Health Evidence Review Commission

November 18, 2021

1:30 PM - 3:30 PM

Online Meeting

Join online meeting here

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Section 1.0

Call to Order

AGENDA

HEALTH EVIDENCE REVIEW COMMISSION

Online Meeting

November 18, 2021

1:30-3:30 pm

(All agenda items are subject to change and times listed are approximate)

#	Time	Item	Presenter	Action Item
1	1:30 PM	Call to order	Kevin Olson	
2	1:35 PM	Approval of VbBS minutes (10/7/2021) Approval of advisory panel highlights: GAP, BHAP and OHAP	Kevin Olson	X
3	1:40 PM	Director's report • Subcommittee appointments	Jason Gingerich	
4	1:50 PM	Value-based Benefits Subcommittee report	Ariel Smits	X
8	3:20 PM	Next steps • Schedule next meeting – January 20, 2022	Kevin Olson	
9	3:30 PM	Adjournment	Kevin Olson	

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

MINUTES

HEALTH EVIDENCE REVIEW COMMISSION
Online Meeting
October 7, 2021

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, MBA, Vice-Chair; Gary Allen, DMD; Devan Kansagara, MD; Lynnea Lindsey, PhD; Leslie Sutton; Adriane Irwin, PharmD, Kathryn Schabel, MD; Max Kaiser, DO; Mike Collins; Deborah Espesete, LAc, MAcOM, MPH, DiplOM; Cris Pinzon, MPH, BSN, BS, RN.

Members Absent: Michael Adler, MD.

Staff Present: Ariel Smits, MD, MPH; Jason Gingerich; Liz Walker, PhD, MPH; Daphne Peck.

Also Attending: David Inbody (Oregon Health Authority); Bethany Godlewski & Val King, (OHSU Center for Evidence-based Policy); Carissa Bishop; DeAnn; John Hermes; John's iPhone; Maria Gonzalez-Cress; Kerry Potter; Renee Taylor.

Call to Order

Kevin Olson, Chair of the Health Evidence Review Commission (HERC), called the meeting to order; roll was called. A quorum of members was present at the meeting.

Minutes Approval

MOTION: To approve the minutes of the August 12, 2021 meeting as presented. CARRIES 12-0.

Director's Report

Prioritized List
Jason Gingerich reported no errata to the Prioritized List of Health Services. Gingerich stated staff had conducted a claims analysis regarding Guideline Note A4 SMOKING CESSATION AND ELECTIVE SURGICAL PROCEDURES and reported no trend changes before and after the guideline's implementation.

Membership
Gingerich said Dr. Mike Adler and Dr. Gary Allen are both leaving the Commission at the end of the year. He said staff are actively recruiting for both Commissioners and for subcommittee members and to refer to the HERC's website for application information.

Conflicts of Interest Rule
Gingerich said that after September's rules advisory committee meeting, the new rule is posted for public comment by the Secretary of State. Once effective, staff will distribute updated conflict of interest disclosure forms for all members.

In Lieu of Services
Meeting materials Handout

David Inbody, OHA's Coordinated Care Organization (CCO) Operations Manager, gave a presentation on In Lieu of Services (ILOS).

Olson asked if there was a role for the HERC in this process. Inbody said the work HERC does complements and informs the kinds of ILOS that CCOs may want to adopt beginning in 2022.

Michael Collins asked if there has been any discussion about including this program for the Fee-For-Service (FFS) or Open Card populations, stating that a handful of the nine tribes in Oregon, including Warm Springs, is pursuing the development of an Indian Managed Care Entity (IMCE). Collins asked if they need to include this program in their contracts with the Oregon Health Authority (OHA). Inbody said they are just currently focused on the Coordinated Care Organization (CCO) population but stated it is worthwhile to consider how ILOS might be applied to FFS or the new IMCEs once this process begins in 2022. Inbody did stress it is optional for the CCOs to participate in this program and not all CCOs are participating in this first round.

Kathryn Schabel said she had confusion about the name of the program, since *in lieu* means *instead of*. She said it sounds like this program would provide additional services, so the program name is potentially a misnomer and it might be misinterpreted. Inbody said the name aligns with the federal direction; that is the language they use, and the state wanted to be consistent.

Cris Pinzon asked about medically appropriate and cost-effective services. Inbody said there is an expectation of medical oversight.

Value-based Benefits Subcommittee (VbBS) Report on Prioritized List Changes
Meeting materials, pages 50-116

Ariel Smits reported the VbBS met earlier in the day, 10/7/2021. She summarized the subcommittee's recommendations.

RECOMMENDED CODE MOVEMENT (changes to the 1/1/22 Prioritized List unless otherwise noted)
- Add Several new COVID related vaccine and treatment codes to covered lines
- Add codes to the preventive services line to allow falls prevention services
- Add several diagnosis and procedure codes to a covered line to allow treatment of acquired penile anomalies
- Add the procedure code for neurectomy for wrist arthritis to a covered line
- Add the diagnosis code for vitiligo to a covered line
- Make various straightforward coding changes

RECOMMENDED GUIDELINE CHANGES (changes to the 1/1/22 Prioritized List unless otherwise noted)
- Edit the neuropsychological testing guideline to specify that patients being considered for epilepsy surgery could be tested as part of their pre-operative work up to determine surgical candidacy
- Edit the preventive services guideline to specify coverage of falls prevention programs

- Edit the penile anomalies guideline to specify coverage for acquired anomalies after surgeries if specific criteria are met
- Add a new guideline regarding when neurectomy for wrist arthritis is covered
- Edit the severe inflammatory skin disease guideline to include vitiligo
- Edit the guideline on kyphoplasty and vertebroplasty to specify how long a patient needed to be treated with conservative management.
- Make several straightforward guideline changes

MOTION: To accept the VbBS recommendations on *Prioritized List changes* as stated. See the VbBS minutes of 10/7/2021 for a full description. Carries: 12-0.

