertigo in Ménière's disease with promising results.

Objectives

To assess the effectiveness of intratympanic gentamicin in the treatment of vertigo in Ménière's disease.

Search strategy

We searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL); PubMed; EMBASE; CINAHL; Web of Science; BIOSIS Previews; Cambridge Scientific Abstracts; ISRCTN and additional sources for published and unpublished trials. The date of the most recent search was 30 June 2010.

Selection criteria

All randomised or quasi-randomised controlled trials of intratympanic gentamicin versus placebo, or versus another treatment for Ménière's disease.

Data collection and analysis

Two review authors independently assessed trial quality and extracted data. We contacted study authors for further information.

Main results

We identified two trials, involving 50 participants, which fulfilled the inclusion criteria. Both of these trials are prospective, double-blind, placebo-controlled randomised clinical trials on the effect of intratympanic gentamicin on vertigo complaints. After assessing the risk of bias of both studies, we concluded that one had a greater risk of bias and deemed the other to be of higher quality. Both of these trials found a significant reduction in vertigo complaints in the gentamicin group when compared to the placebo group. Due to clinical heterogeneity we could not perform a meta-analysis. One study described an increase in hearing loss in four patients (25%) treated with gentamicin while the other described no increase in hearing loss. No other adverse effects were noted by either study.

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Authors' conclusions

Based on the results of the two included studies, intratympanic gentamicin seems to be an effective treatment for vertigo complaints in Ménière's disease, but carries a risk of hearing loss.

PLAIN LANGUAGE SUMMARY

Intratympanic gentamicin for Ménière's disease or syndrome

Ménière's disease is characterised by three major symptoms: rotational dizziness (vertigo), hearing loss and ringing in the ears (tinnitus), sometimes accompanied by aural fullness. Intratympanic gentamicin is a relatively new therapy with promising results. Gentamicin is an antibiotic which damages the inner ear and the balance organ when it is applied behind the ear drum. This treatment may decrease the spells of vertigo in Ménière's disease. In this review we assess the effectiveness of this kind of treatment for Ménière's disease. Two randomised controlled trials, including a total of 50 patients, were identified which fulfilled the review inclusion criteria. Both of these found a beneficial effect of intratympanic gentamicin therapy for Ménière's disease, although the size of the effect differed between the two trials. Based on these findings, we conclude that intratympanic gentamicin may be an effective treatment for vertigo complaints in Ménière's disease, but it carries a risk of increasing hearing loss. Further research is needed to clarify the effect of intratympanic gentamicin on vertigo in Ménière's disease and the risk of inducing or increasing hearing loss.

BACKGROUND

Description of the condition

Ménière's disease is an incapacitating disease in which recurrent attacks of vertigo are accompanied by hearing loss, tinnitus and/or aural fullness. The attacks of vertigo may follow each other with intervals of days, weeks or even months. While the attacks are discontinuous, these symptoms are synchronous. Usually, the attacks become less severe and disappear after two to eight years in 60% to 80% of sufferers (Portmann 1980; Silverstein 1989), with profound lasting hearing loss and tinnitus, although there is great variability in the presentation and natural course of the disease. When no known cause of the disease is identified, the term Ménière's *disease* is applicable. When the symptoms are secondary to a known disease (e.g. meningitis), the term Ménière's *syndrome* is used.

Few articles have been published on the epidemiology of Ménière's disease. Great variation exists in the published reports of the incidence and prevalence of Ménière's disease, ranging from 17 cases per 100,000 population in Japan (Nakae 1984) to 46 cases per 100,000 population in Sweden (Stahle 1978). There seems to be a slight female preponderance, with up to 1.3 times more women affected than men. The disease is more common in adults in their fourth and fifth decade of life (Kotimaki 1999; Sajjadi 2008). The frequency of bilateral disease is unclear. Published reports vary greatly between 2% and 78% (Balkany 1980). In a large population study by Kitahara in Japan, bilaterality of disease was noted in 9.1% of patients in their first year of experiencing symptoms. This increased steadily to 41.5% after 20 years of disease (Kitahara 1991).

In 1861 Prosper Ménière first recognised that this disorder originated from the inner ear (the membranous labyrinth), but wrongly attributed the cause to haemorrhage (Meniere 1861). In 1938 Hallpike and Yamakawa independently described a hydrops (i.e. accumulation of fluid) of the endolymphatic system in patients with Ménière's disease (Hallpike 1938; Yamakawa 1938). In 1965 Kimura introduced an experimental model in which an endolymphatic hydrops was produced in guinea pigs after surgical obliteration of the endolymphatic sac and duct (Kimura 1967). Endolymphatic hydrops caused by an abnormality in the absorption of endolymph at the endolymphatic sac remains the most promising theory to explain the symptoms of Ménière's disease. Other explanations for the cause of an endolymphatic hydrops, such as a hypoplasia of the vestibular aqueduct (Egami 1978; Yamamoto 1992), a genetic predisposition (Morrison 1995), or a viral aetiology (Vrabec 2003), have been suggested.

Currently no 'gold standard' diagnostic test for Ménière's disease exists. Diagnostic criteria vary among practitioners who mostly diagnose Ménière's disease based upon the patient's history, neurotologic and audiologic evaluation and imaging. In 1972 the American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) produced diagnostic guidelines (Alford 1972), which were revised in 1985 (Pearson 1985) and 1995 (Monsell 1995b). According to these guidelines Ménière's disease is 'definite' when at

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Diuretics for Ménière's disease or syndrome (Review)

Burgess A, Kundu S

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2010, Issue 4

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[Intervention Review]

Diuretics for Ménière's disease or syndrome

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Editorial group: Cochrane Ear, Nose and Throat Disorders Group.
Publication status and date: Edited (no change to conclusions), published in Issue 4, 2010.
Review content assessed as up-to-date: 15 April 2009.

Citation: Burgess A, Kundu S. Diuretics for Ménière's disease or syndrome. *Cochrane Database of Systematic Reviews* 2006, Issue 3. Art. No.: CD003599. DOI: 10.1002/14651858.CD003599.pub2.

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ABSTRACT

Background

This is an update of a review first published in *The Cochrane Library* Issue 3, 2006.

Ménière's disease is a disorder characterised by hearing loss, tinnitus and disabling vertigo. Diuretics are used to try to reduce the severity and frequency of episodes but there is little evidence behind this treatment.

Objectives

To assess the effect of diuretic treatment in patients with Ménière's disease.

Search strategy

We searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL); PubMed; EMBASE; CINAHL; Web of Science; BIOSIS Previews; Cambridge Scientific Abstracts; mRCT and additional sources for published and unpublished trials. The date of the most recent search was 16 April 2009.

Selection criteria

Randomised controlled trials of diuretic versus placebo in Ménière's patients.

Data collection and analysis

Search results from the original and update searches were screened independently. We retrieved full text of potentially relevant articles and applied the inclusion criteria. Ten studies were excluded from the review due to inappropriate study design or absence of randomisation.

Main results

There were no trials of high enough quality to meet the standard set for this review.

Authors' conclusions

There is insufficient good evidence of the effect of diuretics on vertigo, hearing loss, tinnitus or aural fullness in clearly defined Ménière's disease.

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PLAIN LANGUAGE SUMMARY

Diuretics for the treatment of Ménière's disease or syndrome

Diuretics (drugs which reduce fluid accumulation in the body) are commonly used in the management of the symptoms of vertigo, hearing loss, tinnitus or aural fullness in patients with Ménière's disease. 'Endolymphatic hydrops' is an increase in the pressure of the fluids in the chambers of the inner ear and is thought to be the underlying cause of Ménière's disease. Diuretics are believed to work by reducing the volume (and therefore also the pressure) of these fluids. The authors of this systematic review carried out an extensive search but could not identify any randomised controlled trials of sufficient quality to include in the review. There is no good evidence about the effect of diuretics on the symptoms of Ménière's disease and further research is needed.

BACKGROUND

This is an update of a review first published in *The Cochrane Library* Issue 3, 2006.

Description of the condition

Definition

Prosper Ménière gave his name to a disorder characterised by recurrent episodes of spontaneous vertigo, fluctuating hearing loss and tinnitus, often with a feeling of fullness in the ear. The disorder may be subdivided into two categories. It is usually idiopathic (i.e. without known cause), in which case it is referred to as Ménière's disease. It may also be secondary to a number of known inner ear disorders, in which case it is referred to as Ménière's syndrome.

Aetiology

Ménière's disease is thought to be associated with endolymphatic hydrops, i.e. raised endolymph pressure in the membranous labyrinth of the inner ear (Hallpike 1938). The cause of the hydrops is not known in most cases. Specific disorders affecting the inner ear which are also associated with hydrops include temporal bone fracture, syphilis, hypothyroidism, Cogan's syndrome and Mondini dysplasia.

Prevalence

Ménière's disease is most common between 40 and 60 years of age, although younger people can also be affected (da Costa 2002; Morales 2003; Takeda 1998; Watanabe 1995). The incidence is estimated to be between 100 and 200 per million new cases per year. Acute episodes of Ménière's tend to occur in clusters with a mean frequency of between 6 and 11 clusters per year, though remission may last several months. Episodes have been observed to occur with increasing frequency over the first few years after presentation and then decrease in association with a sustained deterioration in hearing (Moffat 1997). In most cases, vertiginous episodes eventually cease completely (Silverstein 1989). This fluctuating natural history makes formal evaluation of any treatment effect in Ménière's difficult.

Diagnosis

The disorder is not always easy to diagnose and there is no 'gold standard' diagnostic test. It is almost certainly over-diagnosed by non-specialists. The American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) has produced diagnostic guidelines (Alford 1972) which have been revised twice (Ménière's Guide 1995; Pearson 1985), but these are not universally accepted. Nevertheless, they provide a standard which can be applied easily to make the diagnosis in normal clinical practice. In brief, these guidelines now stipulate that a 'definite' diagnosis can only be made on the basis of:

1. at least two spontaneous episodes of rotational vertigo lasting at least 20 minutes;
2. audiometric confirmation of a sensorineural hearing loss;
3. tinnitus and/or a perception of aural fullness.

These criteria exclude most other vestibular conditions, but further investigation is also necessary to exclude other disease processes such as an acoustic neuroma.

Treatment

Ideally, the aim of treatment is to:

1. reduce the number and severity of acute attacks of vertigo;
2. abort or ameliorate the hearing loss and tinnitus associated with such attacks;
3. alleviate any chronic symptoms (e.g. tinnitus and imbalance);
4. prevent progression of the disease, in particular the loss of hearing and balance function which characterises the disorder.

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The Journal of International Advanced Otology

J Int Adv Otol 2018; 14(2): 317–21 • DOI: 10.5152/iao.2018.140818

Review

European Position Statement on Diagnosis, and Treatment of Meniere's Disease*

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Cite this article as: Magnan J, Özgirgin N, Trabalzini F, Lacour M, Lopez Escamez A, Magnusson M, et al. European Position Statement on Diagnosis, and Treatment of Meniere's Disease. J Int Adv Otol 2018; 14(2): 317-21.

Meniere Disease keeps challenges in its diagnosis and treatment since was defined by Prosper Meniere at the beginning of 19th Century. Several classifications and definition were made until now and speculations still exist on its etiology. As the etiology remains speculative the treatment models remain in discussion also.

The European Academy of Otology and Neurotology Vertigo Guidelines Study Group intended to work on the diagnosis and treatment of Meniere's disease and created the European Positional Statement Document also by resuming the consensus studies on it.

The new techniques on diagnosis are emphasized as well as the treatment models for each stage of the disease are clarified by disregarding the dilemmas on its treatment. The conservative, noninvasive and invasive therapeutic models are highlighted.

KEYWORDS: Meniere's disease, treatment, betahistine, neurectomy, intratympanic treatment, diuretics, enedolymphatic sac surgery, intratympanic gadolinium, videohead impulse test

INTRODUCTION

Meniere's disease (MD) is a heterogeneous group of disorders defined by three core symptoms: episodic vertigo, tinnitus, and sensorineural hearing loss. The relevance of defining the diagnosis and treatment of MD could not be significantly achieved, as there still appear many arguments and few randomized double-blind prospective studies in this regard. The definition and classification have showed several revisions as the proposal made by the Barany Society in 2015 has received a significant support.

The working group on vertigo guidelines established by the European Academy of Otology and Neurotology (EAONO) Otologic Guidelines began studying on MD in 2011, and the group members met several times to discuss and offer the EAONO consensus on the diagnosis and treatment of MD. A comprehensive literature search was performed using PubMed and Embase as well to conclude this review.

The evidence has been low in many aspects of diagnosis and treatment options in MD and because of this the EAONO working group needed to make this review for a better clarification.

***Documented by European Academy of Otology & Neurotology (EAONO) Working Group on Vertigo Guidelines**

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Submitted: 13.08.2018 • **Accepted:** 14.08.2018

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Meniere's disease is characterized by episodic vertigo, low frequency fluctuating sensorineural hearing loss, tinnitus, and fullness on the affected side. Gait problems, postural instability, and drop attacks may accompany.

There has been the consensus with the published temporal bone studies that Meniere's disease has signs of endolymphatic hydrops. However, saccular endolymphatic hydrops can be found also in 10% of normal subjects and in 40% patients with >45 dB sensorineuaral hearing loss without any vestibular symptom [2].

Gurkov et al [3] categorizes endolymphatic hydrops as "primary hydropic ear disease" (PHED) and secondary hydropic ear disease (SHED). The primary disease is still assumed to be idiopathic and covers the whole inner ear. The term "secondary hydropic ear disease" describes the conditions that cause hydrops of the inner ear secondarily (such as endolymphatic sac tumors). This needs to be defined by imaging techniques.

In contrast to the AAO-HNS criteria published in 1972, 1985, and 1995, Barany Society in collaboration with AAO-HNS, the Japan Society for Equilibrium Research, the EAONO, and the Korean Balance Society published the criteria for the diagnosis of Meniere's disease. The Definite Meniere's disease is characterized with episodic vertigo and fluctuating low to medium frequency sensorineural hearing loss, fullness, and tinnitus being manifested at least with two episodes. The duration is mentioned to be between 20 min to 12 hours. Hearing loss in close temporal relationship to the episodes should also be considered [1].

Meniere's disease showed comorbidities with several disorders including autoimmune diseases and migraine [4, 5]. Several lines of evidence support that genetic factors contribute to phenotype variations [6]. Some patients (as high as 10%) may have first and second-degree relatives confirming the familial aggregation [6, 7]. Most of these families show an autosomal dominant pattern of inheritance with incomplete penetrance and variable expressivity [8, 9].

The Ménière's Disease Consortium (a European multicenter initiative to collect clinical data and biological samples) have conducted 2 large epidemiological studies using cluster analyses and it has identifed 5 subtypes of MD disease in patients with uni or bilateral involvement [10,11]. In unilateral MD, group 1 was the clinical variant most frequently observed (53%) and it included patients without a familial history of MD, migraine, or autoimmune comorbidity; MD type 2 was termed delayed MD and was found in 8% of cases and characterized by SNHL which antedated the vertigo episodes; familial MD or type 3 (13%) included all familial cases of MD; MD type 4 (15%) was associated with migraine with or without aura, and MD type 5 (11%) was defined by a concurrent autoimmune disorder [11].Moreover, the allelic variant rs4947296 is associated with bilateral MD and it has been found in 18% of patients with a comorbid autoimmune disorder [12]. When this advanced diagnosis can be achieved, MD should be treated according to its subtype characterization.

Assessment

Low to medium frequency sensorineural hearing loss as mentioned above is the most significant finding of MD. Therefore, an audiologic evaluation following a relevant history taking is mandatory for diagnosis of MD. Recurring and fluctuant characteristics of the hearing loss pattern is important to mention. The bedside eye movement evaluation represents a fundamental diagnostic step both in the first stage and during the follow-up.

Vestibular test battery

The methods to assess MD have now been enriched with new laboratory techniques. Videonystagmography (VNG) replaced electronystagmography, as it gave the opportunity of realtime observation of nystagmus with its third dimension. Caloric tests are still applicable.

Video head impulse tests are based on analyzing the vestibulo-ocular reflex with two parameters; gain and presence of overt/covert saccades. It is significantly the parameter of peripheral disease and can give access for evaluation of all semicircular canals indivdually. Video head impulse tests and caloric tests by VNG are the tests not competing but but are complementary to each other possibly because they test different frequency parts of the vestibular function [13].

Vestibular evoked myogenic potentials (VEMPs) help evaluate the function of the utricule and saccule as well as the superior and inferior vestibular nerves. VEMPs are the reflexes rising as a response obtained through the sternocleidomastoid and orbital muscles due to high intense acoustic stimuli. These can either be applied as bone conduction or air conduction to stimulate the otolith organs. Today VEMPs are rather used for monitoring the ototlith function and the effect of intratympanic gentamicin applications [14].

Electrocochleography was supposed to be the most specific test to diagnose Meniere's disease for a long time. As it detects the summating and action potentials (SPs and APs) arising from the cochlea and the nerve due to the click stimulations, the belief of elevation of the SP/AP ratio in hydrops populated this evaluation technique. There were difficulties in obtaining the evoked responses, as the ideal location was promontorium, which was not practical to put electrodes nearby the round window routinely in office-based conditions, and the response quality has been low with the tympanic membrane surface electrodes. Electrocochleography has lost its popularity over time [15].

Imaging

In 2007, Nakashima et al. [16] proposed 3 Tesla magnetic resonance imaging (MRI) evaluation of the inner ear following intratympanic gadolinium injection. Gadolinium that perfuses through the round window membrane allows the boundary between the endolymphatic space and the perilymphatic space to be distinguished.

MRI with intravenous (IV) administration of gadolinium has also been suggested. A delay of 4 hours is necessary following the injection of double dose of gadolinium. Both ears can be assessed but there is the risk of systemic toxicity due to the high dose of gadolinium [17].

While the T2-weighted images represent both perilymphatic and endolymphatic fluids, the bright signal on the 3D-FLAIR images represents only the perilymphatic fluid and internal dark signal represents the endolymphatic fluid [18].

In case the endolymphatic duct expands more than 33%, it should be argued as endolymphatic hydrops. However, the visualization of endolymphatic hydrops is not required to define MD and the MRI imaging should not be used to replace the diagnostic criteria of MD when also all definition criteria are fulfilled.

Firstline Management (Preventive)

A personalized approach for MD patients is strongly recommended. So, if a patient presents a comorbid condition such as allergy, migraine or autoimmune arthritis, they should be treated. The familial history of hearing loss and episodes of vertigo are also recommended, since genetic testing will identify the causal variant in 30% of familial cases, paving the way for gene therapy in few years.

Diet

The known adverse effects of caffeine and salt in MD is not clear. Low sodium diet and high water intake may prevent the release of vasopressin and help to maintain inner ear homeostasis [19, 20]. The AAO-HNS scale restricts caffeine in MD with the argument that caffeine can provoke modifications in the endolymph volume with its sympathomimetic action. The habitual consumption of caffeine varies due to the geography; hence, the relation of habitual intake of caffeine and Meniere's disease symptoms also differ. It is possible to assume that low amounts of caffeine, such as 100 mg/day, will not trigger Meniere's symptoms [21].

Betahistine

Betahistine is a weak histamine H1 agonist and a stronger H3 antagonist. This is the medication currently being used worldwide except for the USA. There have been remarkable studies about the efficacy of betahistine on reducing the vertigo episodes of MD, and some studies suggest its dosedependent effect in suppressing the frequency of vertigo attacks [22-25].