Pinzon asked about looking at the cost-effectiveness of different options for colorectal cancer screening tests. Smits said staff are working on this internally and the topic will be on a future agenda.

Public Comment

There was no public comment.

Adjournment

Meeting adjourned at 2:30 pm. Next meeting will be from 1:30-4:30 pm on Thursday, November 18, 2021 and will be held online.

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on October 7, 2021

For specific coding recommendations and guideline wording, please see the text of the 10/7/2021 VbBS minutes.

RECOMMENDED CODE MOVEMENT (changes to the 1/1/22 Prioritized List unless otherwise noted)

- Add several new COVID-related vaccine and treatment codes to covered lines
- Add codes to the preventive services line to allow falls prevention services
- Add several diagnosis and procedure codes to a covered line to allow treatment of acquired penile anomalies
- Add the procedure code for neurectomy for wrist arthritis to a covered line
- Add the diagnosis code for vitiligo to a covered line
- Make various straightforward coding changes

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- No change in current non-coverage of wireless capsule endoscopy for esophageal or gastrointestinal motility indications
- No expansion of current coverage of continuous glucose monitoring was recommended
- No change in the current limitations on diabetic test strips was recommended
- No changes were made to lack of coverage of cranial electrical stimulation
- No change was made to lack of coverage for minimally invasive lumbar decompression for spinal stenosis
- No change was made to lack of coverage for interspinous/interlaminar process spacer devices
- No changes were made to lack of coverage of various interventions for treatment of acute and chronic pain

RECOMMENDED GUIDELINE CHANGES (changes to the 1/1/22 Prioritized List unless otherwise noted)

- Edit the neuropsychological testing guideline to specify that patients being considered for epilepsy surgery could be tested as part of their pre-operative work up to determine surgical candidacy
- Edit the preventive services guideline to specify coverage of falls prevention programs
- Edit the penile anomalies guideline to specify coverage for acquired anomalies after surgeries if specific criteria are met
- Add a new guideline regarding when neurectomy for wrist arthritis is covered
- Edit the severe inflammatory skin disease guideline to include vitiligo
- Edit the guideline on kyphoplasty and vertebroplasty to specify how long a patient needed to be treated with conservative management
- Make several straightforward guideline changes

VALUE-BASED BENEFITS SUBCOMMITTEE
Online meeting
October 7, 2021
8:00 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair (arrived 8:30 AM); Holly Jo Hodges, MD, MBA, Vice-chair; Cris Pinzon, MPH, BSN, BS, RN; Kathryn Schabel, MD; Brian Duty, MD (arrived 9:00 AM); Mike Collins; Adriane Irwin, PharmD.

Members Absent: Regina Dehen, ND, Lac.

Staff Present: Ariel Smits, MD, MPH; Jason Gingerich; Liz Walker, PhD, MPH; Daphne Peck.

Also Attending: Bethany Godlewski (OHSU Center for Evidence-based Policy); Brandon Fair; Chris Tanaka (DEXCOM); Christine Fallabel; Cindy Seger; Dave Inbody (Oregon Health Authority) Jay Halaj; Josh Briley; Julie Dhossche (OHSU); Liz Custer; Paul Konovodoff; Renee Taylor; Sabra Leitenberger; Scott Bowen; Vishal Khemlani; YJ Shukla; Elena Burns.

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

  The meeting was called to order at 8:05 am and roll was called. A quorum of members was present at the meeting. Minutes from the August 12, 2021 VbBS meeting were reviewed and approved.

  Gingerich reported to the VBBS that staff had conducted a claims analysis to determine whether select elective procedures reduced due to the smoking cessation and elective procedures ancillary guideline and found no major changes after guideline implementation.

  Gingerich announced several open positions on HERC and its subcommittees and asked members to let colleagues and contacts know about the vacancies and encourage applications.

  Gingerich clarified current coverage on breast electrolysis for gender dysphoria. He also reported on the pending new conflicts-of-interest rule from September's rules advisory committee.

  David Inbody, Oregon Health Authority (OHA)'s CCO Operations Manager, gave a presentation on In Lieu of Services (ILOS). Members had a robust discussion of the Prioritized List's role in helping CCOs decide which ILOS to pursue. Inbody clarified that this new option will be available to CCOs beginning in 2022.

  There were no errata to report.

- **Topic: Straightforward/Consent Agenda**

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

  Recommended Actions:
  1) Remove CPT 64792 (Excision of neurofibroma or neurolemmoma; extensive) from lines 207 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT and 528 DEFORMITIES OF UPPER BODY AND ALL LIMBS
     a. Add 64792 to line 199 CANCER OF SOFT TISSUE
  2) Add CPT 45800 (Closure of rectovesical fistula) to line 230 URINARY FISTULA
  3) Add CPT 95873 (Electrical stimulation for guidance in conjunction with chemodenervation) and 95874 (Needle electromyography for guidance in conjunction with chemodenervation) to line 410 MIGRAINE HEADACHES
  4) Modify Ancillary Guideline A4 as shown in Appendix A
  5) Modify Guideline Note 173 as shown in Appendix A
  6) Add CPT 30520 (Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft) to line 577 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT
  7) Add ICD-10-CM Q67.4 (Other congenital deformities of skull, face and jaw) to line 577 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT
  8) Modify Guideline Note 118 as shown in Appendix A

  MOTION: To approve the recommendations stated in the consent agenda. CARRIES 6-0. *(Absent: Duty)*

- **Topic: COVID-19 Coding Updates**

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

  Recommended Actions:
  1) Add CPT 0013A (IMM ADMN SARSCOV2 100 MCG/0.5 ML 3RD DOSE) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
  2) Add HCPCS M0240 (Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring, subsequent repeat doses) and M0241 (Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring in the home or residence, this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency, subsequent repeat doses) to line 399 INFLUENZA, COVID-19 AND OTHER NOVEL RESPIRATORY VIRAL ILLNESS
  3) Add CDT D0606 (molecular testing for a public health-related pathogen, including coronavirus) to the Diagnostic Procedure File
  4) Add the following CDT codes to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
     a. D1701 Pfizer-BioNTech COVID-19 vaccine administration — first dose
     b. D1702 Pfizer-BioNTech COVID-19 vaccine administration — second dose
     c. D1703 Moderna COVID-19 vaccine administration — first dose

d. D1704 Moderna COVID-19 vaccine administration — second dose
e. D1705 AstraZeneca COVID-19 vaccine administration — first dose
f. D1706 AstraZeneca COVID-19 vaccine administration — second dose
g. D1707 Janssen COVID-19 vaccine administration

MOTION: To recommend the code changes as presented. CARRIES 6-0. *(Absent: Duty)*

- **Topic: Clarification of when neuropsychological testing is covered prior to epilepsy surgery**

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

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

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

- **Topic: Fall prevention programs**

Discussion: Smits reviewed the summary document. The discussion centered around the fact that people younger than age 65 can be at risk for falls due to medication or other reasons. There are standardized tools such as the STEADI that can identify people at risk for falls, or providers can identify patients based on their specific disease, having a facility fracture, or by other means. The group requested that the guideline wording be expanded to include patients younger than 65 at increased risk of falls.

Recommended Actions:
1) Add HCPCS S9451 (Exercise classes, non-physician provider, per session) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
2) Modify Guideline Note 106 as shown in Appendix A

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

- **Topic: Continuous glucose monitoring**

Discussion: Smits reviewed the summary document. Smits noted that after the meeting materials had been sent out, there was a CCO request to clarify the continuous glucose monitoring (CGM) guideline to specify that CGM is not covered for type 2 diabetes or gestational diabetes; the group felt that this change was appropriate. There was discussion about whether CGMs could be covered in certain clinical situations; Hodges replied that medical directors can look at case by case requests and approve by exception if medically justified.

Recommended Actions:
1) Modify Guideline Note 108 as shown in Appendix A

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

- **Topic: Limits on diabetic test strips**

  Discussion: Smits reviewed the summary document. Olson noted that OHP is more limiting on test strips that Medicare. No change to current limitations on diabetic test strips was recommended.

- **Topic: Treatment of acquired penile anomalies**

  Discussion: Smits reviewed the summary document. Duty noted that the guideline would apply to adults as well as children who meet criteria. This was felt to be appropriate.

  Recommended Actions:
  1) Add to line 424 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
     a. CPT 54162 (Lysis or excision of penile post-circumcision adhesions)
     b. ICD-10-CM N48.89 (Other specified disorders of penis)
     c. ICD-10-CM T81.9XXA (Unspecified complication of procedure, initial encounter)
     d. ICD-10-CM N48.83 (Acquired buried penis)
  2) Modify Guideline Note 73 as shown in Appendix A

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

- **Topic: Neurectomy for wrist arthritis**

  Discussion: Smits reviewed the summary document. There was a question about whether this service is available in Oregon. Schabel reported that it is widely done by hand surgeons as an alternative to wrist fusion.

  Recommended Actions:
  1) Add CPT 64772 (Transection or avulsion of other spinal nerve, extradural) to line 356 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE Treatment: ARTHROPLASTY/ RECONSTRUCTION
  2) Add a new guideline to line 356 as shown in Appendix B

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

- **Topic: Cranial electrical stimulation**

  Discussion: Smits reviewed the summary document.

  Public testimony
  1) Josh Briley, PhD, Science and Education Director for EPI (manufacturer), clinical psychologist: Dr. Briley testified regarding his experience using Alpha Stim to treat thousands of patients. He noted that the HERC staff literature reviewed included only a small portion of the literature on Alpha Stim. He personally has seen clinically significant improvement in depression, anxiety and insomnia. User surveys show very significant improvement in symptoms as well. Alpha Stim is

very safe, side effect rate is <1% and are mild and self-limiting. This technology is also less expensive than extensive therapy and has fewer side effects than medications. It also works faster than therapy.