Furthermore, there are others, such as the Cochrane reviews, which support the positive effect of the medication on reducing the symptoms with good tolerance, also by arguing significant methodological limitations over the conducted studies; hence, larger studies for reaching to higher quality evidence on suggesting the use of betahistine [26].

A meta-analysis by Nauta [27] suggested the therapeutic benefit of betahistine in Meniere's disease.

The recently conducted multicenter study also known as BEMED suggested that two different doses (48 and 144 mg/day) of betahistine did not show any difference from placebo regarding the incidence of attacks and vestibular function [28].

The conflicting findings among different studies motivate further studies with well-defined inclusion and exclusion criteria and higher doses of betahistine to be accomplished. According to the clinical experience, the use of Betahistine 48 mg bid for 3-6 months to prevent Meniere's attacks can be advised.

Diuretics

The Cochrane report by Burgess & Kundu (2006) identified ten trials executed on diuretics' effect and among them two were placebo-controlled. As all were lacking the high quality of evidence, some studies have reported the efficacy of diuretics. The report concluded that there has been no good evidence of using diuretics in MD [29].

Diuretics are generally issued as first-line therapy for MD. The studies that support using diuretics have a low level of evidence [30]. The thiazide group diuretics can be a part of the medical treatment.

Secondline Management (Preventive)

In case medical treatments and refraining from excess of caffeine and salt does not control Meniere's episodes, a second-line treatment must be considered.

Intratympanic treatment has been very popular since the last two decades as being practical to apply even in the office setup.

Among the two available steroids derivatives, dexamethasone is practical to use due to better tolerance by the patients, as methylprednisolone creates burning sensation in the middle ear mucosa. The challenge with dexamethasone is its availability with low concentrations, such as 4 mg/mL.

The studies executed on application of intratympanic steroids for MD not show any homogeneity regarding the treatment protocols. Lavigne et al. [31] could only find one article being in favor of controlling tinnitus and vertigo in Meniere's disease. Being safe in terms of complications, such as hearing loss, has been the main advantage of using steroids. Individual based application of intratympanic dexamethasone can be favored.

Beyea et al. [32] reported that the effect of intratympanic dexamethasone application can have a shortterm control over the Meniere episodes as being effective in only 5% to avoid ablative surgery.

The Cochrane review by Westerberg [33] showed limited evidence to support the effectiveness of intratympanic steroids in MD treatment. Of note, the recent Oto-104 study with 12 mg dexamethasone can have the potential of discarding the disadvantages of intratympanic dexamethasone treatment regarding its low concentration [34].

Thirdline Management

Endolymphatic sac surgery was first defined by Portmann in 1927. There have been several discussions in favor and against this technique. The most remarkable argument against endolymphatic sac surgery was introduced by Jens Thomsen [35], which mentioned that the procedure has only a placebo effect.

The evidence level to support this surgery is low. Additionally, there are welldesigned randomized, double-blind, placebo-controlled studies for it [36].

The Cochrane review by Pullens et al. [37] over two randomized controlled studies showed that no significant effect could be achieved using the endolymphatic sac surgery, providing insufficient evidence for the beneficial effect.

Kitahara [38] proposed the injection of dexamethasone into the sac. As the endolymphatic sac is the only location for immune reactions in the temporal bone the hypothesis by Kitahara makes sense. In a retrospective study, Wick et al. suggested that endolymphatic sac shunt procedures may benefit from steroid instillation at the time of shunt placement [39].

Fourthline Management

Intratympanic Gentamicin Injection

Gentamicin is an aminoglycoside antibiotic having more vestibulotoxic than cochleotoxic effect. Its effect is mainly causing atrophy on type 1 vestibular cells as well as the neuroepithelium [40].

Although the intratympanic application of gentamicin poses the risk of hearing loss, many clinical studies have been designed to find out the lowest risk of its application with the maximum control of vertigo in MD. Hence, due to the toxic effect over the peripheral vestibular end-organ, dizziness and unsteadiness following the injection can be a minor problem that can be resolved by vestibular rehabilitation [41].

The intratympanic application of gentamicin has received more interest due to its strong effect over the Meniere episodes, that also beat the frequency of vestibular neurectomies.

The recommended application of gentamicin is one injection of 26.7 mg/mL concentration and scanning the vestibular physiological responses by the number of vertigo spells, a bedside evaluation, VEMPs, and video head impulse tests.

Fifthline Management

Advanced Surgery

Among the treatment techniques the only methods for MD that have gained high evidence are labyrinthectomy and vestibular neurectomy. Among these two, vestibular neurectomy is a selective technique issued to superior and inferior vestibular nerves and keeping the cochlear nerve safe. The efficiency of both techniques is good [42].

Vestibular neurectomy is believed to be the most efficient technique for drop attacks (Tumarkin's disorder) and for incapacitating Ménière' disease.

Labyrinthectomy is the oldest surgical method to treat MD, and today is limited to older patients. The technique can be associated with cochlear implantation within the same stage in case of profound bilateral hearing loss [43].

CONCLUSION

The definition of MD has reached a large international consensus, diagnosis and especially treatment still represent a debated topic. The main aim of this position paper is to identify a common path for medical professionals dealing with Meniere's disease diagnosis and treatment based on literature evidences and expert opinions.

Peer-review: Internally reviewed.

Author contributions: Concept – F.T., J.M.; Design – N.O., M.M., A.L.E., M.Magnusson; Supervision – J.M.; Resource & Materials – J.M., O.N.Ö., F.T., M.L., A.L.E., M.Magnusson, E.A.G., J.P.G., D.N., M.M.; Literature Search – N.Ö., A.L.E., M.M.; Writing – N.Ö., M.M.; Critical Reviews – J.M.

Conflict of Interest: The authors have no conflict of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

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Section 6.0

Previously Discussed Items

Bone Marrow Transplant for Severe Sickle Cell Disease

Question: Should bone marrow transplant (BMT) be covered for qualifying patients with severe sickle cell disease (SSD)?

Question source: OHSU BMT transplant program, CCO, OHSU sickle cell program

Issue: Bone marrow transplant for sickle cell disease was discussed at the January 2020 VbBS meeting, and testimony was heard from a variety of experts. The HERC staff evidence review concluded that "bone marrow transplant for sickle cell disease from an HLA matched sibling is recommended by expert groups and has retrospective cohort data to support its effectiveness. There are no RCT level data to support this intervention; however, transplants in the US are being performed as part of clinical trials to collect such data. Unrelated matched donor transplant has higher risks of graft-vs-host disease and lower survival rates compared to sibling transplants. Sickle cell disease affects a vulnerable population, which should be considered in decisions regarding therapy."

The VbBS members generally agreed that the evidence supports coverage of BMT for SSD. However, there was debate about whether this coverage should be restricted to HLA matched relative donor, or whether unrelated donors should be considered. The outcome data is significantly worse for unrelated donors, but most SSD patients do not have a matched relative donor. Experts suggested coverage for any SSD patient with a matched relative donor, and coverage for a non-relative donor only if the patient meets clinical trial criteria (generally requires significant adverse events from the SSD to have occurred). Private insurers are covering BMT for SSD for patients 40 and younger with no restriction on relative vs non-relative donor.

HERC staff was directed to work with the experts to fine tune the guideline wording on this topic and bring back to a future VbBS meeting.

HERC staff reviewed ClinicalTrials.gov and found 37 studies actively recruiting patients as of January 2020, examining BMT for SSD. These studies were examining various BMT protocols. Generally, related and unrelated donors were included, and the patient criteria varied from simply having SSD to having specified complications. NOTE: the FDA has approved this therapy; therefore, the therapy itself is not experimental. The need to be in a trial is to ensure data is collected on best candidates, best regimens, etc. due to the fact that this is a rare disease.

After the January 2020 VbBS meeting, HERC staff worked with experts to clarify the best coverage. Experts felt that including an age limit in the guideline was not the best approach, as the age for transplant is rapidly expanding.

> From Dr. Nemecek: I think stating an age limit can pose a risk of having to bring this up for review very soon again. Our field changes very quickly. Our clinical trials are set to adjust for these changes. A more general statement may prevent having to do multiple revisions of these guidelines without posing the risk of someone not eligible (too old/too sick) receiving a transplant. I have confirmed with my colleagues in Georgia and Maryland (where the busiest sickle cell disease centers are, that their approvals refer to children and adults, with no mention of age)

Population in Oregon with sickle cell disease

1) **HHS 2019**: 2012 data found 79 patients on Oregon Medicaid with SCD (0.14% of Medicaid patients)
2) **HERC staff data query**: 34 patients hospitalized for a collective total of 73 admissions in a one year period on Oregon Medicaid with sickle cell crisis (19 adults, 15 children)

HERC staff recommendations:

1) Add the ICD-10 D57.0 series (sickle cell disease with crisis) and D57.1 (Sickle-cell disease without crisis) to line 113 APLASTIC ANEMIAS; AGRANULOCYTOSIS Treatment: BONE MARROW TRANSPLANT
    1) Modify the line title of line 113 to APLASTIC ANEMIAS; AGRANULOCYTOSIS; SICKLE CELL DISEASE
    2) Keep the D57 series on line 194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN for medical therapy
3) Add a guideline to line 114 as shown below

GUIDELINE XXX BONE MARROW TRANSPLANT FOR SICKLE CELL DISEASE

Line 114

Allogeneic hematopoietic cell transplantation for sickle cell disease is included on this line only when:

1) Patient has a related human leukocyte antigen (HLA) matched donor; *or*
2) Patient has an unrelated or HLA mismatched related donor AND severe sickle cell disease (e.g. recurrent chest syndrome, recurrent vaso-occlusive crises, red blood cell alloimmunization on chronic transfusion therapy).

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF MINORITY HEALTH

DATA HIGHLIGHT
NO. 16| JUNE 2019

Prevalence of Sickle Cell Disease among Medicaid Beneficiaries in 2012

Shondelle M. Wilson-Frederick, PhD, Mary Hulihan, DrPH, and Karyn Kai Anderson, PhD, MPH

Introduction

Multiple medical advancements and health care interventions [1] have transformed sickle cell disease (SCD), a once fatal childhood disease, into a chronic condition. Previous studies have estimated that approximately 100,000 people are living with SCD in the United States [2]. Sickle cell disease, the most prevalent lifelong genetic blood disorder in the United States, causes the body to produce abnormal red blood cells shaped like sickles or crescents, which fail to properly deliver oxygen to body tissues. This shape change disrupts the normal flow of red blood cells through the blood vessels of the body, ultimately causing excruciating acute and chronic pain episodes (called pain crises). Sickle cell disease affects all racial and ethnic groups; however, in the United States, Black and Hispanic populations are disproportionately impacted. Despite the likelihood of people with SCD living longer, there are no national prevalence estimates on the Medicaid population living with SCD.

Key Findings:

- 55,349 people who were covered by Medicaid were identified with SCD.
- The national prevalence of SCD in the Medicaid population, expressed as a rate per 1,000 beneficiaries, was 0.73.
- Mississippi (2.20) had the highest SCD prevalence rate, per 1,000 beneficiaries, followed by District of Columbia (1.93), South Carolina (1.77), Louisiana (1.77), and Georgia (1.71).
- New York (10.59%) and Florida (9.75%) had the two largest populations of Medicaid beneficiaries with SCD.
- More than one out of five (23.54%) Medicaid beneficiaries with SCD were between the ages of 19-30 years.

Data Source: Estimates were produced using the CMS CCW SCD Indicator and data from the 2012 Medicaid Analytic eXtract (MAX) files.

In 2004, an optional Medicaid benefit for SCD was included in the American Jobs Creation Act of 2004 (AJCA)[1] in order to provide a new optional benefit in the Medicaid program and to make available federal matching funds for education and outreach to Medicaid-eligible adults and children with SCD. Additionally, the Medicaid program's benefit for children and adolescents, known as Early and Periodic Screening, Diagnostic and Treatment services (EPSDT), provides a comprehensive array of prevention, diagnostic, and treatment services for low-income infants, children and adolescents under age 21[2], including care for SCD. The federal government continues to support and increase awareness of improving care for people living with SCD. In September 2018, the White House released a Presidential Message for National Sickle Cell Disease Awareness Month, and in December 2018, President Donald Trump signed the Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act, which reauthorizes a SCD prevention and treatment program and provides grants for research, surveillance, prevention, and treatment of heritable blood disorders.

[1] American Jobs Creation Act of 2004 (AJCA) (Pub. L. No. 108-357), which was signed by the President on October 22, 2004. Section 712 of the AJCA amends title XIX of the Social Security Act (the Act)

[2] The Early and Periodic Screening, Diagnostic and Treatment services (EPSDT) provides a comprehensive array of prevention, diagnostic, and treatment services for low-income infants, children and adolescents under age 21, as specified in Section 1905(r) of the Social Security Act (the Act)

In commemoration of World Sickle Cell Day, the Centers for Medicare & Medicaid Services (CMS) has released a new SCD indicator in the CMS Chronic Conditions Data Warehouse (CCW).[3] We hope that this indicator will facilitate analysis by internal and external CCW users of the Medicare and Medicaid population living with SCD.

Using the CCW SCD indicator, this data highlight provides the first national prevalence estimates on the Medicaid population with SCD in 2012. The estimates described herein were produced using the 2012 Medicaid Analytic eXtract (MAX) files, the most current comprehensive data available for this study. This information will be useful for health plans and care providers who aim to improve the quality of care delivered to patients with sickle cell disease. Understanding the unique health needs of this vulnerable federally insured population will inform the development of interventions to increase awareness and understanding of people living with SCD.

Methods

The CMS SCD indicator is available for internal and external researchers who use data stored in the CMS CCW. The CCW creates a unique beneficiary identifier that can be used to link individual level beneficiary information with multiple files across multiple years of data. Within the CCW environment, SAS Enterprise Guide (V.9.4; SAS, Cary, NC) was used to produce state-level estimates and the 'maptile' function in STATA 13 (College Station, TX) was used to create the maps. The details of the algorithm and the codes used to assign the indicator have been documented in the CCW (www.ccwdata.org) [3].

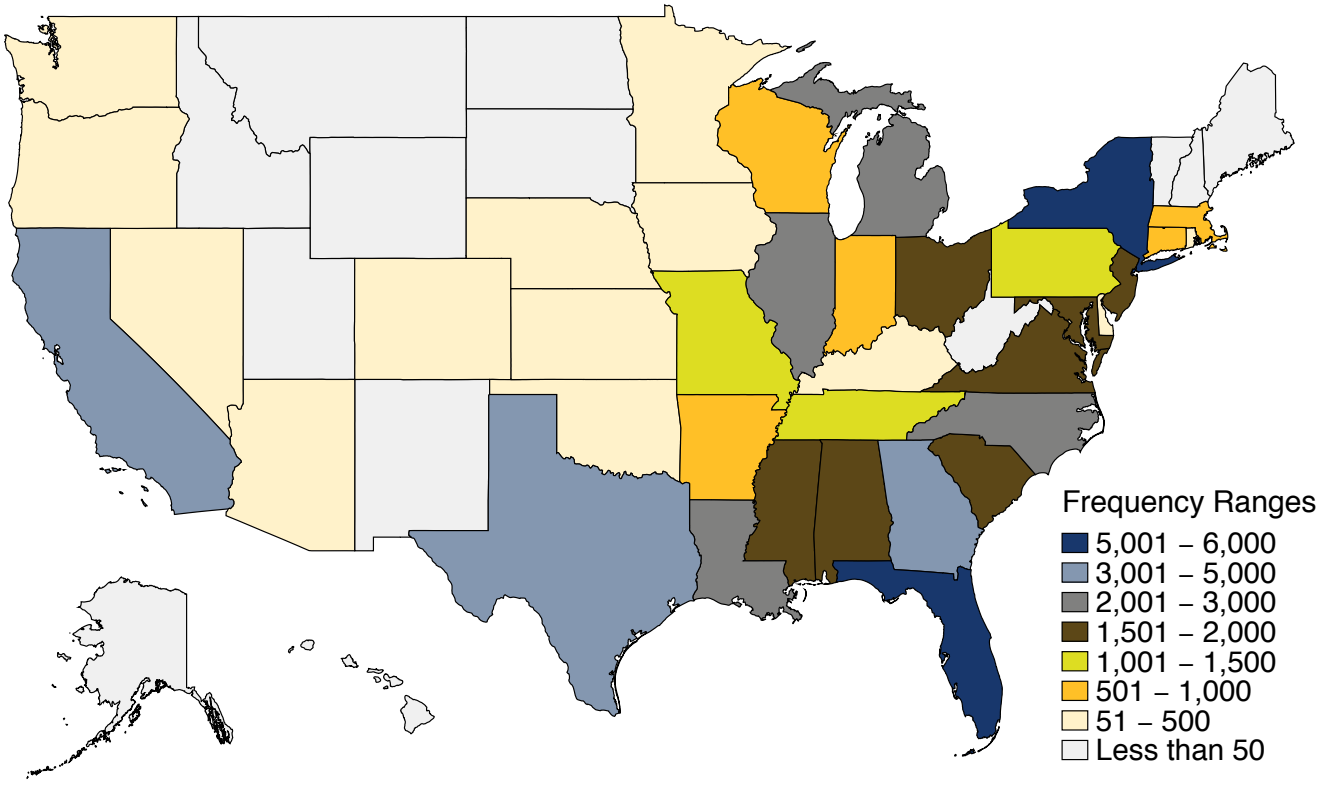
The CCW uses diagnosis codes to identify SCD. The algorithm requires three or more of any claim type (not including pharmacy claims) during a five calendar year "look-back" period (e.g., 2012 data would glean from claims data 2008 through 2012). Given that SCD is a chronic life-long health condition, a five-year look-back period was appropriate to best identify beneficiaries with SCD. Because individuals with SCD tend to have many encounters with the healthcare system, the algorithm required for claims to be separated by one day to account for multiple claims that may be associated with a single healthcare visit. There is evidence that claims-based algorithms are highly sensitive for SCD if three claims are required [4]. The diagnosis codes employed by this algorithm are consistent with the specifications employed by the CMS OMH [5] as well as other notable studies [4].

Using the SCD indicator in the CMS CCW, MAX data were pooled from 2008-2012 to identify beneficiaries with ICD-9 diagnosis codes for SCD. Individuals with sickle cell trait were excluded from the SCD indicator. These analyses included beneficiaries residing in the contiguous United States. Like all indicators in the CCW, the SCD indicator provides a standardized way to assess person-level research files indicating whether or not the given condition is present in our claims-based administrative database. This indicator along with its algorithm is designed to be flexible enough to facilitate a broad range of research studies, as well as to facilitate sickle-cell based exclusion criteria on studies of opioid use disorder. There are no restrictions or exclusions on these data for beneficiaries in hospice, residents of long-term care facilities, or beneficiaries receiving palliative care. In addition, for the algorithms to be flexible enough to meet different research needs, we did not build age constraints into the algorithms.

[3] More information on the SCD CCW indicator can be found at: https://www.ccwdata.org/web/guest/condition-categories

Results

Figure 1. Geographic Distribution of Medicaid Beneficiaries Living with Sickle Cell Disease in the United States in 2012



There was considerable representation of Medicaid beneficiaries living with SCD on the East Coast and in Southern states in 2012. Among Medicaid beneficiaries living with SCD, New York (n=5,863; 10.59% of Medicaid beneficiaries with SCD) and Florida (n=5,395; 9.75% of Medicaid beneficiaries with SCD) had the largest populations.