2) Jay Halaj, PhD, Senior Consultant for Allevia Health (manufacturer): Dr. Halaj testified that the Portland VA and other VAs cover Alpha Stim. Hundreds of practitioners use this device and thousands of patients are using it. After about 20 minutes of using the device, patients have a response and are able to push through barriers in processing trauma. It brings on a sense of calm and reduces arousal. Device use can avoid costly emergency visits for situations like panic attacks. It's also especially useful in addition treatment as a non-chemical way to reduce anxiety and insomnia from treatment in that population.

Pinzon asked the presenters if the VA has done studies on the outcomes of Alpha Stim. The response was that the VA has only done small pilot studies. The group felt that larger studies were feasible and needed before this technology should be considered for adoption to the Prioritized List.

Recommended Actions:
1) Modify Guideline Note 173 as shown in Appendix A

MOTION: To recommend the guideline note changes as presented. CARRIES 6-0. *(Abstained: Pinzon)*

- **Topic: Minimally invasive lumbar decompression for spinal stenosis**

Discussion: Smits reviewed the summary document.

Public Testimony

1) Vishal Khemlani, MD, anesthesiologist, Vertos Medical affiliate (manufacturer): Dr. Khemlani gave a brief presentation of the MILD procedure and said he has done over 150 procedures. His presentation gave an overview of the procedure's effectiveness and included patient success stories.

2) Paul Konovodoff, Director for Market Access, Vertos Medical (manufacturer): Mr. Konovodoff began his testimony by addressing cost of the MILD procedure, stating the procedure has a Medicare cost of $4,000 for an ambulatory surgical center, or $6200 for hospitals charges and $600-700 cost for the physician fee. He said that the MILD procedure is covered for 92 million lives, including many commercial lives. He said 41,000 procedures have been done nationwide and 1500 certified providers are currently doing this procedure, 15 or 20 of which are in Oregon. Ohio and Illinois Medicaid have recently added coverage. MILD has been FDA approved since 2005.

The subcommittee discussed whether there are active trials ongoing, and the testifiers indicated there are ongoing trials. Schabel asked about the risk of needing spine surgery after the 5 years the patients were observed in the studies. Khemlani stated that the effects seemed to last in his experience. He noted that the Cleveland Clinic study included in the staff review was following

patients who were initially in the MIDAS study, and so may have been followed for more than 5 years.
Schabel expressed concern that this procedure was being introduced into a patient care area in which there is no current surgical interventions. The patients that were studied for MILD were probably not candidates for fusion, and their only other options would be conservative therapy and epidural steroid injections. This makes MILD a new treatment paradigm, which may introduce more care than these patients needed.

Olson expressed concern that the patient sample sizes were small.

Schabel asked Konovodoff when he expected a non-experimental CPT or HCPCS code for the procedure to be issued; Konovodoff stated that his company is not pursuing a Category 1 CPT code designation.

Recommended Actions:
1) Add CPT 0275T and HCPCS G0276 to Line 662
2) Modify Guideline Note 173 as shown in Appendix A

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

- **Topic: Interspinous/interlaminar process spacer devices**

Discussion: Smits reviewed the summary document. There was no significant discussion on this topic.

Recommended Actions:
1) Modify Guideline Note 173 as shown in Appendix A

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

- **Topic: Vitiligo**

Discussion: Smits reviewed the summary document.

Public testimony
Drs. Julie Dhossche and Sara Leitenberger, OHSU pediatric dermatology: Dr. Dhossche began the brief invited presentation by declaring no conflicts of interest. She gave an overview on vitiligo, current therapies for repigmentation, and maintenance therapies.

The subcommittee discussed whether any step therapy requirements would be appropriate. The group decided since the only medications currently used are topical/oral steroids and tacrolimus, it was felt that step therapy would not need to be spelled out. There was also discussion about this condition being an equity issue, as it affect persons with more pigmented/darker skin to a higher degree. There was discussion about if a patient only receives partial remission with therapy, if that would be enough to reduce anxiety, depression or other negative consequences. The experts stated that in their experience, even some reduction in depigmentation can have a large effect on

psychological outcomes. Leitenberger stated that reduction of depigmentation to a small area allows the use of cosmetics or other products to cover up the area.

Recommended Actions:
1) Add ICD-10 L80 (Vitiligo) to line 426 SEVERE INFLAMMATORY SKIN DISEASE
2) Modify Guideline Note 21 as shown in Appendix A

MOTION: To recommend the code and guideline note changes as presented. CARRIES 6-0. *(Absent: Duty)*

- **Topic: Interventional therapies for treatment of acute and chronic pain**

Discussion: Smits reviewed the summary documents. There was no discussion of the treatments with no evidence of effectiveness.

For the kyphoplasty and vertebroplasty summary, Hodges noted that NICE, AAOS and other groups require a 4-to-6-week trial of conservative management prior to kyphoplasty and vertebroplasty. The group agreed to add this requirement to the guideline.

There was minimal discussion regarding radiofrequency denervation for sacroiliac pain.