Figure 2. Prevalence Rates of Sickle Cell Disease, Per 1,000 Medicaid Beneficiaries, in 2012

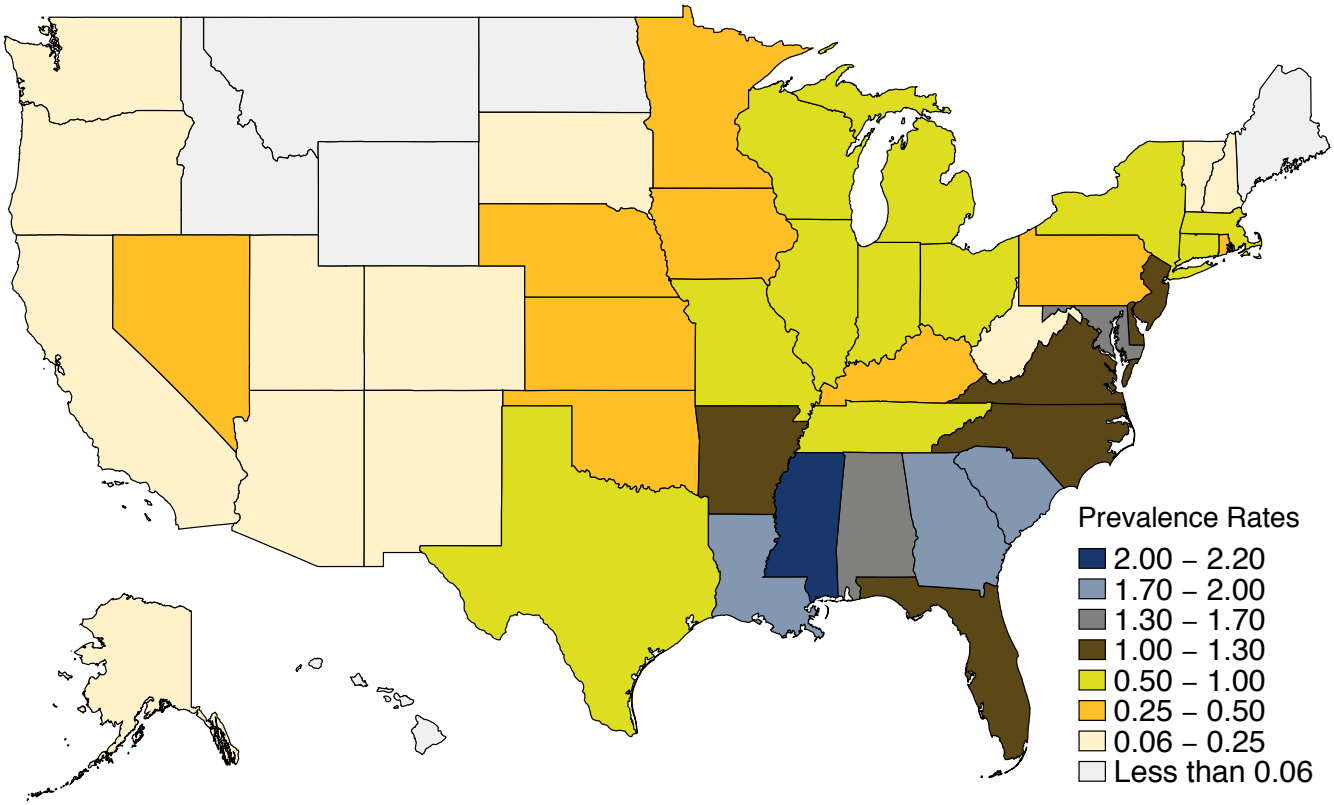


Figure 2 shows that Mississippi, with SCD prevalence rate of 2.20 per 1,000 Medicaid beneficiaries, was the only state with an SCD prevalence rate of 2.00 or greater in 2012. Several other states had SCD prevalence rates of 1.50 or greater: District of Columbia (1.93), South Carolina (1.77), Louisiana (1.77), Georgia (1.71), Alabama (1.61), and Maryland (1.53).

Table 1 shows that the prevalence of SCD in the Medicaid population, expressed as a rate per 1,000 beneficiaries, was 0.73 for the nation as a whole, in 2012. The following four states ranked within both the top ten states with the highest prevalence as well as the top ten states in terms of proportion of the SCD population: Georgia, Louisiana, North Carolina, and South Carolina.

Table 2 shows the state-level distribution of SCD among Medicaid beneficiaries by age. Among Medicaid beneficiaries with SCD the following age categories had the largest representation: 19-30 years (23.54%), 6-12 years (17.49%), ≤5 years (16.75%), and 31-45 years (15.95%).

Table 1. National and State-level Total Counts and Prevalence Rates of Sickle Cell Disease, Per 1,000 Medicaid Beneficiaries, in 2012

States	Number of Medicaid beneficiaries with SCD	Total number of Medicaid beneficiaries	Percent of all Medicaid beneficiaries with SCD	Prevalence rate of SCD Per 1,000 Medicaid beneficiaries
Alabama	1,754	1,087,010	3.17	1.61
Alaska	20	150,164	0.04	0.13
Arizona	320	1,725,214	0.58	0.19
Arkansas	812	787,503	1.47	1.03
California	3,015	13,374,370	5.45	0.23
Colorado	155	892,670	0.28	0.17
Connecticut	598	819,167	1.08	0.73
Delaware	276	256,188	0.50	1.08
District of Columbia	474	245,657	0.86	1.93
Florida	5,395	4,190,547	9.75	1.29
Georgia	3,752	2,191,946	6.78	1.71
Hawaii	11	332,913	0.02	0.03
Idaho	<11	302,709	*	*
Illinois	2,890	3,212,810	5.22	0.90
Indiana	789	1,304,423	1.43	0.60
Iowa	164	632,643	0.30	0.26
Kansas	220	439,698	0.40	0.50
Kentucky	372	1,007,306	0.67	0.37
Louisiana	2,559	1,445,249	4.62	1.77
Maine	13	383,602	0.02	0.03
Maryland	1,835	1,202,260	3.32	1.53
Massachusetts	877	1,651,901	1.58	0.53
Michigan	2,008	2,340,824	3.63	0.86
Minnesota	446	1,138,352	0.81	0.39
Mississippi	1,853	843,045	3.35	2.20
Missouri	1,134	1,208,261	2.05	0.94
Montana	<11	162,842	*	*
Nebraska	138	298,944	0.25	0.46
Nevada	186	389,816	0.34	0.48
New Hampshire	18	176,497	0.03	0.10
New Jersey	1,669	1,559,563	3.02	1.07
New Mexico	36	648,720	0.07	0.06
New York	5,863	6,013,629	10.59	0.97
North Carolina	2,667	2,116,498	4.82	1.26
North Dakota	<11	89,212	*	*
Ohio	1,900	2,687,125	3.43	0.71
Oklahoma	421	1,069,958	0.76	0.39

States	Number of Medicaid beneficiaries with SCD	Total number of Medicaid beneficiaries	Percent of all Medicaid beneficiaries with SCD	Prevalence rate of SCD Per 1,000 Medicaid beneficiaries
Oregon	79	809,796	0.14	*
Pennsylvania	1,162	2,559,639	2.10	0.45
Rhode Island	124	246,701	0.22	0.50
South Carolina	1,965	1,107,832	3.55	1.77
South Dakota	<11	143,989	*	*
Tennessee	1,388	1,566,821	2.51	0.89
Texas	3,314	5,922,736	5.99	0.56
Utah	39	420,302	0.07	0.09
Virginia	1,551	1,208,362	2.80	1.28
Vermont	18	204,146	0.03	0.09
Washington	234	1,438,670	0.42	0.16
Wisconsin	773	1,352,378	1.40	0.57
West Virginia	36	420,749	0.07	0.09
Wyoming	<11	84,334	*	*
Total	55,349	75,865,691	100	0.73

NOTE: Cells with <11 observations were censored.

Table 2: National and State-Level Distribution of Medicaid Beneficiaries Living with Sickle Cell Disease by Age in 2012

States	Age Categories									Total Number of:	
	≤5y	6-12y	13-18y	19-30y	31-45y	46-54y	55-64y	>65y	Unknown	Medicaid beneficiaries with SCD	Medicaid beneficiaries
Alabama	300	307	259	425	287	97	<11	<11	25	1,754	1,087,010
Alaska	<11	<11	<11	<11	<11	<11	<11	<11	<11	20	150,164
Arizona	45	53	45	64	58	27	<11	<11	15	320	1,725,214
Arkansas	137	148	132	163	131	43	<11	<11	30	812	787,503
California	439	435	359	708	578	244	118	44	90	3,015	13,374,370
Colorado	22	34	21	41	16	<11	<11	<11	11	155	892,670
Connecticut	103	92	77	151	96	38	<11	<11	15	598	819,167
Delaware	55	48	37	65	42	12	<11	<11	<11	276	256,188
District of Columbia	79	61	44	112	79	46	<11	<11	30	474	245,657
Florida	1,054	995	680	1,297	800	246	<11	<11	168	5,395	4,190,547
Georgia	702	714	527	817	537	174	<11	<11	158	3,752	2,191,946
Hawaii	<11	<11	<11	<11	<11	<11	<11	<11	<11	11	332,913
Idaho	<11	<11	<11	<11	<11	<11	<11	<11	<11	<11	302,709
Illinois	420	471	396	697	503	217	<11	<11	85	2,890	3,212,810
Indiana	146	145	109	165	112	53	<11	<11	32	789	1,304,423
Iowa	24	17	12	45	30	12	<11	<11	16	164	632,643
Kansas	39	31	18	47	25	11	<11	<11	42	220	439,698
Kentucky	80	65	44	85	54	23	<11	<11	<11	372	1,007,306
Louisiana	422	498	378	580	346	117	73	24	121	2,559	1,445,249
Maine	<11	<11	<11	<11	<11	<11	<11	<11	<11	13	383,602
Maryland	365	365	233	420	254	92	<11	<11	48	1,835	1,202,260
Massachusetts	156	156	119	194	158	51	<11	<11	17	877	1,651,901
Michigan	274	310	298	533	323	120	<11	<11	89	2,008	2,340,824
Minnesota	86	75	57	93	72	22	<11	<11	21	446	1,138,352
Mississippi	347	340	256	418	305	82	<11	<11	43	1,853	843,045
Missouri	138	213	135	257	188	91	<11	<11	33	1,134	1,208,261
Montana	<11	<11	<11	<11	<11	<11	<11	<11	<11	<11	162,842
Nebraska	30	33	15	29	18	<11	<11	<11	<11	138	298,944
Nevada	12	29	24	49	28	12	<11	<11	25	186	389,816
New Hampshire	<11	<11	<11	<11	<11	<11	<11	<11	<11	18	176,497
New Jersey	288	331	216	382	246	93	30	13	70	1,669	1,559,563
New Mexico	<11	<11	<11	<11	<11	<11	<11	<11	<11	36	648,720
New York	905	871	665	1,483	1,037	418	215	136	133	5,863	6,013,629
North Carolina	436	467	361	577	448	143	80	73	82	2,667	2,116,498
North Dakota	<11	<11	<11	<11	<11	<11	<11	<11	<11	<11	89,212

States	Age Categories									Total Number of:	
	≤5y	6-12y	13-18y	19-30y	31-45y	46-54y	55-64y	>65y	Unknown	Medicaid beneficiaries with SCD	Medicaid beneficiaries
Ohio	297	321	228	454	318	124	74	33	51	1,900	2,687,125
Oklahoma	72	72	68	81	64	24	<11	<11	20	421	1,069,958
Oregon	12	12	<11	25	<11	<11	<11	<11	<11	79	809,796
Pennsylvania	171	168	159	309	189	72	<11	<11	56	1,162	2,559,639
Rhode Island	13	29	19	24	26	<11	<11	<11	<11	124	246,701
South Carolina	314	359	268	498	318	96	53	15	44	1,965	1,107,832
South Dakota	<11	<11	<11	<11	<11	<11	<11	<11	<11	<11	143,989
Tennessee	255	259	192	340	207	55	<11	<11	41	1,388	1,566,821
Texas	606	682	469	771	454	149	<11	<11	108	3,314	5,922,736
Utah	<11	<11	<11	<11	<11	<11	<11	<11	<11	39	420,302
Vermont	<11	<11	<11	<11	<11	<11	<11	<11	49	1,551	204,146
Virginia	237	289	238	327	249	94	<11	<11	<11	18	1,208,362
Washington	43	37	27	60	45	<11	<11	<11	<11	234	1,438,670
West Virginia	<11	<11	<11	<11	<11	<11	<11	<11	<11	36	420,749
Wisconsin	119	105	86	204	148	54	<11	<11	33	773	1,352,378
Wyoming	<11	<11	<11	<11	<11	<11	<11	<11	<11	<11	84,334
Total	**9,273**	**9,680**	**7,300**	**13,013**	**8,830**	**3,193**	**1,555**	**623**	**1,864**	**55,349**	**73,865,691**
Percent of Medicaid beneficiaries with SCD[1]	**16.75**	**17.49**	**13.19**	**23.54**	**15.95**	**5.77**	**2.81**	**1.13**	**3.37**	**100**	

NOTE: Cells with <11 observations were censored.

[1] Each column total was divided by the total number of Medicaid beneficiaries with SCD (55,349)

Conclusion

This study identified 55,349 Medicaid beneficiaries living with SCD in 2012, a majority of whom were non-elderly (less than 65 years of age). In 2012, the national prevalence of SCD in the Medicaid population, expressed as a rate per 1,000 beneficiaries, was 0.73, with the following states having the highest prevalence of SCD among Medicaid beneficiaries: Mississippi (2.20), District of Columbia (1.93), Louisiana (1.77), and South Carolina (1.77).

The data analyzed in this study are commonly referred to as healthcare services utilization data or claims data [6]. Derived from reimbursement information or the payment of bills, these data are clinically valid and include beneficiary level information for admission and discharge dates, diagnosis and procedure codes, source of care, and various demographic characteristics (race and ethnicity, age and place of residence) [6]. While claims data provide a rich source of information on the prevalence of various chronic conditions, these data do not reveal the duration of or the severity of a condition. Also, undiagnosed conditions do not appear in utilization files and claims do not provide information on the care needed. Covered services for which claims are not submitted (such as immunizations provided through a free clinic) are not included in these data. Despite these limitations, claims data provide a reliable source of information to study chronic conditions, such as SCD and allowed for reporting the prevalence rate for SCD among the Medicaid population in 2012.

CMS is committed to advancing equity for all beneficiaries including those with SCD [7]. The Pediatric Quality Measures Program (PQMP), established in 2011 by the Agency for Healthcare Research and Quality's (AHRQ) and CMS under Title IV the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), increased the portfolio of evidenced-based, consensus pediatric quality measures. Additionally, through the PQMP several Centers of Excellence have been funded to develop new and innovative pediatric measures for Transcranial Doppler, a known method for preventing strokes in children, and appropriate antibiotic prophylaxis for children diagnosed with SCD. In 2016, the CMS Quality Improvement Organization Program created Special Innovation Project to Quality Improvement Organizations (QIOs)[4] focused on improving care received in the emergency department and addressing acute pain management in SCD patients. With the release of the CCW SCD indicator, we hope that others will join us on the path to equity by improving care for all Medicaid beneficiaries, including those living with SCD.

Keywords

Medicaid, Sickle Cell Disease, Prevalence Rate, Administrative or Claims Data

[4] In April 2019, atom Alliance, a CMS QIO, release the Sickle Cell Disease Resources for Providers and Patients and an overview highlighting the importance of the NHLBI Evidenced-Based Evidence-based Guidelines for Improving the Management of Sickle Cell Disease [3]. Recently, CMS funded the national expansion of an intervention developed by Qsource and atom Alliance that has improved acute pain management through patient education for 3,000 patients with SCD in Memphis, TN, and reduced hospital utilization resulting in an estimated savings of nearly $1.7M.

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Suggested Citation

Wilson-Frederick SM, Hulihan M, Anderson KK. *Prevalence of Sickle Cell Disease among Medicaid Beneficiaries in 2012*. CMS Office of Minority Health Data Highlight, No. 16. Baltimore, MD. 2019.

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Peripheral Nerve Ablation

Question: Should peripheral nerve ablation procedures of all types be added to the line/guideline for ineffective services?

Question source: HERC staff

Issue: During the November 2019 discussion of the 2020 CPT codes, CPT 64640 (Destruction by neurolytic agent; other peripheral nerve or branch) was removed from line 662/GN173 and placed on the Ancillary List due to updated CPT codes for genicular nerve ablation being published. CPT 64640 had been added to line 662/GN73 to represent genicular nerve ablation, and the only previous evidence review had been for genicular nerve ablation. However, it has come to HERC staff attention that a recent Washington HTA report has been published regarding peripheral nerve ablation procedures of all types which does not find evidence of effectiveness.

Additionally, the WA HTA report specifically looked at ablation of the plantar nerve, CPT 64632 (Destruction by neurolytic agent; plantar common digital nerve), which is on line 539 LESION OF PLANTAR NERVE; PLANTAR FASCIAL FIBROMATOSIS.

Other neurolytic related CPT codes are on various lines on the Prioritized List, but these codes do not relate to peripheral nerves. Instead, they related to cranial or central nerves. The CPT codes for neurolysis of paravertebral nerves already are placed on line 662/GN173.

Evidence

1) **Washington HTA 2018**, review of peripheral nerve ablation https://www.hca.wa.gov/assets/program/pna-final-report-20181211.pdf
    a. 13 RCTs met inclusion criteria: 7 for osteoarthritic knee pain, 4 for shoulder pain, and 2 for pain from plantar fasciitis. In addition, 8 nonrandomized studies on the harms associated with nerve ablation procedures met inclusion criteria.
    b. We found very low quality of evidence in favor of peripheral nerve ablation to improve some short-term functional and pain measures. Overall, 7 RCTs found some improvements in short-term functional status and level of pain that were both statistically significant and likely to be clinically meaningful. However, these improvements were generally small in magnitude and not consistent. Positive outcomes were often reported in only 1 RCT, on 1 scale or subscale, or at 1 time period.
    c. Potential harms of these procedures appear to be uncommon but have been poorly reported in published studies.
    d. We found no studies that reported RCTs for peripheral nerve ablation to treat pain at other anatomical sites, including the wrist, elbow, hip, ankle, or the digits.

Other coverage policies

1) Washington State Health Care Authority 2019
    a. Based on these findings [see above], the committee voted to not cover peripheral nerve ablation, using any technique, for limb pain due to osteoarthritis or other conditions for adults and children

HERC staff recommendations:

1) Add CPT 64640 (Destruction by neurolytic agent; other peripheral nerve or branch) to line 662/GN173 with a guideline entry as shown below
    a. Advise HSD to remove CPT 64640 from the Ancillary List
2) Add CPT 64632 (Destruction by neurolytic agent; plantar common digital nerve) to line 662/GN173 with a guideline entry as shown below
    a. Remove CPT 64632 from line 539 LESION OF PLANTAR NERVE; PLANTAR FASCIAL FIBROMATOSIS.

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
64632	Destruction by neurolytic agent; plantar common digital nerve	Insufficient evidence of effectiveness	March 2020
64640	Destruction by neurolytic agent; other peripheral nerve or branch	Insufficient evidence of effectiveness	March 2020

Washington State Health Care Authority

Health Technology Clinical Committee
Findings and Decision

Topic: Peripheral nerve ablation for limb pain
Meeting date: January 18, 2019
Final adoption: May 17, 2019

Meeting materials and transcript are available on the HTA website.

Number and coverage topic:

20190118B – Peripheral nerve ablation for limb pain

HTCC coverage determination:

Peripheral nerve ablation, using any technique, to treat limb pain including for knee, hip, foot, or shoulder due to osteoarthritis or other conditions, is **not a covered benefit** for adults and children.