Recommended Actions:
1) Add CPT 64555 (Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)) to line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
2) Modify Guideline Note 173 as shown in Appendix A
3) Modify Guideline Note 37 as shown in Appendix A
4) Modify Guideline Note 109 as shown in Appendix A

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

- **Public Comment:**

No additional public comment was received.

- **Next meeting:**

November 18, 2021 as a virtual meeting

- **Adjournment:**

The meeting adjourned at 1:05 PM.

Appendix A

Revised Guideline Notes

ANCILLARY GUIDELINE A4, SMOKING CESSATION AND ELECTIVE SURGICAL PROCEDURES

Surgical consultation is covered for patients who actively smoke and who are referred for surgical consultations; if elective surgery is recommended based on a consultation, the requirements of this guideline note apply.

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

Elective surgical procedures in this guideline are defined as surgical procedures which are flexible in their scheduling because they do not pose an imminent threat nor require immediate attention within 1 month. Procedures for contraceptive/sterilization purposes, procedures targeted to active cancers (i.e. when a delay in the procedure could lead to cancer progression), ~~and~~ diagnostic procedures, and bloodless surgery (e.g. cataract surgery~~, certain skin procedures~~) are not subject to the limitations in this guideline note. This guideline applies regardless of procedure location and anesthesia type.

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

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

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

DIAGNOSTIC GUIDELINE 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:

A) Symptoms are not explained by an existing diagnosis; AND
B) 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 as part of the process to determine if the patient is an appropriate surgical candidate or post-operative follow up after epilepsy surgery.

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

Lines 426,482,504,532,541,656

Inflammatory skin conditions included in this guideline are:

Appendix A

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

The conditions above are included on Line 426 if severe, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on other validated tool) AND one or more of the following:

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

Otherwise, these conditions above are included on Lines 482, 504, 532, 541 and 656.

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.

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

Lines 346,529

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

A) Decompressive surgery is included on Line 346 to treat debilitating symptoms due to central or foraminal spinal stenosis, and only when the patient meets the following criteria:
    1) Has MRI evidence of moderate or severe central or foraminal spinal stenosis AND
    2) Has neurogenic claudication OR
    3) Has objective neurologic impairment consistent with the MRI findings. Neurologic impairment is defined as objective evidence of one or more of the following:
        a) Markedly abnormal reflexes
        b) Segmental muscle weakness
        c) Segmental sensory loss

d) EMG or NCV evidence of nerve root impingement
e) Cauda equina syndrome
f) Neurogenic bowel or bladder
g) Long tract abnormalities

Foraminal or central spinal stenosis causing only radiating pain (e.g. radiculopathic pain) is included only on Line 529.

B) Spinal fusion procedures are included on Line 346 for patients with MRI evidence of moderate or severe central spinal stenosis only when one of the following conditions are met:
1) spinal stenosis in the cervical spine (with or without spondylolisthesis) which results in objective neurologic impairment as defined above OR
2) spinal stenosis in the thoracic or lumbar spine caused by spondylolisthesis resulting in signs and symptoms of neurogenic claudication and which correlate with xray flexion/extension films showing at least a 5 mm translation OR
3) pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of facet joints per level expected to be resected)

For all other indications, spine surgery is included on Line 529.

The following interventions are not included on these lines due to lack of evidence of effectiveness for the treatment of conditions on these lines, including cervical, thoracic, lumbar, and sacral conditions:
- local injections (including ozone therapy injections)
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- percutaneous laser disc decompression
- radiofrequency denervation
- corticosteroid injections for cervical pain
- intradiscal injections, including platelet rich plasma, stem cells, methylene blue, or ozone

Corticosteroid injections for low back pain with or without radiculopathy are only included on Line 529. Diagnostic anesthetic injections for selective nerve root blocks are included on Line 529 for lumbar or sacral symptoms.

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

GUIDELINE NOTE 73, PENILE ANOMALIES

Lines 424,433,571,658

Congenital a~~A~~nomalies of the penis (ICD-10-CM Q54.4, Q55.5 and Q55.6) are included on Line 433 only when they

A. Are associated with hypospadias, OR

B. Result in documented urinary retention, OR
C. Result in repeated urinary tract infections, OR
D. Result in recurrent infections such as meatitis or balanitis, OR
E. Involve 35 degrees of curvature or greater for conditions resulting in lateral or ventral curvature, OR
F. Involve 60 degrees of rotation or greater for conditions resulting in penile torsion, OR
G. Involve aplasia/congenital absence of the penis.

Otherwise, these diagnoses are included on Line 658

Acquired anomalies of the penis (ICD-10-CM N48.83, N48.89 or T81.9XXA) are included on line 424 only when they are the result of a prior penile procedure AND either

A. Result in a skin bridge. OR
B. Result in a buried penis; OR
C. Are associated with hypospadias, OR
D. Result in documented urinary retention, OR
E. Result in repeated urinary tract infections, OR
F. Result in recurrent infections such as meatitis or balanitis, OR
G. Involve 35 degrees of curvature or greater for conditions resulting in lateral or ventral curvature, OR
H. Involve 60 degrees of rotation or greater for conditions resulting in penile torsion.

Otherwise, these diagnoses are included on line 571 or 658.