HTCC reimbursement determination:

Limitations of coverage: N/A

Non-covered indicators: N/A

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee decided that the current evidence on peripheral nerve ablation for limb pain due to osteoarthritis is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for the use of peripheral nerve ablation. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to not cover peripheral nerve ablation, using any technique, for limb pain due to osteoarthritis or other conditions for adults and children

	Not Covered	Covered under certain conditions	Covered unconditionally
Peripheral nerve ablation, using any technique, for chronic limb pain due to osteoarthritis or other conditions for adults and children.			
Foot, Shoulder, Hip	10	0	0
Knee	6	4	0

Discussion

The committee reviewed and discussed the available studies for use of peripheral nerve ablation for limb pain. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that use of peripheral nerve ablation for the foot, shoulder or hip, using any technique, for limb pain for osteoarthritis or other conditions was unproven for being safer, more effective, or more cost-effective than comparators. The committee found that peripheral nerve ablation of the knee, using any technique, for limb pain for osteoarthritis or other conditions was unproven for being safer or more cost-effective than comparators. The committee did find that in some cases, peripheral knee ablation of the knee, using any technique, for limb pain due to osteoarthritis or other conditions is more efficient.

Additional Considerations

The Committee recognizes, from information provided in the review process, that ongoing studies could impact the evidence-based determination: they will re-review this topic following publications of new research findings that could change the determination.

Limitations

N/A

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). Medicare does not have a NCD for peripheral nerve ablation for limb pain.

The committee discussed clinical guidelines, however, none of identified clinical practice guidelines made a recommendation for the use of nerve ablation procedures for limb pain. Organizational guidelines:

- Association of Extremity Nerve Surgeons (2014)
- American College of Occupational and Environmental Medicine (2013)
- American College of Foot and Ankle Surgeons (ACFAS) (2018)
- American Academy of Orthopaedic Surgeons (2013)
- National Institute for Health and Care Excellence (NICE) (2014)
- Veterans Administration/Department of Defense (2014)

The committee's determination is consistent with these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on use of peripheral nerve ablation for limb pain for public comment to be followed by consideration for final approval at the next public meeting.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Director.

Key questions and background

Peripheral nerve ablation for the treatment of limb pain

Background

Clinical need and target population

Severe limb pain can markedly limit quality of life if it is not effectively managed. Chronic Limb pain can occur in a joint, such as the hip, shoulder or knee and is most often due to osteoarthritis.[1] Other causes of chronic limb pain include traumatic injury, rheumatoid arthritis, postoperative pain syndromes, or soft tissue (e.g., muscles, tendons, ligaments) dysfunction.[2] Standard treatments for chronic limb pain include physical activity, weight loss, medications (prescription drugs and over-the-counter pain relievers), physical therapy, complementary and alternative therapies (e.g., massage, acupuncture), and surgery.[3] Treatments for osteoarthritis aim to reduce symptoms and improve function, although most treatments do not modify the natural history or progression of the disease.[2]

Technology of interest

Nerve ablation can be accomplished in several ways, including radiofrequency ablation, chemical ablation, and surgical ablation. There are three different types of radiofrequency ablation that have been developed. Standard thermal radiofrequency nerve ablation is a minimally invasive procedure that uses heat and coagulation necrosis to damage or destroy nerve tissue.[2] A high frequency electrical current is applied to the target tissue, using a needle electrode that is inserted through the skin.[2] The electrode generates heat (80 to 90°C) which coagulates a small volume of tissue.[2] The goal is to destroy peripheral sensory nerve endings, resulting in alleviation of pain.[2] However, the affected nerves may regenerate, causing the pain to return.[4]

Cooled radiofrequency is a newer technology that uses a water cooled radiofrequency probe to create a larger lesion size and therefore treat a larger area than standard thermal radiofrequency ablation.[5] Cooled radiofrequency devices apply more energy at the desired location, but use water cooling to prevent as much heat diffusing beyond the target area.[5] COOLIEF, produced by Haylard Health, Inc., is a cooled radiofrequency treatment that was cleared for marketing by the FDA in 2017.[6] It is used to treat hip and knee osteoarthritis pain and is performed as an outpatient procedure.[5]

Pulsed radiofrequency treatment uses short bursts of radiofrequency current, rather than continuous current of standard radiofrequency ablation.[2] The heat from pulsed radiofrequency ablation (not exceeding 45°C) may cause less damage than standard thermal radiofrequency ablation.[2] Pulsed radiofrequency has been proposed as a possibly safer alternative to continuous radiofrequency ablation in the treatment of variety pain syndromes.[2]

Policy context

Peripheral nerve ablation is one of many available treatments for patients with limb pain. This topic was selected for a health technology assessment because of high concerns for the safety and efficacy of the procedure and medium/high concern for cost.

This evidence review will help to inform Washington's independent Health Technology Clinical Committee as the committee determines coverage regarding peripheral nerve ablation for patients with limb pain.

Key questions

1. What is the evidence of efficacy and effectiveness for peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?
2. What direct harms are associated with peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?
3. Do important patient efficacy/effectiveness outcomes or direct harms from peripheral nerve ablation for limb pain vary by:
    a. Indication
    b. Patient characteristics
4. What are the cost-effectiveness and other economic outcomes of peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?

Scope

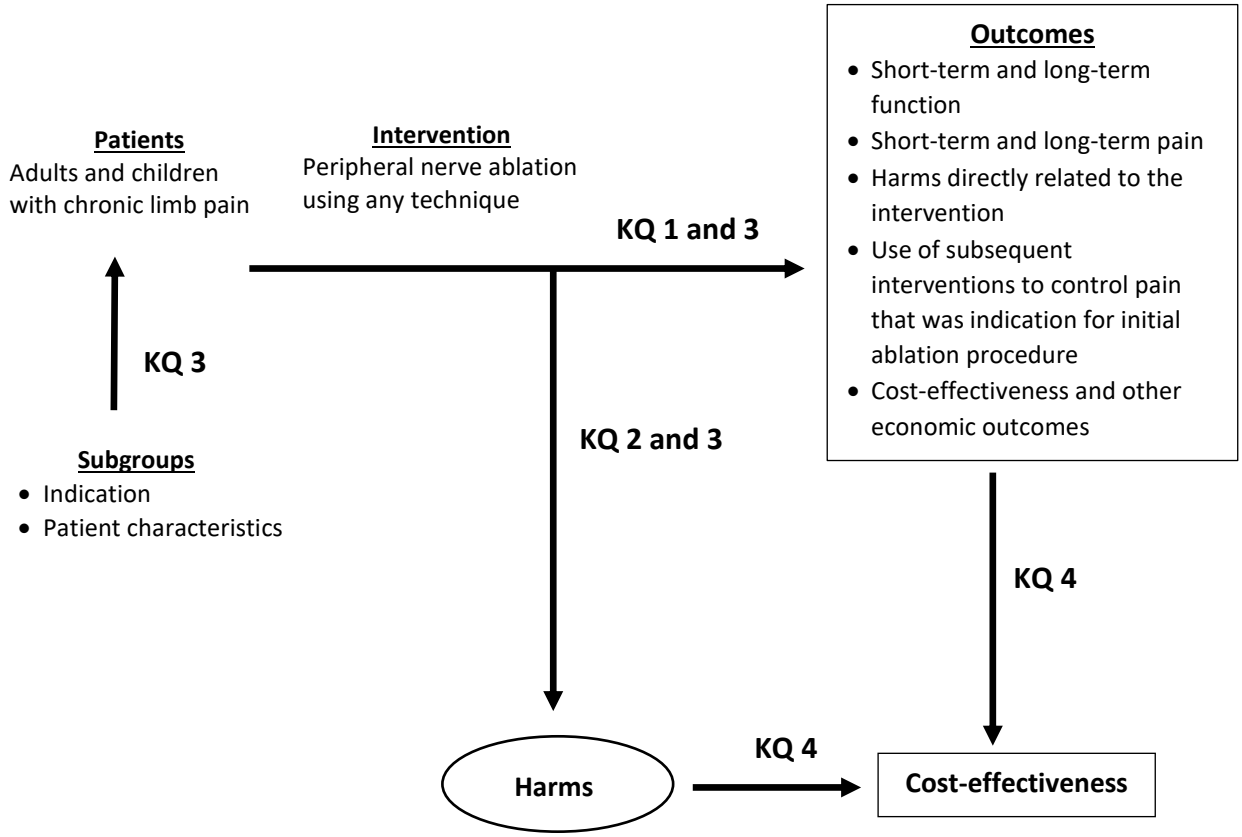
Study component	Inclusion	Exclusion
Populations	Adults and children with chronic limb pain due to osteoarthritis or other conditions	Pain that does not arise from an extremity joint or soft tissue
Interventions	Peripheral nerve ablation using any technique	Ablation as part of another surgical intervention Procedures involving the central nervous system
Comparators	Other treatments for limb pain, including: • Medication • Surgery • Behavioral or psychological interventions	Studies without a comparator intervention Studies with indirect comparisons Studies with an outdated comparator or a comparator

Study component	Inclusion	Exclusion
	• Physical therapy or other non-invasive non-medication therapies • Placebo • Sham procedures • No treatment	intervention that is not available in the U.S.
Outcomes	• Primary outcomes: short-term and long-term function measured by a validated method • Secondary outcomes: short-term and long-term pain measured by a validated method • Safety: harms directly related to the intervention • Indirect outcomes: use of subsequent interventions to control pain that was the original indication for the initial peripheral nerve ablation procedure • Economic: cost-effectiveness outcomes (e.g., cost per improved outcome) or cost-utility outcomes (e.g., cost per quality adjusted life year [QALY], incremental cost effectiveness ratio [ICER])	Other outcomes
Study design	• KQ 1–4 ○ Randomized controlled trials ○ Systematic reviews of randomized controlled trials • Additional studies/data for KQ 2–3 (harms) ○ Non-randomized comparative studies ○ Non-randomized studies without a comparator will be assessed for harms only, if evidence for the intervention is included in KQ1 ○ Governmental or other registries and databases containing reports of procedure-related harms or device recalls (e.g., FDA MAUDE database, FDA Medical Device Recall database) • Additional studies/data for KQ 4 ○ Cost-effectiveness studies and other formal comparative economic evaluations	Abstracts, conference proceedings, posters, editorials, letters, case reports and case series with fewer than 10 subjects (for harms only), studies with harms outcomes for an intervention that is not included in KQ1

Study component	Inclusion	Exclusion
	○ Systematic reviews of cost-effectiveness studies and other formal comparative economic evaluations	
Publication	• Studies in peer reviewed journals, technology assessments or publically available FDA or other federal government reports • Published in English • Published from database inception through September 2018	Studies whose abstracts do not allow study characteristics to be determined Studies that cannot be located Duplicate publications of the same study that do not report different outcomes or follow-up times, or single site reports from multicenter studies • Studies in languages other than English

Analytic framework

The analytic framework below will guide the selection, synthesis, and interpretation of available evidence.



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Public comment and response

See **Draft Key Questions: Comment and response** document published separately.

Section 7.0

New Discussion Items

Bone Grafts

Question: Should bone grafts be removed from the Prioritized List and placed on the Ancillary List?

Question source: HSD Medical Management Committee

Issue: Various bone graft codes (CPT 20955-20973) are currently multiple lines. However, these grafts might be required for reconstruction after surgical removal of malignancies or congenital lesions or for other reasons. The MMC receives requests for these codes as part of the prior authorization for larger surgeries and needs to review them as exceptions. The HERC has made similar skin and soft tissue graft CPT codes Ancillary for the same reason (reconstruction after surgery).

CPT code	Code description	Current Placement
20955	Bone graft with microvascular anastomosis; fibula	184 ACUTE OSTEOMYELITIS 200 CANCER OF BONES 254 CHRONIC OSTEOMYELITIS 401 BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS 442 MALUNION AND NONUNION OF FRACTURE 558 BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE INCLUDING OSTEOID OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE
20956	Bone graft with microvascular anastomosis; iliac crest	184,200,254,401,442,558
20957	Bone graft with microvascular anastomosis; metatarsal	184,200,254,401,442,558
20962	Bone graft with microvascular anastomosis; other than fibula, iliac crest, or metatarsal	184,200,254 287 CANCER OF ORAL CAVITY, PHARYNX, NOSE AND LARYNX 401,442,558
20969	Free osteocutaneous flap with microvascular anastomosis; other than iliac crest, metatarsal, or great toe	112 CANCER OF EYE AND ORBIT 184,200,254,401,442,558
20970	Free osteocutaneous flap with microvascular anastomosis; iliac crest	184,200,254,401,442,558
20972	Free osteocutaneous flap with microvascular anastomosis; metatarsal	131 CRUSH INJURIES OTHER THAN DIGITS; COMPARTMENT SYNDROME 160 TRAUMATIC AMPUTATION OF ARM(S), HAND(S), THUMB(S), AND FINGER(S) (COMPLETE)(PARTIAL) WITH AND WITHOUT COMPLICATION 184,200,254,401,442,558
20973	Free osteocutaneous flap with microvascular anastomosis; great toe with web space	160,184,200,254, 289 CRUSH AND OTHER INJURIES OF DIGITS 401,442,558

Bone Grafts

HERC staff recommendation:

1) Remove CPT 20955-20973 (bone flaps) from all current lines on the Prioritized List
    a. Advise HSD to place CPT 20955-20973 on the Ancillary Procedures File

Cranial Electrical Stimulation Therapy

Question: Should cranial electrical stimulation therapy be paired with anxiety and/or depression?

Question source: Allevia Health (manufacturer of Alpha-Stim)

Issue: Cranial electrical stimulation (Alpha-Stim and similar products) is an electrotherapy device for treating symptoms of anxiety, insomnia and depression. The device uses cranial electrotherapy stimulation, providing variable electrical microcurrent to the brain which stimulates alpha wave electrical activity. The current is applied by clips that attach to the ear lobes.

Cranial electrical stimulation was reviewed in 2017 and included in the GN173 entry for the HCPCS code that included TENS, as these codes were also used for CES. A new HCPCS code specific for alpha stim was released for 2020. The TENS entry was updated in January 2020 to include frequency specific microcurrent therapy and similar therapies; cranial electrical stimulation was not reviewed at that time.

HCPCS K1002: Cranial electrotherapy stimulation (ces) system, includes all supplies and accessories, any type

The manufacturer submitted updated literature and requested re-review of this technology. Only one RCT published after the 2017 HERC review was identified and was too small for inclusion in this review (N=17).

No updates were found to the previously reviewed Cochrane evaluations of cranial electrical stimulation for depression or other indications.

Evidence

1) **NICE 2019**, Alpha Stim for anxiety
    a. N=1 RCT (Barclay 2014—included in the 2017 HERC review) and 3 observational studies (Morriss 2019, Bystritsky 2008, Chen 2007)
        i. Bystritsky and Chen had very small sample sizes (N=12, 30) and were not included in the 2017 HERC review
        ii. Morriss 2019
            1. N=161
            2. 72 (44.7%) and 77 (47.8%) had remission on the GAD-7 scale at 12 and 24 weeks respectively. There were 122 (75.8%) who had at least 6 weeks CES. The mean GAD-7 score at baseline significantly improved from 15.77 (SD=3.21) to 8.92 (SD=5.42) and 8.99 (SD=6.18) at 12 and 24 weeks respectively ($p<0.001$). There were 80 (49.7%) patients who needed further individual CBT.
            1. This is a before-after comparative study, and there was no control group. 55.2% of patients lost to follow up. The study was funded by the company.
    b. The studies show that the Alpha-Stim AID is effective at reducing the level of anxiety and depression in patients diagnosed with anxiety disorders.
    c. Key uncertainties around the evidence are a lack of generalisability to the NHS and no evidence from randomised controlled trials on the long-term effect of the technology on treating people with anxiety disorders.

HERC staff summary:
No new high-level evidence has been produced which would indicate that cranial electrical stimulation is effective at long term treatment of anxiety or other disorders. NICE reviewed alpha stim, and did not add it to their guidance on treatment of anxiety.

HERC staff recommendation:

1) Modify 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
K1002	Cranial electrotherapy stimulation system	No clinically important benefit (CES) for chronic pain; insufficient evidence of effectiveness for all other indications	September, 2017
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~~ Insufficient evidence of effectiveness for chronic pain and all other indications	January 2020

NICE advice

Alpha-Stim AID for anxiety

Medtech innovation briefing
Published: 16 September 2019
www.nice.org.uk/guidance/mib193

Summary

- The **technology** described in this briefing is Alpha-Stim AID. It is used for treating anxiety, insomnia and depression. This briefing focuses only on anxiety.
- The **innovative aspect** is that the device has a patented electrical wave pattern that is transmitted to the brain using cranial electrotherapy stimulation.
- The intended **place in therapy** would be an alternative to or in addition to current treatment options for people with anxiety disorder. The device would be provided by primary care services and mental health outpatient services for use at home.
- The **main points from the evidence** summarised in this briefing are from 1 randomised trial and 3 observational studies including 318 adults and 30 children with anxiety disorders. They show that the Alpha-Stim AID is effective at reducing the level of anxiety and depression in patients diagnosed with anxiety disorders.
- **Key uncertainties** around the evidence are a lack of generalisability to the NHS and no evidence from randomised controlled trials on the long-term effect of the technology on treating people with anxiety disorders.

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- The typical cost of a course of patient treatment with Alpha-Stim AID is £70. The company claims the technology could be resource releasing by reducing the need for medications and psychological interventions. There is currently no published evidence to support reduced need for medications.

The technology

Alpha-Stim AID (Electromedical Products International, Inc.) is an electrotherapy device for treating symptoms of anxiety, insomnia and depression. The technology was developed in 1981 in the US, and Alpha-Stim AID is the latest model. The device uses cranial electrotherapy stimulation, providing variable electrical microcurrent to the brain which stimulates alpha wave electrical activity. The current is applied by clips that attach to the ear lobes. The device has a pulse repetition rate of 0.5 hertz. The wave is composed of bipolar asymmetric rectangular waves in a cycle that repeats periodically at 10-second intervals.

The device is the size of a mobile phone and has a pair of small clips that can be wetted with a coating solution. When it is turned on, a small vibration is felt in the ears, like a mild electrical current. The strength of this can be adjusted. Alpha-Stim AID can be used for between 20 and 60 minutes every day, every other day, or on an as-needed basis. The higher the strength of the current, the shorter the time the patient needs to wear it. Alpha-Stim AID is battery powered, which allows users to be mobile when using it.

Innovations

Alpha-Stim AID generates a patented pattern of waves of microcurrents (0.5 hertz), which are transmitted to the brain. This repeats every 10 seconds. This is compared with the normal or beta waves which are 13 to 25 hertz and is the state that most people are in during the day. The company claims that alpha waves are thought to be associated with a feeling of relaxation similar to that of meditation.

Current care pathway

NICE's guideline on the management of generalised anxiety disorder and panic disorder in adults provides principles of care for people with generalised anxiety disorder (GAD). It also recommends a stepped-care model to organise service provision and to help people with GAD, their families, carers and practitioners to choose the most effective intervention. The stepped-care model includes interventions for identification and assessment of GAD (step 1), low-intensity psychological interventions (step 2), high-intensity psychological intervention (cognitive

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behavioural therapy [CBT]/applied relaxation) or drug treatment (step 3) and highly specialist treatment (step 4). The company notes that the product can be used as an alternative or as well as existing treatment options (interventions included in step 3) for anxiety disorders including medication and high-intensity talking therapies.

Population, setting and intended user

Alpha-Stim AID is for people with anxiety, insomnia and depression. The focus of this briefing is for people with anxiety.

The device would be provided by primary care services and mental health services for patients to use at home. Patients would be taught how to use the device by a healthcare professional. An information leaflet is also provided, so people can use the device unsupervised at home. Training is needed and would be given to all relevant staff. Training for patients and healthcare providers is included in the cost of the device. The company claims that there are few changes needed to the current mental health service set up. It states that the only change to existing care would be staff training at a local level (such as GP surgeries) to provide the device and show it to the patient.

Costs

Technology costs

The cost of an Alpha-Stim AID is £450 (excluding VAT) per device. The device can be re-used by multiple patients. For example, the company states typical usage based on an individual patient treatment of 10 weeks use (including additional staff time, postage and consumables cost, estimated at £40), per patient treatment cost is £70 (Morriss et al. 2019). There is a 5-year warranty. The company notes anecdotal data from users suggesting the cost per patient could be as low as £40 in primary care.

Costs of standard care

There was no estimate identified for the overall cost of existing standard care for anxiety disorder by the company. NICE advice on the improving access to psychological therapies programme (IAPT) for adults with general anxiety disorder provides the estimated costs for interventions, included in the stepped-care model depending on the intensity of interventions.

The cost of interventions for people with anxiety

Low-intensity psychological interventions:

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- Non-facilitated self-help: £10 per person, 6-week course.
- Guided bibliotherapy: £110 per person, 5-session course.
- Psycho-educational groups: £29 per person, estimated 12 people in the group, 6-week course.

High-intensity psychological interventions (CBT, applied relaxation):

- Individual CBT: the total cost of either CBT or applied relaxation would cost £733 per person, 13-week course.
- Group CBT sessions: £93 per person, 11-week course.
- Pharmacological therapy: £75 per person, based on a minimum daily dose for 6 months, a course of a selective serotonin reuptake inhibitor.

Resource consequences

The device is currently used in 3 NHS trusts. If Alpha-Stim AID was adopted as an add-on treatment to existing interventions, the cost per treatment of anxiety disorder would increase by £70. The company claims that this could be offset if the device replaced or reduced the use of medication and intensive psychological interventions.

A recent published study using a cost minimisation model assessed the cost impact of Alpha-Stim AID in the NHS (Morriss et al. 2019). This study was sponsored by the company. It included a sample of 161 patients with GAD who were waiting for individual CBT. Results suggested that mean general anxiety disorder-7 (GAD-7) score significantly improved from 15.77 (standard deviation [SD]=3.21) at baseline to 8.92 (SD=5.42) and 8.99 (SD=6.18) at 12 and 24 weeks respectively ($p<0.001$). There were 80 people (49.7%) who needed further individual CBT. Alpha-Stim AID provided an estimated saving of £540.88 per patient (95% confidence interval [CI] −£648.69 to −£327.12). This saving is compared with an 8-session standard care model of individual therapist-led CBT.

Training is needed for relevant staff. Few changes are needed to facilities or infrastructure to adopt the technology because it is designed to be used in patients' homes.

Regulatory information

Alpha-Stim AID was CE marked as a class IIa medical device in 2012.

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A search of the Medicines and Healthcare products Regulatory Agency website shows no manufacturer field safety notices or medical device alerts for the technology.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Generalised anxiety disorder (GAD) is a long-term condition and people with GAD feel anxious most days. This can cause both psychological and physical symptoms including feeling restless or worried, and having trouble concentrating or sleep. The condition can have a substantial effect on individuals' daily lives. This may mean someone is disabled if their anxiety disorder has a substantial and long-term effect on their ability to do daily activities. Disability is a protected characteristic under the Equality Act. People from certain socially excluded groups that would benefit from psychological interventions might be less likely to access them, such as black and minority ethnic groups; older people; those in prison or in contact with the criminal justice system; and ex-service personnel. Sex, age and family origin are all protected characteristics under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

There are 4 studies including 1 randomised trial and 3 before-after studies summarised in this briefing. The other relevant study (Lu and Hu, 2014) was excluded because its full text was not published in English. One trial (Barclay and Barclay, 2014) assessed the efficacy of the Alpha-Stim device in 115 people with anxiety disorder. Two observational studies (Morriss et al. 2019 and Bystritsky et al. 2008) examined changes in anxiety scores in 173 adults with anxiety disorder before and after cranial electrotherapy stimulation (CES) treatment. Chen et al. (2007) examined the impact of CES treatment for 30 children with anxiety disorders.

Table 1 summarises the clinical evidence as well as its strengths and limitations.

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Overall assessment of the evidence

In general, the evidence from the trial shows that the Alpha-Stim device (Alpha-Stim 100) was associated with statistically significant improvements in anxiety and depression compared with control interventions. Results of 3 observational studies were consistent with the findings reported in the trial. This suggests a significant decrease in patients' anxiety and depression score after treatment. However, there is little evidence from randomised controlled trials on the long-term effects of the device.

The evidence is limited in quantity; 3 of 4 included studies are not from the UK, which may limit the generalisability to the NHS. The device was developed in the early 1980s, and evidence from 3 studies are based on old models of the device (Alpha-Stim 100 and Alpha-Stim SCS). The company advised that included evidence is generalisable to the latest version of the Alpha-Stim device because the mechanism of the device remains the same, and the only change is inclusion of a LED screen.

Table 1 Summary of selected studies

Morriss et al. (2019)	
Study size, design and location	A before-after study of 161 patients with GAD. UK.
Intervention and comparator(s)	Alpha-Stim AID. No comparator.
Key outcomes	The 161 patients included had 60 minutes per day of Alpha-Stim AID for 6 to 12 weeks. Of these, 72 (44.7%) and 77 (47.8%) had remission on the GAD-7 scale at 12 and 24 weeks respectively. There were 122 (75.8%) who had at least 6 weeks CES. The mean GAD-7 score at baseline significantly improved from 15.77 (SD=3.21) to 8.92 (SD=5.42) and 8.99 (SD=6.18) at 12 and 24 weeks respectively ($p<0.001$). There were 80 (49.7%) patients who needed further individual CBT.
Strengths and limitations	This is a before-after comparative study, and there was no control group. 55.2% of patients lost to follow up. The study was funded by the company.
Barclay and Barclay (2014)	

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Study size, design and location	A double-blind parallel trial of 115 people with anxiety disorder. USA.
Intervention and comparator(s)	Alpha-Stim 100. Sham CES devices.
Key outcomes	At baseline, there were no statistically significant differences in mean of HAM-A and HAM-D_{17} between the 2 groups measured, although scores were higher in the active CES group (scores increased with the severity of anxiety). After a 5-week study follow up, the active CES group had significant lower anxiety score on HAM-A and HAM-D_{17} than the sham CES group from baseline to the end of the study. In the active CES group, 83% had a decrease of more than 50% in anxiety score (HAM-A) from baseline to the end of study follow up. The decrease in the HAM-A in the active CES group was 32.8%, which was more than 3 times the mean decrease seen in the same CES group (9.1%). In the active CES group, 82% had a decrease of more than 50% in depression score (HAM-D_{17}) from baseline to the end of the study. The average decrease of depression score was 32.9% in the active CES group compared with 2.6% in the shame CES group.
Strengths and limitations	A double-blind study design. Short study follow up. The self-selected people joined the study by responding to the study announcement, and each person had to pay $30 to enter. Both anxiety and depression were primary outcomes, but only 23 people had an anxiety disorder and comorbid depression.
Bystritsky et al. (2008)	
Study size, design and location	A before-after study of 12 patients with a diagnosis of GAD. USA.
Intervention and comparator(s)	Alpha-Stim SCS. No comparator.

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Key outcomes	Mean HAM-A score decreased significantly from 21.25 (SD=5.82) at baseline to 12.67 (SD=5.47) the end of the study (6 weeks, p=0.01). Six patients (50%) had a 50% decrease on HAM-A and a score of 1 or 2 on the Clinical Global Impression – Improvement scale and GAD was considered to respond to treatment. The FDADS-anxiety subscale score reduced significantly from 30.58 (SD=11.24) at baseline to 23.83 (SD=7.57) at the end of the study. Mean HAM-D score also changed significantly from 10.51 (SD=15.01) at baseline to 6.00 (SD=3.64) at week 6 (p=0.01).
Strengths and limitations	Small sample size, and only 75% of people completed the treatment. Short study follow up.
Chen et al. (2007)	
Study size, design and location	A comparative study of 30 children aged between 8 and 16 years who were diagnosed with mixed anxiety and depressive disorder. China.
Intervention and comparator(s)	Alpha-Stim 100. Sham (the power supply for CES disconnected).
Key outcomes	Mean SDS scores were 49.60 (SD=7.03) in the experimental group and 47.23 (SD=5.86) in the control group before the treatment, but 34.08 (SD=7.79) and 46.83 (SD=10.35) respectively after the treatment. Mean SAS scores were 48.27 (SD=7.01) in the experimental group and 46.03 (SD=6.24) in the control group before the treatment, but 29.67 (SD=6.03) and 39.17 (SD=12.73) respectively after the treatment. Analysis of variance indicated changes in both SDS and SAS were significantly greater in the treatment group than in the control group (p<0.001).
Strengths and limitations	Small sample size. A course of treatment lasted 5 days, and each child had 3 courses of treatment with a 2-day interval between treatment. The total study follow up was 19 days.
Abbreviations: CBT, cognitive behavioural therapy; CES, cranial electrotherapy stimulation; FDADS, four-dimensional anxiety and depression scale-anxiety subscale; GAD, generalised anxiety disorder; HAM-A, Hamilton Anxiety Rating Scale; HAM-D, Hamilton Depression Rating Scale; SAS, self-rating anxiety; SDS, self-rating depression; SD, standard deviation.	

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Recent and ongoing studies

- CES in the treatment of post-traumatic stress disorder. ClinicalTrial.gov identifier: NCT 03757494. Status: recruiting. Indication: post-traumatic stress disorder. Intervention: Alpha-Stim. [29 November 2018, USA]
- Efficacy of CES in new mothers during the postpartum period. ClinicalTrial.gov identifier: NCT 03210155. Status: terminated. Indication: anxiety, depression, insomnia and sleep quality. Intervention: Alpha-Stim AID. [6 July 2017, USA]
- CES in reducing perioperative anxiety. ClinicalTrial.gov identifier: NCT 00928772. Status: terminated (lack of efficacy). Indication: anxiety. Intervention: Alpha-Stim AID. [20 April 2017, USA]

The company advised that 2 evaluation studies are planned in NHS trusts to assess the impact of Alpha-Stim AID for people with generalised anxiety disorder.

Specialist commentator comments

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Three experts were familiar with or had used this technology before.

Level of innovation

One expert thought that Alpha-Stim AID was a novel concept and its design was innovative compared with current treatment such as medications or psychological interventions. This expert noted that other technologies were available to the NHS such as cranial electrical stimulation, which uses different frequencies and the current is delivered through electrodes. The other 2 experts agreed that the technology was innovative compared with current standard care in the NHS. One thought that more evidence was needed on the acceptability of the technology from patients and clinicians' perspectives.

Potential patient impact

Potential patient benefits identified by experts included a moderate reduction in anxiety and depression symptoms. One expert noted that the potential benefit of Alpha-Stim AID was

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associated with the compliance of using the device at recommended currents daily for 20 or 60 minutes over 6 weeks. The expert stated that there was evidence suggesting the effect of Alpha-Stim AID could last for 3 months but such an improvement in anxiety and depression symptoms might not be sustained in the long term. Experts thought that the Alpha-Stim AID being designed for use at home was a benefit for patients. Two experts thought that using the device in patients' own homes could improve their compliance of using the device and their self-management of anxiety. Another expert considered that the device might improve people's access and choices for anxiety treatment. Two experts thought that Alpha-Stim AID would most benefit patients who were unwilling or unable to have some treatments including medications or psychological interventions.

Potential system impact

Potential system benefits identified by experts included a reduction in the need for psychological treatment and a reduction in the cost of care, including medication prescribing and admission for people with severe anxiety disorder. One expert thought that care for some people with anxiety or depression, or both, could be transferred from inpatient settings to outpatient clinics if Alpha-Stim AID was adopted. Experts agreed that minimal training was needed for healthcare staff, and there would be no extra staff or other equipment needed to adopt the device.

General comments

One expert thought the technology was more likely to be used in the NHS if it was used as an add-on to other interventions, and this would need little change in the care pathway. If this was an add-on treatment, more evidence would be needed to show the clinical and cost effectiveness of the combined intervention.

Patient organisation comments

Representatives from 3 patient organisations including Anxiety UK, Mind and Mental health for Self Help and the Big Life Group gave the following comments:

There is still significant stigma attached to seeking help for a mental health condition. Traditional therapy or medication treatment would prevent some people from seeking support. Alpha-Stim AID has the potential to be used for patients experiencing anxiety symptoms who do not wish to have pharmacological or psychological treatments.

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Specialist commentators

The following clinicians contributed to this briefing:

- Cormac Doyle, mental health nurse, Henmore Health. Uses Alpha-Stim in private practice. Did not declare any interests.
- Karina Lovell, professor of mental health, director of research division of nursing, midwifery and social work, school of health science, faculty of biology, Medicine and Health, University of Manchester. Did not declare any interests.
- Richard Morriss, professor of psychiatry and community mental health, Faculty of Medicines and Health Sciences, University of Nottingham. Co-author of Morriss et al. 2019. The study was funded by the company.
- Chris Griffiths, senior research and evaluation fellow at Northamptonshire Healthcare NHS Foundation Trust, contributed to this briefing.

Representatives from the following patient organisations commented on this briefing:

- Mind.
- Mental health for Self Help and the Big Life Group.
- Anxiety UK.

Development of this briefing

This briefing was developed by NICE. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

ISBN: 978-1-4731-3533-8

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Acupuncture for Cancer Related Pain

Question: Should acupuncture be paired for treatment of cancer related pain?

Question source: HERC staff

Issue: Currently, acupuncture is not paired with any cancer diagnosis. A new high quality systematic review and meta-analysis found evidence that acupuncture is effective at reducing cancer pain and cancer related analgesic requirements, including reduced opioid requirements.

Current Prioritized List status
ICD-10 G89.3 (Neoplasm related pain (acute) (chronic)) is on 40+ cancer lines
Acupuncture (CPT 97810-97814) is on 8 lines, governed by Guideline Note 92 ACUPUNCTURE

Acupuncture is listed in the Palliative Care Statement of Intent

STATEMENT OF INTENT 1: PALLIATIVE CARE

It is the intent of the Commission that palliative care services are covered for patients with a life-threatening or serious progressive illness to alleviate symptoms and improve quality of life.

Palliative care services should include culturally appropriate discussions and medical decision making aligned with patient's personal goals of therapy, assessment of symptom burden, assistance with advance care planning, care coordination, emotional, psychosocial and spiritual support for patients and their families. Palliative care services may be provided concurrently with life prolonging/curative treatments.

Some examples of services associated with an encounter for palliative care (ICD-10 Z51.5) that should be available to patients without regard to Prioritized List line placement:

A) Inpatient palliative care consultations
    1) Hospital Care E&M (CPT 99218-99233)
B) Outpatient palliative care consultations provided in either the office or home setting
    1) E&M Services (CPT 99201-99215)
    2) Transitional Care Management Services (CPT 99495-6)
    3) Advance Care Planning (CPT 99497-8)
    4) Chronic Care Management (CPT 99487-99490)
C) Psychological support and grief counseling (CPT 99201-99215)
D) Medical equipment and supplies for the management of symptomatic complications or support activities of daily living
E) Medications or acupuncture to reduce pain and symptom burden
F) Surgical procedures or therapeutic interventions (for example, palliative radiation therapy) to relieve pain or symptom burden

Other services associated with palliative care includes:

A) Social Work
B) Clinical Chaplain/ Spiritual Care
C) Care Coordination

It is NOT the intent of the Commission that coverage for palliative care encompasses those treatments that seek to prolong life despite substantial burdens of treatment and limited chance of benefit. See Guideline Note 12 PATIENT-CENTERED CARE OF ADVANCED CANCER.

Evidence

1) **He 2019**, systematic review and meta-analysis of acupuncture for the treatment of cancer related pain
    a. N=17 RCTs (1111 patients)
    b. Seven sham-controlled RCTs (35%) were notable for their high quality, being judged to have a low risk of bias for all of their domains, and showed that real (compared with sham) acupuncture was associated with reduced pain intensity (mean difference [MD], −1.38 points; 95%CI, −2.13 to −0.64 points; $I2$ = 81%), with a moderate level of certainty (downgraded due to substantial heterogeneity among studies)
    c. A favorable association was also seen when acupuncture and acupressure were combined with analgesic therapy in 6 RCTs for reducing pain intensity (MD, −1.44 points; 95% CI, −1.98 to −0.89; $I2$ = 92%) Low level of certainty
    d. 2 RCTs found acupuncture reduced opioid dose (MD, −30.00mg morphine equivalent daily dose; 95%CI, −37.5mg to −22.5mg). Moderate level of certainty
    e. 3 studies comparing acupuncture to wait list controls found a mean difference in pain of -1.63 points (95%CL -1.98 to -0.89); moderate level of certainty
    f. The adverse events reported were minor, did not require medical evaluation or any specific intervention
    g. CONCLUSIONS AND RELEVANCE The findings of this systematic review and meta-analysis suggest that, based on moderate-level evidence, acupuncture and/or acupressure may be associated with significant reductions in pain intensity and opioid use.

HERC staff recommendations:

1) Add acupuncture (CPT 97810-97814) to any line with ICD-10 G89.3 (Neoplasm related pain (acute) (chronic))
2) Modify GN92 as shown below

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,5, 92,111,112,114,125,129,133,135,157,158,191,199,200,202,361, 208,210,214,215,229,234,237,238,258,259,261,262,271,276,286,287,294,314,315,316,329,342, 372,396,397,401,409, 420,434,461,538, 558

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

Line 1 PREGNANCY

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

Hyperemesis gravidarum

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

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

Breech presentation

ICD-10-CM: O32.1

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

Back and pelvic pain of pregnancy

ICD-10-CM: O99.89

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

Line 5 TOBACCO DEPENDENCE

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

Line 92 and all other cancer-related lines

Acupuncture is paired only with the ICD-10 code G89.3 (Neoplasm related pain (acute) (chronic)) when there is active cancer and limited to 12 total sessions per year; patients may have additional visits authorized beyond these limits if medically appropriate.

Line 202 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS

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

Line 361 SCOLIOSIS

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

Line 401 CONDITIONS OF THE BACK AND SPINE

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

Line 409 MIGRAINE HEADACHES

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

Line 461 OSTEOARTHRITIS AND ALLIED DISORDERS

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

*Line 538 TENSION HEADACHES

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

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

*Below the current funding line.

JAMA Oncology | Original Investigation

Clinical Evidence for Association of Acupuncture and Acupressure With Improved Cancer Pain

A Systematic Review and Meta-Analysis

Yihan He, PhD; Xinfeng Guo, PhD; Brian H. May, PhD; Anthony Lin Zhang, PhD; Yihong Liu, MM; Chuanjian Lu, MD; Jun J. Mao, MD; Charlie Changli Xue, PhD; Haibo Zhang, MD

IMPORTANCE Research into acupuncture and acupressure and their application for cancer pain has been growing, but the findings have been inconsistent.

OBJECTIVE To evaluate the existing randomized clinical trials (RCTs) for evidence of the association of acupuncture and acupressure with reduction in cancer pain.

DATA SOURCES Three English-language databases (PubMed, Embase, and CINAHL) and 4 Chinese-language biomedical databases (Chinese Biomedical Literature Database, VIP Database for Chinese Technical Periodicals, China National Knowledge Infrastructure, and Wanfang) were searched for RCTs published from database inception through March 31, 2019.