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Lines 3,622

Included on Line 3 are the following preventive services:

A) US Preventive Services Task Force (USPSTF) "A" and "B" Recommendations in effect and issued prior to January 1, 2021 ~~2020~~.
   1) http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/
      a) Treatment of falls prevention with exercise interventions is included on Line 292.
   2) USPSTF "D" recommendations are not included on this line or any other line of the Prioritized List.

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

C) Health Resources **and Services Administration (HRSA) Women's Preventive Services-Required Health Plan Coverage Guidelines a**s updated by HRSA in December 2019. Available at https://www.hrsa.gov/womens-guidelines-2019 as of September 4, 2020.

Appendix A

D) Immunizations as recommended by the Advisory Committee on Immunization Practices (ACIP): http://www.cdc.gov/vaccines/schedules/hcp/index.html or approved for the Oregon Immunization Program: https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Documents/DMAPvactable.pdf
   1) COVID-19 vaccines are intended to be included on this line even if the specific administration code(s) do not yet appear on the line when the vaccine has both 1) FDA approval or FDA emergency use authorization (EUA) and 2) ACIP recommendation.

Colorectal cancer screening is included on Line 3 for average-risk adults aged 45 to 75, using one of the following screening programs:

A) Colonoscopy every 10 years
B) Flexible sigmoidoscopy every 5 years
C) Fecal immunochemical test (FIT) every year
D) Guaiac-based fecal occult blood test (gFOBT) every year

CT colonography CPT 74263), FIT-DNA (CPT 81528) and mSEPT9 (HCPCS G0327) are included on line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS.

Colorectal cancer screening for average-risk adults aged 76 to 85 is covered only after informed decision making between patients and clinicians which includes consideration of the patient's overall health, prior screening history, and preferences.

Supervised evidence-based exercise programs for fall prevention for persons age 65 and older OR younger patients who are at increased risk of falls are included on line 3 using CPT 98961 or 98962 or HCPCS S9451. HCPCS S9451 is only included on Line 3 for the provision of supervised exercise therapy for fall prevention. Programs should be culturally tailored/culturally appropriate when feasible.

Note: CPT code 96110 (Developmental screening (eg, developmental milestone survey, speech and language delay screen), with scoring and documentation, per standardized instrument) can be billed in addition to other CPT codes, such as evaluation and management (E&M) codes or preventive visit codes.

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

GUIDELINE NOTE 108, CONTINUOUS GLUCOSE MONITORING

Line 1, 8, 27

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

A) Adults with type 1 diabetes mellitus not on insulin pump management:
   1) Who have received or will receive diabetes education specific to the use of CGM AND
   2) Who have used the device for at least 50% of the time at their first follow-up visit AND
   3) Who have baseline HbA1c levels greater than or equal to 8.0%, frequent or severe hypoglycemia, or impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM).
B) Adults with type 1 diabetes on insulin pump management (including the CGM-enabled insulin pump):

1) Who have received or will receive diabetes education specific to the use of CGM AND
2) Who have used the device for at least 50% of the time at their first follow-up visit.

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

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

CPT 95250 and 95251 (Ambulatory continuous glucose monitoring) are included on this line for services related to real-time continuous glucose monitoring but not retrospective (professional) continuous glucose monitoring.

Continuous glucose monitors are not covered for people with type 2 diabetes or gestational diabetes.

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

GUIDELINE NOTE 109, VERTEBROPLASTY, KYPHOPLASTY, AND SACROPLASTY

Line 478

Vertebroplasty and kyphoplasty are not included on this line (or any other line) for the treatment of routine osteoporotic compression fractures.

Vertebroplasty and kyphoplasty are only included on this line for the treatment of vertebral osteoporotic compression fractures when they are considered non-routine and meet all of the following conditions:

A) The patient is hospitalized under inpatient status due to pain that is primarily related to a well-documented acute fracture, and
B) The severity of the pain prevents unassisted ambulation, and
C) The pain is not adequately controlled with oral or transcutaneous medication, and
D) The patient must have failed an appropriate 4-to-6 week trial of conservative management.

Sacroplasty is not included on these or any lines of the Prioritized List for coverage consideration.

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

GUIDELINE NOTE 118 SEPTOPLASTY

Lines 42,119,246,287,465,506,525,577

Septoplasty is included on these lines when

A) The septoplasty is done to address symptomatic septal deviation or deformity which
1) Fails to respond to a minimum 6 week trial of conservative management (e.g. nasal corticosteroids, decongestants, antibiotics); AND
2) Results in one or more of the following:
a. Persistent or recurrent epistaxis, OR

b. Documented recurrent sinusitis felt to be due to a deviated septum and the patient meets criteria for sinus surgery in Guideline Note 35, SINUS SURGERY; OR

c. Nasal obstruction with documented absence of other causes of obstruction likely to be responsible for the symptoms (for example, nasal polyps, tumor, etc.) [note: this indication is included only on line ~~506~~ 577]; OR

B) Septoplasty is performed in association with cleft lip or cleft palate repair or repair of other congenital craniofacial anomalies; OR

C) Septoplasty is performed as part of a surgery for a neoplasm or facial trauma involving the nose.

Septoplasty is not covered for obstructive sleep apnea.

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
0275T G0276	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar Blinded procedure for lumbar stenosis, PILD, or placebo control, performed in an approved coverage with evidence development (CED) clinical trial	Insufficient evidence of effectiveness	October 2021
22867-22870 C1821	Insertion of interlaminar/ interspinous process stabilization/ distraction device, without fusion, including image guidance when performed, with open decompression, lumbar Interspinous process distraction device (implantable)	Insufficient evidence of effectiveness	~~November, 2016~~ October 2021

Appendix A

Procedure Code	Intervention Description	Rationale	Last Review
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)	Insufficient evidence of effectiveness	October 2021
64625	Anesthetic or steroid injection and/or radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance	Insufficient evidence of effectiveness	~~November 2019~~ October 2021
64633-64634	Radiofrequency ablation of the cervical and thoracic spine	Insufficient evidence of benefit	~~March, 2015~~ October 2021
64635-64636 C9752, C9753	Radiofrequency ablation of the lumbar and sacral spine	Insufficient evidence of benefit	~~November, 2014~~ ~~Coverage guidance~~ October 2021
64640	Destruction by neurolytic agent; other peripheral nerve or branch	Insufficient evidence of effectiveness	~~March 2020~~ October 2021
~~90875-90876~~ ~~90901~~	~~Individual psychophysiological therapy incorporating biofeedback training by any modality~~ ~~Biofeedback training by any modality~~	~~Insufficient evidence of effectiveness~~	~~January 2021~~
91111	Capsule endoscopy, esophagus	~~No~~ Insufficient evidence of effectiveness	~~December, 2012~~ October 2021
91112	Gastrointestinal transit and pressure measurement	Insufficient evidence of effectiveness	~~December, 2012~~ October 2021
97014, 97032, 0278T, E0720, E0730, G0283	Transcutaneous electrical nerve stimulation (TENS), frequency specific microcurrent therapy, microcurrent electrical stimulation, and all similar therapies; Scrambler therapy; all similar transcutaneous electrical neurostimulation therapies	Insufficient evidence of effectiveness for chronic pain and all other indications	January 2020 for TENS October 2021 for cranial electrical stimulation

Appendix A

Appendix B

New Guideline Notes

GUIDELINE NOTE XXX PARTIAL WRIST NEURECTOMY

Line 356

CPT 64772 is only included on this line for partial wrist neurectomy and is only covered when the alternative is wrist arthrodesis.

HIghlights

Behavioral Health Advisory Panel
Virtual meeting
October 18, 2021
3:00 pm--5:00 pm

Members Present: Lynnea Lindsey, PhD; Kathy Savicki, LCSW; Sheldon Levy, PhD; John Bischof, MD; Sondra Marshal MD; Eric Davis, MSW, CADC III, PSS, MSCP

Members Absent: Gary Cobb

Staff Present: Jason Gingerich; Ariel Smits, MD, MPH; Daphne Peck, Liz Walker

Also Attending: Laurie Theodorou (Oregon Health Authority (OHA)), Dana Peterson (OHA), Dalila Morales (OHA), Donny Jardine (OHA), Trevor Douglass (OHA), Andrew Gibler (OHA), Amanda Parish (OHA), Amy Gordin (OHA); Alison Noice (CODA); Ann Ford, CHC, PMP, MBA, MPH; Yvonne Hubbard, Ruth Miles (Salem Health), Tami Stump (Polk County behavioral health), Diane Bocking-Byrd, Keith Cheng MD; Andrea Vannata; Charles Gallia; DeAnn; Deborah Rumsey; Eileen Watters; Emilie Smith (Rogue Community Health); Heidee Love Sevilla; Jeremy Fleming; Kim Duerst; Kim Valdez; Liz Custer; Rob McAdam; Sabirin Barkadle; Sarina Roher; Shari; Tracy Zent; Yolanda Toledo

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1. CALL TO ORDER

The meeting was called to order at 3:00 PM.

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2. STAFF REPORT

Gingerich reviewed the purpose of the behavioral health advisory panel, which is to inform the HERC Medical Director in making recommendations for VbBS and HERC consideration.

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3. PRIORITIZED LIST ISSUES

1) Nightmare disorder
    a. Dr. Lindsey noted that nightmare disorder is often diagnosed in children because providers don't want to give the child a diagnosis of PTSD. She felt it was appropriate to move the diagnosis to a covered line. There was general agreement from all members that treatment is appropriate for all ages. There was unanimous agreement that the diagnosis should be moved to a funded line.