STUDY SELECTION Randomized clinical trials that compared acupuncture and acupressure with a sham control, analgesic therapy, or usual care for managing cancer pain were included.

DATA EXTRACTION AND SYNTHESIS Data were screened and extracted independently using predesigned forms. The quality of RCTs was appraised with the Cochrane Collaboration risk of bias tool. Random-effects modeling was used to calculate the effect sizes of included RCTs. The quality of evidence was evaluated with the Grading of Recommendations Assessment, Development and Evaluation approach.

MAIN OUTCOMES AND MEASURES The primary outcome was pain intensity measured by the Brief Pain Inventory, Numerical Rating Scale, Visual Analog Scale, or Verbal Rating Scale.

RESULTS A total of 17 RCTs (with 1111 patients) were included in the systematic review, and data from 14 RCTs (with 920 patients) were used in the meta-analysis. Seven sham-controlled RCTs (35%) were notable for their high quality, being judged to have a low risk of bias for all of their domains, and showed that real (compared with sham) acupuncture was associated with reduced pain intensity (mean difference [MD], −1.38 points; 95% CI, −2.13 to −0.64 points; I^2 = 81%). A favorable association was also seen when acupuncture and acupressure were combined with analgesic therapy in 6 RCTs for reducing pain intensity (MD, −1.44 points; 95% CI, −1.98 to −0.89; I^2 = 92%) and in 2 RCTs for reducing opioid dose (MD, −30.00 mg morphine equivalent daily dose; 95% CI, −37.5 mg to −22.5 mg). The evidence grade was moderate because of the substantial heterogeneity among studies.

CONCLUSIONS AND RELEVANCE This systematic review and meta-analysis found that acupuncture and/or acupressure was significantly associated with reduced cancer pain and decreased use of analgesics, although the evidence level was moderate. This finding suggests that more rigorous trials are needed to identify the association of acupuncture and acupressure with specific types of cancer pain and to integrate such evidence into clinical care to reduce opioid use.

JAMA Oncol. doi:10.1001/jamaoncol.2019.5233
Published online December 19, 2019.

Supplemental content

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Psoriasis Guideline

Question: Should the definition of "severe" psoriasis be broadened in the psoriasis guideline?

Question source: Leona O'Keefe, MD

Issue: Psoriasis (ICD-10 L40) is included on line 426 SEVERE INFLAMMATORY SKIN DISEASE if severe, and on line 541 MILD PSORIASIS; DERMATOPHYTOSIS: SCALP, HAND, BODY if mild or moderate. Dr. O'Keefe contacted the HERC to request a broadening of the criteria for inclusion on line 426.

From Dr. O'Keefe

I have a number of patients with psoriasis that truly impacts their lives, but they cannot get adequate treatment because they don't meet the criteria of Guideline Note 21:

- severe, defined as having functional impairment (e.g. inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction) AND one or more of the following: A) At least 10% of body surface area involved B) Hand, foot or mucous membrane involvement.

These are patients with 30-75% body surface area involved, but their faces are fine and they can still use their hands. I hope that this can be altered to use different criteria so that these patients can obtain appropriate treatment for their psoriasis in order to live full lives

Current Prioritized List status
Line 426 SEVERE INFLAMMATORY SKIN DISEASE
Line 541 MILD PSORIASIS; DERMATOPHYTOSIS: SCALP, HAND, BODY

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

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

Inflammatory skin conditions included in this guideline are:

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

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

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

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

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

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

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

Expert guidelines

1) **AAD-NSF 2019** guideline for treatment of psoriasis with biologics https://www.jaad.org/article/S0190-9622(18)33001-9/pdf
    a) Although the severity of psoriasis is defined in part by the total body surface area (BSA) involved, with involvement of less than 3% of BSA considered mild, involvement of 3% to 10% of BSA considered moderate, and involvement of greater than 10% considered severe disease, psoriasis can be severe irrespective of BSA when it has serious emotional consequences or when it occurs in select locations, including but not restricted to, the hands, feet, scalp, face, or genital area, or when it causes intractable pruritus
2) **NICE 2019** guideline for treatment of psoriasis https://www.nice.org.uk/guidance/cg153/resources/psoriasis-assessment-and-management-pdf-35109629621701
    a) use a validated tool to assess the impact of any type of psoriasis on physical, psychological and social wellbeing, for example the:
        i) Dermatology Life Quality Index (DLQI) for adults or
        ii) Children's Dermatology Life Quality Index (CDLQI) for children and young people.
    b) Offer systemic non-biological therapy to people with any type of psoriasis if:
        i) it cannot be controlled with topical therapy and
        ii) it has a significant impact on physical, psychological or social wellbeing and
        iii) one or more of the following apply:
            (a) psoriasis is extensive (for example, more than 10% of body surface area affected or a Psoriasis Area and Severity Index (PASI) score of more than 10) or
            (b) psoriasis is localised and associated with significant functional impairment and/or high levels of distress (for example severe nail disease or involvement at high impact sites) or
            (c) phototherapy has been ineffective, cannot be used or has resulted in rapid relapse (rapid relapse is defined as greater than 50% of baseline disease severity within 3 months).
3) **Canadian 2009 Guidelines** for treatment of plaque psoriasis
    a) Definition of severe psoriasis:
        i) PASI ≥ 10 or DLQI ≥ 10 or BSA ≥ 10%

Notes

DLQI (Dermatology Life Quality Index)

A patient questionnaire to assess itch, pain, feelings of embarrassment/self-consciousness, problems with treatment and interference of skin disease with the patient's daily activities, relationships, and sexual activity. Score from 0 (no impairment) to 30 (maximal impairment)

PASI (Psoriasis Area and Severity Index)

An index of the severity (thickness, redness, scaling) and extent of body surface coverage of psoriasis. Scores range from 0 to 72 (0 — no disease, 72 — maximal disease). The PASI combines assessment of four body areas: head and neck (H), upper limbs (U), trunk (T), and lower limbs (L). The proportion of skin affected by psoriasis in each area is given a numerical score (A) representing the proportion involved:

- 1: 0–9%
- 2: 10–29%
- 3: 30–49%
- 4: 50–69%
- 5: 70–89%
- 6: 90–100%

Within each area the severity of each of three signs, erythema (E), thickness/ induration (I), and desquamation/scaling (S), is assessed on a five-point scale:

- 0: none
- 1: mild
- 2: moderate
- 3: severe
- 4: very severe

For each of the four body areas, the three signs' scores are added and then multiplied by the area score. Each body region's score is then multiplied by the following proportions to reflect its contribution to total body area:

- neck and head: 0.1
- upper limbs: 0.2
- trunk: 0.3
- lower limbs: 0.4

Finally, the scores for all four body areas are added to yield the overall
PASI score

HERC staff recommendation:

1) Modify GN21 as shown below
   a) Clarifies definition of severe skin disease per national and NICE guidelines
   b) Utilizes validated quality of life score rather than objective measures of impairment

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

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

Inflammatory skin conditions included in this guideline are:

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

The conditions above are included on Line 424 if severe, defined as having functional impairment (e.g. Dermatology Life Quality Index (DLQI) ≥ 10 or Children's Dermatology Life Quality Index (CDLQI) > 12 ~~e.g. inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction~~) AND one or more of the following:

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

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

For severe psoriasis, first line agents include topical agents, phototherapy and methotrexate. Second line agents include other systemic agents and oral retinoids and should be limited to those who fail, or have contraindications to, or do not have access to first line agents. Biologics are included on this line only for the indication of severe plaque psoriasis; after documented failure of first line agents and failure of (or contraindications to) a second line agent.

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

J Cutan Med Surg. 2011 Jul-Aug;15(4):210-9.

Canadian guidelines for the management of plaque psoriasis: overview.

Papp K[1], Gulliver W, Lynde C, Poulin Y, Ashkenas J; Canadian Psoriasis Guidelines Committee.

Collaborators (1)

Adams S, Albrecht L, Barankin B, Barber K, Bourcier M, Carey W, Guenther LC, Gulliver W, Ho VC, Lynde CW, Papp KA, Poulin Y, Shear NH, Toole J, Vender R, Wasel N.

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Abstract

New clinical treatment guidelines for plaque psoriasis, written by a panel of 16 Canadian dermatologists, were recently published online. These Canadian Guidelines for the Management of Plaque Psoriasis are evidence based and free of any influence from corporate sponsors and have been endorsed by the Canadian Dermatology Association (CDA). The Guidelines offer treatment recommendations for mild and moderate to severe body psoriasis, as well as for psoriasis affecting specific areas of the skin, such as the facial, flexural, and genital areas; nails; scalp; and palms and soles. The present overview describes the genesis and contents of the Guidelines, which are available in full through the CDA at <http://www.dermatology.ca/guidelines/cdnpsoriasisguidelines.pdf> (English) or <http://www.dermatology.ca/french/psoriasisguidelines.html> (French).

PMID:
21781627
DOI:
10.2310/7750.2011.10066
[Indexed for MEDLINE]

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DERMATOLOGY LIFE QUALITY INDEX (DLQI)

Hospital No: é é é é é é é é é é é é é . **Date:** é é é é é é é é .

Name: é é é é é é é é é é é é é é . **Score:** é é é é é é é é .

Address: é é é é é é é é é é é é é . **Diagnosis:** é é é é é é é é .

é é é é é é é é é é é é é é .

The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please tick (✓) one box for each question.

1.	Over the last week, how **itchy**, **sore**, **painful** or **stinging** has your skin been?	Very much A lot A little Not at all	❒ ❒ ❒ ❒		
2.	Over the last week, how **embarrassed** or **self conscious** have you been because of your skin?	Very much A lot A little Not at all	❒ ❒ ❒ ❒		
3.	Over the last week, how much has your skin interfered with you going **shopping** or looking after your **home** or **garden**?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant	❒
4.	Over the last week, how much has your skin influenced the **clothes** you wear?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant	❒
5.	Over the last week, how much has your skin affected any **social** or **leisure** activities?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant	❒
6.	Over the last week, how much has your skin made it difficult for you to do any **sport**?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant	❒
7.	Over the last week, has your skin prevented you from **working** or **studying**?	Yes No	❒ ❒	Not relevant	❒
	If "No", over the last week how much has your skin been a problem at **work** or **studying**?	A lot A little Not at all	❒ ❒ ❒		
8.	Over the last week, how much has your skin created problems with your **partner** or any of your **close friends** or **relatives**?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant	❒
9.	Over the last week, how much has your skin caused any **sexual difficulties**?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant	❒
10.	Over the last week, how much of a problem has the **treatment** for your skin been, for example by making your home messy, or by taking up time?	Very much A lot A little Not at all	❒ ❒ ❒ ❒	Not relevant	❒

Please check you have answered EVERY question. Thank you.

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DERMATOLOGY LIFE QUALITY INDEX (DLQI) - INSTRUCTIONS FOR USE

The Dermatology Life Quality Index questionnaire is designed for use in adults, i.e. patients over the age of 16. It is self explanatory and can be simply handed to the patient who is asked to fill it in without the need for detailed explanation. It is usually completed in one or two minutes.

SCORING

The scoring of each question is as follows:

Very much	scored 3
A lot	scored 2
A little	scored 1
Not at all	scored 0
Not relevant	scored 0
Question 7, óprevented work or studyingô	scored 3

The DLQI is calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0. The higher the score, the more quality of life is impaired.

HOW TO INTERPRET MEANING OF DLQI SCORES

0 ï 1	no effect at all on patient's life
2 ï 5	small effect on patient's life
6 ï 10	moderate effect on patient's life
11 ï 20	very large effect on patient's life
21 ï 30	extremely large effect on patient's life

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Hongbo Y, Thomas CL, Harrison MA, Salek MS and Finlay AY. Translating the science of quality of life into practice: What do dermatology life quality index scores mean? *J Invest Dermatol* 2005; **125:**659-64.

There is more information about the DLQI, including over 85 translations, at www.dermatology.org.uk. The DLQI is copyright but may be used without seeking permission by clinicians for routine clinical purposes. For other purposes, please contact the copyright owners.

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CHILDREN'S DERMATOLOGY LIFE QUALITY INDEX

Hospital No
Name: Diagnosis: CDLQI
Age: SCORE:
Address: Date:

The aim of this questionnaire is to measure how much your skin problem has affected you OVER THE LAST WEEK. Please tick ✓ one box for each question.

1.	Over the last week, how **itchy**, **"scratchy"**, **sore** or **painful** has your skin been?	Very much Quite a lot Only a little Not at all	☐ ☐ ☐ ☐
2.	Over the last week, how **embarrassed** or **self conscious**, **upset** or **sad** have you been because of your skin?	Very much Quite a lot Only a little Not at all	☐ ☐ ☐ ☐
3.	Over the last week, how much has your skin affected your **friendships**?	Very much Quite a lot Only a little Not at all	☐ ☐ ☐ ☐
4.	Over the last week, how much have you changed or worn **different** or **special clothes/shoes** because of your skin?	Very much Quite a lot Only a little Not at all	☐ ☐ ☐ ☐
5.	Over the last week, how much has your skin trouble affected **going out**, **playing**, or **doing hobbies**?	Very much Quite a lot Only a little Not at all	☐ ☐ ☐ ☐
6.	Over the last week, how much have you avoided **swimming** or **other sports** because of your skin trouble?	Very much Quite a lot Only a little Not at all	☐ ☐ ☐ ☐
7.	Last week, was it **school time?** **OR** was it **holiday time?**	**If school time**: Over the last week, how much did your skin problem affect your **school work**? **If holiday time**: How much over the last week, has your skin problem interfered with your enjoyment of the **holiday**?	Prevented school ☐ Very much ☐ Quite a lot ☐ Only a little ☐ Not at all ☐ Very much ☐ Quite a lot ☐ Only a little ☐ Not at all ☐
8.	Over the last week, how much trouble have you had because of your skin with other people **calling you names**, **teasing**, **bullying**, **asking questions** or **avoiding you**?	Very much Quite a lot Only a little Not at all	☐ ☐ ☐ ☐
9.	Over the last week, how much has your **sleep** been affected by your skin problem?	Very much Quite a lot Only a little Not at all	☐ ☐ ☐ ☐
10.	Over the last week, how much of a problem has the **treatment** for your skin been?	Very much Quite a lot Only a little Not at all	☐ ☐ ☐ ☐

Please check that you have answered EVERY question. Thank you.

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Telehealth coverage

Question: Should HERC modify the telemedicine guideline and add in specific coverage criteria for telehealth (face-to-face) visits?

Question source: HERC Staff, CCO Medical Directors

Issue: HERC has developed a policy on non-face-to-face visits including telephone and electronic visits as well as teleconsultation (provider to provider). However, HERC is currently silent on face-to-face videoconferencing, or traditional "telehealth" visits. There is interest from the CCO Medical Directors to look at updating the policy with regard to telehealth.

Background

MED, 2019

Table 1. Telehealth Modes of Delivery

Mode	How Does It Work?	Examples
Live (synchronous) audio-video connection	Patients receive health care at an originating (also called spoke or patient) site from health care providers located at a distant (or hub) site.	Patients are able to receive care from their regular providers or, in the case of direct-to-consumer telehealth, be connected with the next available clinician in a patient-initiated telehealth visit via personal devices, such as mobile phones.
Store-and-forward	Health care provider or patient at an originating site forwards the patient's records or images to a health care provider at the distant site who provides treatment recommendations.	These "electronic consultation" services involve a delay in treatment and are often used in dermatology, radiology, and other clinical specialties.
Remote patient monitoring	Patients' health data regularly transmitted from their homes to health care providers.	Providers monitor patients' health data and alter treatment as needed. This type of tele-health is often used for patients with chronic conditions such as asthma and diabetes to reduce unnecessary hospital or emergency department visits.
Mobile health (mHealth)	Technology such as tablets and cell phones are used to convey information.	Patients or other public audiences with public health information and education.

Sources: Uscher-Pines et al., 2018[5] and Center for Connected Health Policy.[6]
Store-and-forward, remote patient monitoring, and mobile health are not covered in this brief.

Telehealth coverage

Prioritized List Status

There is the Ancillary Guideline A5 which deals with teleconsultations (provider to provider) and online/telephone non-face-to-face services (between patient and provider). There is no HERC guidance for face-to-face synchronous telehealth services. There are OARs specifying coverage of telehealth for physical and behavioral health services.

Code	Code Description	Prioritized List Status
Q3014	Telehealth originating site facility fee	Never Reviewed

Place of Service Code	Place of Service Name	Place of Service Description
2	Telehealth	The location where health services and health related services are provided or received, through a telecommunication system

A modifier provides the means to report or indicate that a service or procedure that has been performed has been altered by some specific circumstance but not changed in its definition or code.

Modifier	Type	Description
GQ	HCPCS	Via asynchronous telecommunications system
GT	HCPCS	Via interactive audio and video telecommunication systems NOTE: Medicare stopped the use of modifier GT in 2017 when the place of service code **02** (telehealth) was introduced.
95	CPT	Synchronous telemedicine service is defined as a real-time interaction between a physician or other qualified healthcare professional and a patient who is located at a distant site from the physician or other qualified healthcare professional. The totality of the communication of information exchanged between the physician or other qualified healthcare professional and the patient during the course of the synchronous telemedicine service must be of an amount and nature that would be sufficient to meet the key components and/or requirements of the same service when rendered via face-to-face interaction. Modifier 95 may only be appended to the services listed in Appendix P. Appendix P is the list of CPT® codes for services that are typically performed face-to-face but may be rendered via a real-time (synchronous) interactive audio and video telecommunications system.

ANCILLARY GUIDELINE A5, TELECONSULTATIONS AND NON-FACE-TO -FACE TELEHEALTH SERVICES

Patient to Clinician Services (via telephone or electronic)

Telephonic and electronic services, including services related to diagnostic workup (CPT 98966-98968, 99441-99443, 99421-99423, 98970-98972, G2012, G2061-G2063) between a patient and clinician must meet the following criteria:

A) Ensure pre-existing relationship as demonstrated by at least one prior office visit within the past 36 months.
B) Documentation must:
    1) model SOAP charting, or be as described in program's OAR;
    2) include patient history, provider assessment, treatment plan and follow-up instructions;
    3) support the assessment and plan;
    4) be retained in the patient's medical record and be retrievable.
C) Medical decision making (or behavioral health intervention/ psychotherapy) is necessary.
D) Ensure permanent storage (electronic or hard copy) of the encounter.
E) Meet HIPAA standards for privacy.
F) Include a patient-clinician agreement of informed consent, which is discussed with and signed by the patient and documented in the medical record.
G) 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).
H) 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.
I) This service is not billed if the service results in the patient being seen within 24 hours or the next available appointment.
J) 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:

A) Extended counseling when person-to-person contact would involve an unwise delay.
B) Treatment of relapses that require significant investment of provider time and judgment.
C) Counseling and education for patients with complex chronic conditions.

Examples of non-reimbursable telephone consultations include but are not limited to:

A) Prescription renewal.
B) Scheduling a test.
C) Reporting normal test results.
D) Requesting a referral.
E) Follow up of medical procedure to confirm stable condition, without indication of complication or new condition.
F) 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, including use related to diagnostic workup, of telehealth to facilitate collaboration between two or more clinicians. 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.

Telehealth coverage

OARs
https://oregon.public.law/rules/oar_410-130-0610
Rule 410-130-0610 Telemedicine

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(1) For the purposes of this rule, telemedicine is defined as the use of telephonic or electronic communications to medical information from one site to another to improve a patients health status.

(2) Unless authorized in OAR 410-120-1200 Exclusions, other types of telecommunications are not covered, such as telephone calls, images transmitted via facsimile machines and electronic mail:

(a) When those types are not being used in lieu of videoconferencing, due to limited videoconferencing equipment access, or

(b) When those types and specific services are not specifically allowed in this rule per the Oregon Health Services Commissions Prioritized List of Health Services and Practice Guideline.

(3) 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) For Addiction and Mental Health Division (AMH) providers, in addition to being enrolled as a Division provider under (3)(a). AMH providers must have an AMH agency letter of approval, certification of Approval or license issued by AMH. Individuals must also be providing covered services and be authorized to submit claims for covered telemedicine services under this rule.

(c) Providers billing for covered telemedicine services are responsible for the following:

(A) Complying with Health Insurance Portability and Accountability Act (HIPAA) and Oregon Health Authority (Authority/OHA) Confidentiality and Privacy Rules and security protections for the patient in connection with the telemedicine communication and related records. Examples of applicable OHA rules are Confidentiality and Privacy 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, if applicable, HIPAA (45 CFR Parts 160, 162, and 164), and

42 CFR Part 2, 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 Department Privacy and Confidentiality Rules described in subsection (3)(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 Evidence Review Commission (HERC) practice guideline for telephone and email consultation. Refer to the current prioritized list and practice guidelines at www.oregon.gov/OHA/HPA/CSI-HERC/Pages/Prioritized-List.aspx;

(E) Maintaining clinical and financial documentation related to telemedicine services as required in OAR 410-120-1360.

(4) Coverage for telemedicine services:

(a) The telemedicine definition encompasses different types of programs, services and delivery mechanisms for medically appropriate covered services within the patients 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 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 below;

(d) Telephonic codes may be used in lieu of videoconferencing codes, if videoconferencing equipment is not available.

(5) Telephone and E-mail billing requirements: Use the Evaluation and Management (E/M) code authorized in the HSC practice guideline, unless otherwise authorized in OAR 410-120-1200.

(6) Videoconferencing billing requirements:

(a) Only the transmission site (where the patient is located) may bill for the transmission:

(A) Bill the transmission with code 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 (code 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.

(c) In addition, for AMH services specifically identified as allowable for telephonic delivery when appropriate, refer to the procedure code and reimbursement rates published by AMH.

https://oregon.public.law/rules/oar_410-172-0850
Rule 410-172-0850
Telemedicine for Behavioral Health

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(1) Telemedicine encompasses different types of programs, services, and delivery mechanisms for medically appropriate covered services within the recipients benefit package:

(a) 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 Evidence Review Commission and the applicable HERC-approved code requirements, delivered consistent with the HERC Evidence-Based Guidelines;

(b) Patient consultations using videoconferencing, a synchronous (live two-way interactive) video transmission resulting in real time communication between a provider located in a distant site and the recipient being evaluated and

located in an originating site, is covered when billed services comply with the billing requirements stated below.

(2) Behavioral health services specifically identified as allowable for telephonic delivery are listed on the Behavioral Health Fee schedule published by the Authority.

(3) Unless expressly authorized in OAR 410-120-1200 (Exclusions), other types of telecommunications are not covered such as images transmitted via facsimile machines and electronic mail when:

(a) Those methods are not being used in lieu of videoconferencing, due to limited videoconferencing equipment access; or

(b) Those methods and specific services are not specifically allowed pursuant to the Oregon Health Evidence Review Commissions Prioritized List of Health Services and Evidence Based Guidelines.

(4) Providers billing for covered telemedicine services shall:

(a) Comply with HIPAA and the Authoritys Confidentiality and Privacy Rules and security protections for the patient in connection with the telemedicine communication and related records;

(b) Obtain and maintain technology used in the telemedicine communication that is compliant with privacy and security standards in HIPAA and the Authoritys Privacy and Confidentiality Rules set forth in OAR 943 division 14;

(c) Ensure 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 individuals;

(d) Comply with the relevant HERC evidence-based guidelines for telephone and e-mail consultation. Refer to the current prioritized list and evidence based guidelines at http://www.oregon.gov/OHA/HPA/CSI-HERC/Pages/Prioritized-List.aspx;

(e) Maintain clinical and financial documentation related to telemedicine services as required in OAR 410-120-1360.

(5) For purposes of behavioral health services, the Authority shall provide coverage for telemedicine services to the same extent that the services would be covered if they were provided in person.

Evidence Summary

MED, 2020

- Rapid review
- Behavioral health treatment delivered by synchronous telehealth
- Included 4 systematic reviews, 8 RCTs (in 17 publications), and 5 comparative observational studies.
- Effectiveness results:
    - No differences in symptom improvement between synchronous telehealth v in person care for anxiety, depression, substance use disorder, and post-traumatic stress disorder
    - For children with ADHD, improvement in symptoms was greater in telehealth. Also caregivers had decreased levels of caregiver distress in the telehealth group.
    - Otherwise no differences in quality of life
    - Patients reported decreased barriers to accessing treatment
    - No differences in medication adherence
    - No studies identified inferiority of telehealth compared to in person behavioral health treatment
- Economic findings: studies were mixed. Telehealth was less costly when patients provided their own equipement.

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 (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 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, 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:
    - in-home telehealth visits
        - evaluation and management of chronic and acute conditions (e.g. DM, CHF, wounds) or cellulitis, UTI, CAP
    - in-home telerehabilitation
        - improving function and mobility (e.g. post orthopedic surgery, pallitative care, enteral nutrition)
    - direct-to-consumer telehealth visits
        - evaluation of less severe conditions and option of refer to higher level of care (e.g. acute respiratory infections, skin problems, urinary symptoms)
- 15 studies, observational, low quality
    - Initial costs are higher for telehealth but with total decreased costs with hospitalizations. In adults with CHF (Jerant, 2001) initial cost of telehealth was 21x the cost of usual care ($7,487 vs. $353), but costs of subsequent hospitalizations were less than one-third the cost for those in usual care ($29,701 v $93,686).
- 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. Direct-to-consumer telehealth visits were less costly than emergency department or physician office visits for similar conditions. However, 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.

Policy Summary

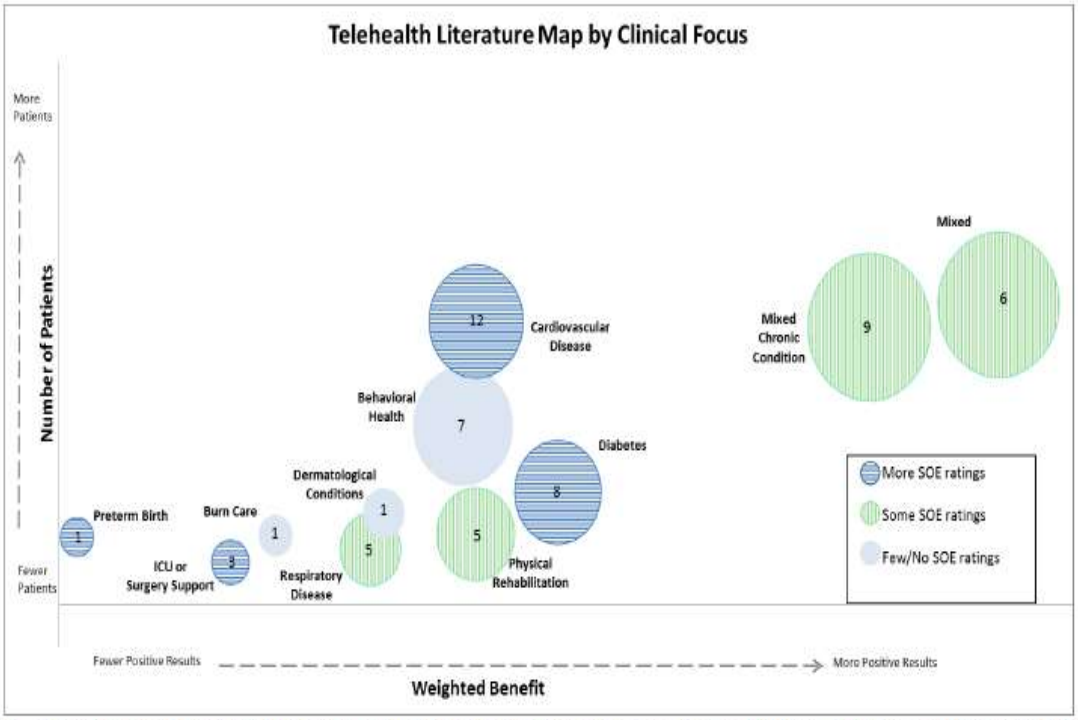
MED, 2019

- Policy brief of Medicaid, Medicare and private payer policies on home-based telehealth
- Historically CMS regulations did not allow patient's homes to be the originating site, but CMS is writing rules to allow this in 2020
- Direct-to-consumer telehealth (virtual visits) is gaining popularity in the commercial realm. Typically these visits are not done by the primary care provider.
- Utilization
    - Personal devices that increases flexibility of patients accessing physicians typically increases utilization for minor acute conditions
    - Home based telehealth is more used by primary care provider for more serious acute or chronic conditions, or for rehabilitation after orthopedic surgery
    - When telehealth use suggests novel utilization, this can increase costs
- State Medicaid programs require home-based telehealth services to meet the same standard of care as in-person visits, including patient privacy and provider scope of practice
    - Privacy concerns, such as patients utilizing video-based technology in coffee shops have been raised
- State Medicaid programs usually reimburse the same amount for telehealth-delivered services as for in-person clinical and primary care–delivered services
- Additionally, Medicaid policies generally do not state that the agency will reimburse for the cost of telehealth equipment needed by the provider and/or the Medicaid recipient. Policies vary as to whether obtaining or purchasing equipment is the responsibility of the provider, patient, or both.
- Medicare generally does not cover telehealth in the home but is incrementally covering telehealth services in certain circumstances
- Medicaid programs do not currently have methods to track and monitor the use of telehealth in the home.
- While telehealth in the home has the potential to make health care more efficient, it also has the potential to increase fragmentation and impede coordination of care. To reduce the potential for care fragmentation, telehealth services should be coordinated with other health services. To this end, telehealth policies could require that information is shared with the patient's care team.

MED, 2017

- Telehealth in urban and suburban settings for direct service to patients

- Policy report
- Potential advantages: improved access to needed specialty care providers, easier access to health car efor patients who are homebound or have difficulty traveling to health care appointments, helps patients avoid perceived stigma of certain health care services such as counseling, and reduces transportation issues
- Potential concerns: patient privacy, alternative payment models, impact of medicare policy, provider education and training, and healthcare utilization and expenditures



a. Bubble size reflects the unduplicated number of individual studies included in the systematic reviews about that clinical focus. The number label on each bubble is the number of systematic reveiws. Smaller bubbles indicate fewer studies, larger bubbles indicate more studies. The color of the bubble represents how many of systematic reviews included strength of evidence assessment.

b. Weighted relative benefit is calculated by weighting the overall conclusion of each review by the number of studies in the review. Bubbles to the right indicate more positive findings while bubbles to the left represent findings that are unclear or found no benefit.

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Cost evidence

Ashwood, 2017

- Commercial claims analysis of over 300,000 patients from 2011-2013
- Focus on acute respiratory illnesses
- Results: 12% of direct-to-consumer telehealth visits replaced visits to other providers, and 88% represented new utilization
- Net annual spending on acute respiratory illness increased $45 per telehealth user
- Per episode, telehealth visits were about 50% of the cost of a physician office visit and less than 5% of the cost of an ED visit. However, the vast majority of telehealth visits for acute respiratory infections were new utilization rather

than substitution. The more convenient the location, the lower the threshold for seeking care and the greater the utilization might be.
- Conclusion: Direct-to-consumer telehealth may increase access by making care more convenient for certain patients, but it may also increase utilization and health care spending.

Other payer policies

CMS patient oriented description

Telehealth services include office visits, psychotherapy, consultations, and certain other medical or health services that are provided by an eligible provider who isn't at your location using an interactive 2-way telecommunications system (like real-time audio and video).

These services are available in rural areas, under certain conditions, but only if you're located at one of these places:

1. A doctor's office
2. A hospital
3. A critical access hospital (CAH)
4. A rural health clinic
5. A Federally qualified health center
6. A hospital-based dialysis facility
7. A skilled nursing facility
8. A community mental health center

Medicare made these changes to telehealth in 2019:

- You can get certain telehealth services at renal dialysis facilities and at home.
- You can get telehealth services for faster diagnosis, evaluation, or treatment of symptoms of an acute stroke no matter where you're located.
- If you have a substance use disorder or a co-occurring mental health disorder, you can get telehealth services from home.

More helpfully summarized through this website:
https://www.cchpca.org/telehealth-policy/telehealth-and-medicare

ELIGIBLE PROVIDERS

Medicare limits the types of health care professionals who can provide telehealth-delivered services. The small group of eligible professionals are:

- Physicians;
- Nurse practitioners;
- Physician assistants;
- Nurse midwives;
- Clinical nurse specialists;
- Certified registered nurse anesthetists;
- Clinical psychologists and clinical social workers (these professionals cannot bill for psychotherapy services that include medical evaluation and management services);
- Registered dietitians or nutrition professionals.

GEOGRAPHIC LOCATION

The patient's location at the time services are received via telehealth is known as the "originating site." Medicare treats telehealth almost exclusively as a tool for rural areas, and has narrowly restricted the geographic areas that are eligible to use telehealth. The originating site must be in a Health Professional Shortage Area (HPSA) as defined by Health Resources and Services Administration (HRSA), or in a county that is outside of any Metropolitan Statistical Area (MSA) as defined by the US Census Bureau. Some argue against this restriction because many underserved areas are still barred from receiving telehealth-delivered services, and those that are eligible may not have an adequate population base to maintain a telehealth network.

In 2019, there were some exceptions made from both the geographic and originating site requirements for the end stage renal disease (ESRD) services, treatment of acute stroke and treatment of substance use disorder and co-occurring mental health conditions. Those exceptions are outlined in a subsequent section.

Effective as of January 2014, CMS redefined rural HPSAs as areas located in rural census tracts as determined by the office of Rural Health Policy (ORHP). This allows eligible facilities located in rural census tracts that are within an MSA to be eligible telehealth originating sites. HRSA also maintains a Medicare telehealth payment eligibility search tool, where eligibility of an originating site may be checked.

ELIGIBLE FACILITIES

In addition to the rural restriction, Medicare limits the originating sites (where the patient is located) eligible for telehealth-delivered services to the following facilities:

- Provider offices;
- Hospitals;
- Critical access hospitals;
- Rural health clinics;
- Federally qualified health centers;
- Skilled nursing facilities;
- Community mental health centers;
- Hospital-based or critical access hospital-based renal dialysis centers.

Note that there are certain exceptions to the facility requirement in the case of end stage renal disease (ESRD) services, treatment of acute stroke and treatment of substance use disorder and co-occurring mental health conditions. These exceptions are outlined in the section below.

Treating Individuals with Substance Use Disorders (SUDs) or co-occurring mental health disorders: The 2018 SUPPORT for Patient and Communities Act required CMS to adjust their reimbursement policy of telehealth for treating individuals with SUDs or a co-occurring mental health disorder. Specifically, it removed the originating site geographic requirements for telehealth services on or after July 1, 2019 for any existing Medicare telehealth originating site (except for a renal dialysis facility). Additionally, the home was made an eligible originating site for purposes of treating these individuals, however the home would not qualify for the facility fee.

CMS has issued an interim final rule with comment period to implement these requirements. They note that the normal telehealth service code limitations still apply. Practitioners would also be responsible for assessing whether individuals have a SUD diagnosis and whether it would be clinically appropriate to furnish the telehealth services for the treatment. This new policy is expected to take effect July 1, 2019 as required in statute.

MEDICARE ADVANTAGE, APMS AND ACOS

Medicare does offer some exceptions to its geographic and originating site requirements through special programs, including the Next Generation ACO; Shared Savings Program; Episode Payment Models; and Comprehensive Care for Joint Replacement Models. Factsheets are available on many of these models on under CCHP's Resources tab. According to the Bipartisan Budget Act of 2018, beginning in 2020, all Medicare two-sided ACOs will be able to be reimbursed for telehealth delivered services to the home and be exempt from Medicare's geographic requirement. CMS has finalized their rule to implement this change in the Shared Savings Program, beginning in 2020.

Telehealth coverage

Currently, Medicare Advantage Plans may also offer telehealth as a supplemental benefit, however patients who elect to receive the benefit may pay for it with higher premiums, additional co-pays or from the plans' rebates. Under the Bipartisan Budget Act of 2018, beginning in 2020, Medicare Advantage plans will be able to (although not required to) offer additional telehealth benefits, without all of the restrictions currently imposed by Medicare. The Secretary solicited comments in Nov., 2018 on the telehealth changes and what should be considered an "additional telehealth benefit". A final rule has not yet been issued.

CMS, 2019
https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes
List of services payable under the Medicare Physician Fee Schedule when furnished via telehealth (as of 11/20/19.

LIST OF MEDICARE TELEHEALTH SERVICES CY 2020	
Code	**Short Descriptor**
90785	Psytx complex interactive
90791	Psych diagnostic evaluation
90792	Psych diag eval w/med srvcs
90832	Psytx pt&/family 30 minutes
90833	Psytx pt&/fam w/e&m 30 min
90834	Psytx pt&/family 45 minutes
90836	Psytx pt&/fam w/e&m 45 min
90837	Psytx pt&/family 60 minutes
90838	Psytx pt&/fam w/e&m 60 min
90839	Psytx crisis initial 60 min
90840	Psytx crisis ea addl 30 min
90845	Psychoanalysis
90846	Family psytx w/o patient
90847	Family psytx w/patient
90951	Esrd serv 4 visits p mo <2yr
90952	Esrd serv 2-3 vsts p mo <2yr
90954	Esrd serv 4 vsts p mo 2-11
90955	Esrd srv 2-3 vsts p mo 2-11
90957	Esrd srv 4 vsts p mo 12-19
90958	Esrd srv 2-3 vsts p mo 12-19
90960	Esrd srv 4 visits p mo 20+
90961	Esrd srv 2-3 vsts p mo 20+
90963	Esrd home pt serv p mo <2yrs

LIST OF MEDICARE TELEHEALTH SERVICES	
90964	Esrd home pt serv p mo 2-11
90965	Esrd home pt serv p mo 12-19
90966	Esrd home pt serv p mo 20+
90967	Esrd home pt serv p day <2
90968	Esrd home pt serv p day 2-11
90969	Esrd home pt serv p day 12-19
90970	Esrd home pt serv p day 20+
96116	Neurobehavioral status exam
96150	Assess hlth/behave init
96151	Assess hlth/behave subseq
96152	Intervene hlth/behave indiv
96153	Intervene hlth/behave group
96154	Interv hlth/behav fam w/pt
96160	Pt-focused hlth risk assmt
96161	Caregiver health risk assmt
97802	Medical nutrition indiv in
97803	Med nutrition indiv subseq
97804	Medical nutrition group
99201	Office/outpatient visit new
99202	Office/outpatient visit new
99203	Office/outpatient visit new
99204	Office/outpatient visit new
99205	Office/outpatient visit new
99211	Office/outpatient visit est
99212	Office/outpatient visit est
99213	Office/outpatient visit est
99214	Office/outpatient visit est
99215	Office/outpatient visit est
99231	Subsequent hospital care
99232	Subsequent hospital care
99233	Subsequent hospital care
99307	Nursing fac care subseq
99308	Nursing fac care subseq
99309	Nursing fac care subseq
99310	Nursing fac care subseq
99354	Prolonged service office
99355	Prolonged service office
99356	Prolonged service inpatient
99357	Prolonged service inpatient
99406	Behav chng smoking 3-10 min

LIST OF MEDICARE TELEHEALTH SERVICES	
99407	Behav chng smoking > 10 min
99495	Trans care mgmt 14 day disch
99496	Trans care mgmt 7 day disch
99497	Advncd care plan 30 min
99498	Advncd are plan addl 30 min
G0108	Diab manage trn per indiv
G0109	Diab manage trn ind/group
G0270	Mnt subs tx for change dx
G0296	Visit to determ ldct elig
G0396	Alcohol/subs interv 15-30mn
G0397	Alcohol/subs interv >30 min
G0406	Inpt/tele follow up 15
G0407	Inpt/tele follow up 25
G0408	Inpt/tele follow up 35
G0420	Ed svc ckd ind per session
G0421	Ed svc ckd grp per session
G0425	Inpt/ed teleconsult30
G0426	Inpt/ed teleconsult50
G0427	Inpt/ed teleconsult70
G0436	Tobacco-use counsel 3-10 min
G0437	Tobacco-use counsel>10min
G0438	Ppps, initial visit
G0439	Ppps, subseq visit
G0442	Annual alcohol screen 15 min
G0443	Brief alcohol misuse counsel
G0444	Depression screen annual
G0445	High inten beh couns std 30m
G0446	Intens behave ther cardio dx
G0447	Behavior counsel obesity 15m
G0459	Telehealth inpt pharm mgmt
G0506	Comp asses care plan ccm svc
G0508	Crit care telehea consult 60
G0509	Crit care telehea consult 50
G0513	Prolong prev svcs, first 30m
G0514	Prolong prev svcs, addl 30m
G2086	Off base opioid tx first m
G2087	Off base opioid tx, sub m
G2088	Off opioid tx month add 30

Telehealth coverage

Aetna
https://www.aetna.com/individuals-families/health-insurance-through-work/health-insurance-information/telemedicine.html

- Promotes Teladoc direct-to-consumer telehealth services

Highmark, 2020
https://content.highmarkprc.com/Files/ClaimsPaymentReimb/ReimbPolicies/rp-046.pdf

- Align with CMS on eligible providers
- Limit behavioral health visits
- Covers teledermatology

Center for Connected Health Policy https://www.cchpca.org/

- Summarizes policies in 50 states and nationally
- CCHPCA, 2019 Summary of all states https://www.cchpca.org/sites/default/files/2019-10/50%20State%20Telehealth%20Laws%20and%20Reibmursement%20Policies%20Report%20Fall%202019%20FINAL.pdf
- Summary:
  - Fifty states and Washington DC provide reimbursement for some form of live video in Medicaid fee-for-service.
  - Fourteen state Medicaid programs reimburse for store-and-forward. However, four additional jurisdictions (HI, MS, NH, and NJ) have laws requiring Medicaid reimburse for store-and-forward but as of the creation of this edition, yet to have any official Medicaid policy indicating this is occurring.
  - Twenty two state Medicaid programs provide reimbursement for RPM. As is the case for store-and-forward, two Medicaid programs (HI and NJ) have laws requiring Medicaid reimburse for RPM but at the time this report was written, did not have any official Medicaid policy. A law in D.C. requiring Medicaid provide reimbursement for store-and-forward and remote patient monitoring, was made contingent on being funded under an approved budget and financial plan. As of September 2019, neither have been funded. Kentucky Medicaid is also required to create an RPM pilot, but CCHP has not seen any evidence that the pilot has been established.
  - Eight state Medicaid programs (Alaska, Arizona, Maryland, Minnesota, New York, Texas, Virginia and Washington) reimburse for all three, although certain limitations apply.
  - Two Medicaid programs (California and Connecticut) reimburse for eConsult.

Telehealth coverage

HERC Staff Summary

Current coverage of telehealth for OHP is guided by OAR and is quite limited. Evidence supports the use of telehealth to improve patient outcomes for a variety of conditions, both behavioral and physical, though evidence is insufficient for some types of services. When not creating demand for new services, telehealth is generally considered cost-saving to cost-neutral. Telehealth for specialty consultation could improve access for Oregon Health Plan patients. Direct to consumer telehealth is associated with new utilization for minor conditions and may be associated with increased spending and not necessarily improved health outcomes.

No specific new coverage is recommended for subcategories of telehealth including store-and-forward and mHealth. Remote monitoring has been addressed elsewhere.

HERC Staff Recommendations:

1. Modify Ancillary Guideline A5 as follows:

   ANCILLARY GUIDELINE A5, TELEHEALTH, TELECONSULTATIONS AND ELECTRONIC/TELEPHONIC SERVICES ~~NON-FACE-TO-FACE TELEHEALTH SERVICES~~

   TELEHEALTH (SYNCHRONOUS AUDIO/VIDEO VISITS)
   Telehealth visits are defined as synchronous visits with both audio and video capability. The patient may be at home or in a health care setting. The originating site code Q3014 may only be used by appropriate health care sites. Codes eligible for telehealth services include 90785, 90791, 90792, 90832-90834, 90836, 90837-90840, 90846, 90847, 90951, 90952, 90954, 90955, 90957, 90958, 90960, 90961, 90963, 90964-90970, 96116, 96150-96154, 96160, 96161, 97802-4, 99201-99205, 99211-99215, 99231-99233, 99307-99310, 99354-99357, 99406-99407, 99495-99498, G0108-G0109, G0270, G0296, G0396, G0397, G0406-G0408, G0420, G0421, G0425-G0427, G0436-G0439, G0442-G0447, G0459, G0506, G0508, G0509, G0513, G0514, G2086-G2088.

   Telehealth visits are covered for outpatient services in the following situations:
   - Primary care-based visits
     - Only within a patient-centered primary care home (PCPCH)
     - Only for established patients
     - Prioritizing management of chronic significant medical conditions (e.g. congestive heart failure, wound care, diabetes, palliative care)
   - Specialty care-based visits when appropriately referred
   - Tele-rehabilitation
   - Behavioral health (including psychiatric and psychologic counseling services and substance use disorder treatment)

Telehealth consultations are covered for emergency and inpatient services in the following situations:

- Remote intensive care unit consultations
- Specialty consultations in the emergency department or hospital when the specialist is not available onsite
- Specialty consultations for emergency medical services

Billing for telehealth visits requires the same level of documentation, medical necessity and coverage determinations as in-person visits.

PATIENT TO CLINICIAN SERVICES (ELECTRONIC/TELEPHONIC)

Telephonic and electronic services, including services related to diagnostic workup (CPT 98966-98968, 99441-99443, 99421-99423, 98970-98972, G2012, G2061-G2063) between a patient and clinician must meet the following criteria:

A) Ensure pre-existing relationship as demonstrated by at least one prior office visit within the past 36 months.
B) Documentation must:
    1) model SOAP charting, or be as described in program's OAR;
    2) include patient history, provider assessment, treatment plan and follow-up instructions;
    3) support the assessment and plan;
    4) be retained in the patient's medical record and be retrievable.
C) Medical decision making (or behavioral health intervention/ psychotherapy) is necessary.
D) Ensure permanent storage (electronic or hard copy) of the encounter.
E) Meet HIPAA standards for privacy.
F) Include a patient-clinician agreement of informed consent, which is discussed with and signed by the patient and documented in the medical record.
G) 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).
H) 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.
I) This service is not billed if the service results in the patient being seen within 24 hours or the next available appointment.
J) 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:

A) Extended counseling when person-to-person contact would involve an unwise delay.
B) Treatment of relapses that require significant investment of provider time and judgment.
C) Counseling and education for patients with complex chronic conditions.

Examples of non-reimbursable telephone/electronic consultations include but are not limited to:

A) Prescription renewal.
B) Scheduling a test.
C) Reporting normal test results.
D) Requesting a referral.
E) Follow up of medical procedure to confirm stable condition, without indication of complication or new condition.
F) Brief discussion to confirm stability of chronic problem and continuity of present management.

CLINICIAN-TO-CLINICIAN ~~TELEHEALTH~~ CONSULTATIONS (TELEPHONIC/ELECTRONIC)

~~Telehealth consultations are defined as the use, including use related to diagnostic workup, of telehealth to facilitate collaboration between two or more clinicians.~~ 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

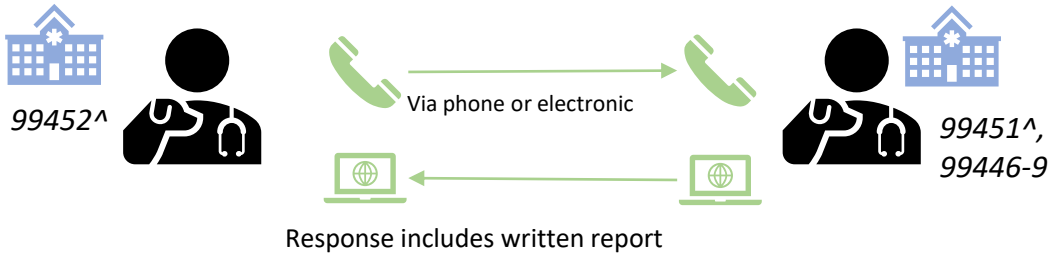
Requesting Providers (99452)

- eConsult must be reported by requesting provider (not for the transfer of a patient or request for face-to-face consult)

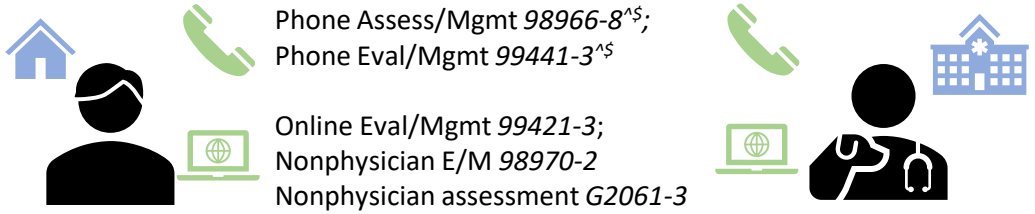
- Reported only when the patient is not on-site and with the provider at the time of consultation
- Cannot be reported more than 1 time per 14 days per patient
- Requires a minimum of 16 minutes. Includes time for referral prep and/or communicating with the consultant.
- Can be reported with prolonged 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.

Teleconsultation
Provider - Provider
Covered by HERC today GL A5



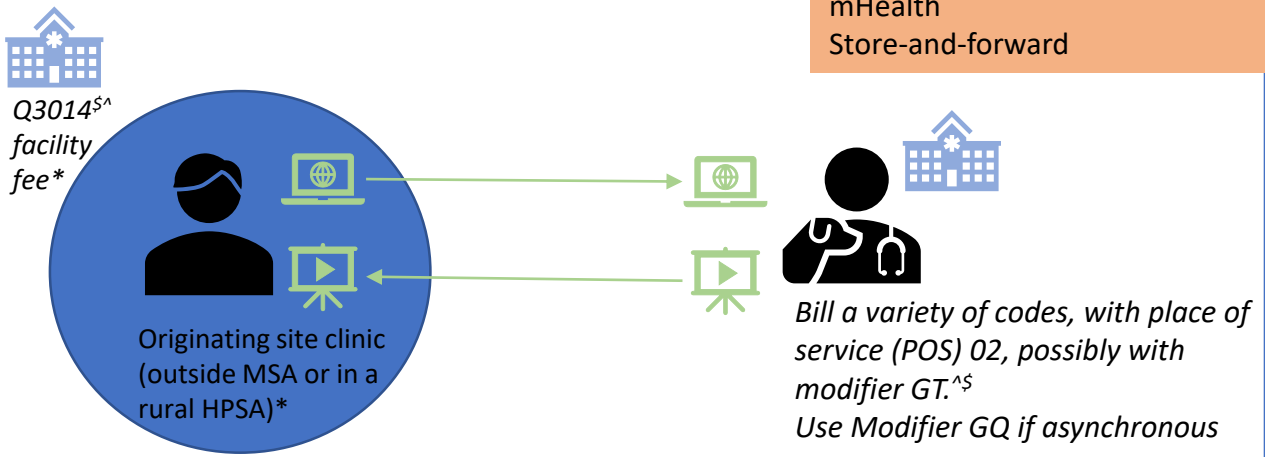
Phone/Online
Patient - Clinician
Covered by HERC today GL A5



Telehealth = face-to-face synchronous visits (based on Medicare)

Proposed addition to GL A5:
Add telehealth (broadly)
Visits from home
ICU/emergency/hospital

Not in GL A5 or new proposed
mHealth
Store-and-forward

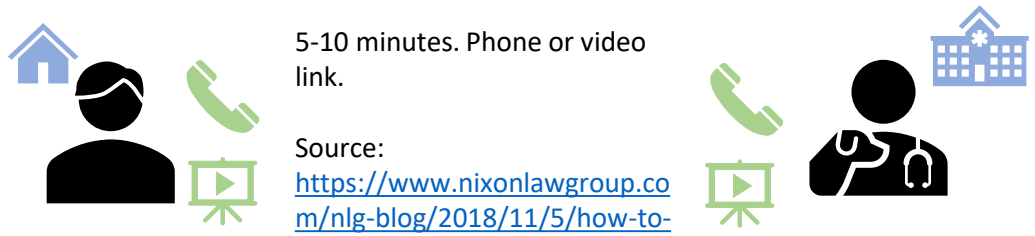


Bill a variety of codes, with place of service (POS) 02, possibly with modifier GT.^$
Use Modifier GQ if asynchronous

*Exceptions for SUD services which can be provided from patient's home eff July 2019; stroke services can be any clinic since Jan. 2019, also some early adopters don't have to be outside MSA/in HPSA

See https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/TelehealthSrvcsfctsht.pdf for details

Virtual check-in *G2012*



5-10 minutes. Phone or video link.

Source: https://www.nixonlawgroup.com/nlg-blog/2018/11/5/how-to-get-reimbursed-for-virtual-check-ins-under-hcpcs-g2012

$Code is on fee schedule and open for payment
^Codes open for payment for FFS for Physical Health provider types only (not behavioral health); not on fee schedule unless there is also a $
Other listed codes are not open for payment at all but listed on Prioritized List

By J. Scott Ashwood, Ateev Mehrotra, David Cowling, and Lori Uscher-Pines

Direct-To-Consumer Telehealth May Increase Access To Care But Does Not Decrease Spending

DOI: 10.1377/hlthaff.2016.1130
HEALTH AFFAIRS 36,
NO. 3 (2017): 485–491
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Foundation, Inc.

ABSTRACT The use of direct-to-consumer telehealth, in which a patient has access to a physician via telephone or videoconferencing, is growing rapidly. A key attraction of this type of telehealth for health plans and employers is the potential savings involved in replacing physician office and emergency department visits with less expensive virtual visits. However, increased convenience may tap into unmet demand for health care, and new utilization may increase overall health care spending. We used commercial claims data on over 300,000 patients from three years (2011–13) to explore patterns of utilization and spending for acute respiratory illnesses. We estimated that 12 percent of direct-to-consumer telehealth visits replaced visits to other providers, and 88 percent represented new utilization. Net annual spending on acute respiratory illness increased $45 per telehealth user. Direct-to-consumer telehealth may increase access by making care more convenient for certain patients, but it may also increase utilization and health care spending.

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Direct-to-consumer telehealth companies such as Teladoc, American Well, and Doctor on Demand offer patients with minor illnesses around-the-clock access to a physician via telephone or videoconferencing on their smartphone, tablet, or laptop. The growth in direct-to-consumer telehealth appears to be accelerating. There were a reported 1.25 million direct-to-consumer telehealth visits in 2015,[1] and Teladoc reported that in that year it provided roughly 600,000 visits—a volume almost double that of the previous year.[2] A recent survey of large employers indicated that 90 percent of them plan to offer a direct-to-consumer telehealth option to their employees in 2017.[3]

One of the key attractions of direct-to-consumer telehealth for employers is the potential cost savings. Direct-to-consumer companies argue that they save money for health plans, employers, and patients by replacing costly visits to physician offices and emergency departments (EDs) with a $40–$50 telehealth visit. Furthermore, patients who use direct-to-consumer telehealth can avoid time and travel costs, including time off from work, that are associated with seeking in-person care.[4] However, the impact of direct-to-consumer telehealth on spending has not been rigorously assessed until now.

While it is clear that the reimbursement for a direct-to-consumer telehealth visit is lower than that for a physician office or ED visit, there are two potential concerns. The first is that if the direct-to-consumer telehealth visit is more likely to result in follow-up appointments, testing, or prescriptions, compared to similar visits to other settings, direct-to-consumer telehealth could increase spending. For example, given liability concerns, direct-to-consumer telehealth physicians may be more likely to recommend that patients have a subsequent in-person visit with a provider. Therefore, although the telehealth visit is less costly, the per episode cost of a direct-to-consumer telehealth visit could be great-

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Milbank Memorial Fund

August 2019

The Evolving Policy Landscape of Telehealth Services Delivered in the Home and Other Nonclinical Settings

Issue Brief

By Brittany Lazur, Andrea Bennett, and Valerie King

Abstract

The rate of telehealth use, in which patients receive a virtual health care visit, in the home or other nonclinical setting has outpaced the release of research about this model of care. As a result, state agencies are developing new policies for home-based telehealth services with little evidence to guide them. This brief identifies key findings for state officials considering such policies, as follows:

- Payers with established telehealth programs employ approaches that are consistent with their organizational goals and resources.
- State Medicaid programs cover home-based telehealth through a variety of approaches.
- State Medicaid programs require home-based telehealth services to meet the same standard of care as in-person visits, including patient privacy and provider scope of practice.

- State Medicaid programs usually reimburse telehealth-delivered services and in-person clinical and primary care–delivered services equally.
- Medicare generally does not cover telehealth in the home, but is incrementally covering telehealth services in certain circumstances.
- Commercial coverage varies based on state laws and how they use third-party vendors.

The brief reviews state Medicaid, Medicare, and private payer policies on home-based telehealth and draws on interviews with policymakers from two Medicaid agencies, two individuals from health care organizations that implemented telehealth programs for patients at home, and a medical officer from a managed care organization (MCO) that offers virtual visits to all of its members. This brief is based on a report developed for the Medicaid Evidence-based Decisions Project (MED), a research collaboration of 21 state Medicaid programs based at the Center for Evidence-based Policy at Oregon Health and Science University.

Background

Concerns about health care access and costs have increased state officials' interest in programs to support telehealth services in the home, workplace, or other nonclinical settings. More than 100 state and federal bills related to telehealth implementation have been introduced annually in the last several years.[1]

The Health Resources and Services Administration defines telehealth as "the use of telecommunications and information technologies to share information, and provide clinical care, education, public health, and administrative services at a distance."[2] While there are four types of telehealth (see Table 1), this issue brief focuses on the rapidly growing technology of telehealth delivered via synchronous audio-video connection in which patients receive health care at an originating site from health care providers located at a distant site.

Historically, for providers to receive reimbursement for the services, public payers such as Medicaid and Medicare have required patients to be physically located in an approved clinical setting, known as the originating site, while telehealth services are being delivered.[1] Under these requirements, patients could not be located in their homes or workplaces.[1] However, the Centers for Medicare and Medicaid Services (CMS), using new leverage provided in the Bipartisan Budget Act of 2018, is finalizing changes that would allow beneficiaries participating in Medicare Advantage plans and the Medicare Shared Savings Program to access additional telehealth benefits, such as receiving telehealth services in their homes, starting in 2020.[3,4] Recent legislation in some states has focused on