2) Changes to the Prioritized list for the OHA SUD waiver. These services can now be funded due to CMS approval of a waiver last spring. CCO rates for 2022 already account for the inclusion of these services.
    a. HCPCS H0022 Alcohol and/or drug intervention service (planned facilitation). This code represents facilitated intervention by treatment providers to get a patient into treatment services and as such as a pre-treatment service. Dana Peterson from the OHA SUD Waiver Team stated the team hoped to use this code to reimburse for services to get a person to reengage in SUD treatment. This code might be used by outreach co-ordinators to reach out to a person who might not have an SUD diagnosis. Savicki noted that adding coverage of this code would be a huge expansion of services. Lindsay noted that there might not be enough information to make a diagnosis of a patient at the point of using this code. All felt that this would be a valuable service. Savicki noted that this service would often be done by a peer support specialist. There were questions about how to bill for a patient who might not have medical insurance or other identification. The group agreed that this was a valuable service, and should be added to line 4; however, there are significant implementation issues that will need to be worked out by HSD prior to opening this code for use.
    b. HCPCS H0039 Assertive community treatment, face-to-face, per 15 minutes: Members felt that this code should be reserved for patients with chronic mental illness. There might be a dual diagnosis, but SUD alone should not be the only diagnosis. The unanimous recommendation was to not add to line 4 SUBSTANCE USE DISORDER.
    c. HCPCS H0043 Supported housing, per diem: Davis felt that supportive housing was an important service to cover. Dalila Morales from the SUD Waiver Team stated that the team wanted to use this code to pay for follow up visit with a patient who was discharged to a subsidized housing to see how the person is doing, how community integration is progressing, etc. BHAP members felt that the SUD Waiver Team should be using a case management code for this type of service. This code is per day, and implies a service being given each day. Members felt that the service envisioned could be provided and billed using a case management code with a modifier to try to achieve the Waiver Team purpose. Advisory panel members recommended adding this code to the Excluded file, and HERC staff was directed to work with the Waiver Team to find other ways to code the service that is intended for coverage.
    d. HCPCS H2023 Supported employment/education: Members felt that addition of this code to line 4 would be appropriate if OHA has a CMS waiver allowing use for SUD. Donny Jardine said that OAR could be written that would satisfy US DOJ requirements. CCO representatives noted that there are very strict criteria that behavioral health providers are required to adhere to for program fidelity and that SUD providers would also have to adhere to these strict criteria. BHAP agreed, and felt as a group that this code would not be appropriate for line 4 unless CMS gives very specific waiver language to the state. HERC staff to work with Waiver Team to see if this is implementable on line 4
    e. HCPCS H2032 Activity therapy: members unanimously felt this code was appropriate for line 4.
    f. HCPCS H2036 Alcohol and/or other drug treatment program, per diem: The Waiver Team indicated that this code would be use for day treatment programs. Day treatment programs are billing as outpatient programs with each service provided during the day being billed separately. The Waiver teams wants to use this code as a bundled fee for all the services (counseling, drug testing, etc.) that are provided in one day. Panel members felt that addition to line 4 was reasonable.

3) Input on merging selective mutism with anxiety disorder line (2024 biennial review)
    a. Smits reviewed the topic summary. The panel members strongly felt that selective mutism was a form of severe anxiety and should be covered like any other anxiety disorder. Marshall noted that this is quite a disabling disorder which is a long term condition unless treated. Keith Cheng, a child psychiatrist, gave verbal testimony that this condition prevents children from attending school.
    b. The group felt that waiting for the 2024 biennial review to move the line to a covered position was too long, given that the patients could receive the same services if coded as anxiety already. HERC staff proposed moving the only ICD-10 code on that line ((ICD-10-CM F94.0) to the Line 414 OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED and having line 473 SELECTIVE MUTISM simply shown as a struck out line on the Prioritized List until the 2024 biennial review list.
    c. BHAP considered the scoring for line 473 and recommended that suffering be changed from a 1 to a 3 due to high level of suffering of the patient and the family, and that need for treatment be changed from 0.8 to 1. This brings the line placement of line 473 almost to the location of line 414, so a line merge is appropriate.
    d. BHAP members did not feel that speech therapy needed to be paired with this diagnosis.
4) Screening for ACES: G9919 (Screening performed and positive and provision of recommendations) and HCPCS G9920 (Screening performed and negative)
    a. Smits reviewed the summary document. BHAP members discussed screening for both current social needs as well as adverse childhood events. They felt that trauma should be evaluated, and providers should practice trauma-informed care, but that the service would be provided in the course of delivering service billed with other existing codes. However, there was a great amount of concern about using some type of standardized instrument that might be given to a patient and not really looked at during the visit. This could be traumatizing to the patient and would also not be helpful. There should be a systematic assessment of trauma, not just a screening. The Panel felt that the screening HCPCS codes (which are not specific to screening for social needs or adverse childhood events) should not be added to the Prioritized List or any other list for reimbursement at this point.

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4. OTHER BUSINESS/PUBLIC COMMENT

There was no other business or public comment

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5. ADJOURNMENT

The meeting was adjourned at 4:35 PM

Highlights
Genetic Advisory Panel (GAP)
Virtual Meeting
September 29, 2021
1:00 PM-3:00 PM

Members Present: Karen Kovak; Sue Richards, PhD; Cary Harding, MD; Carl Stevens, MD; Kathryn Murray; Nicoleta Voian, Becky Clark

Staff Present: Ariel Smits, MD, MPH; Jason Gingerich; Liz Walker, PhD; Daphne Peck

Also Attending: Anil Kumar; Ashley Arthur; Ashley Svenson; Becki; Christin Coffeen (Illumina); Dawn Zenefski; Devki Nagar (Myriad Genetics); Jeanne McLaws; Jeff; Jenn O'Neill; lewisdal; LU; Michele Freeman; Paulina Almaraz; Shayla Logue; Sheri Hearn; Stephine Dudley (OHSU Genetics); Susan Hahn; Taryn Couture

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The meeting was called to order at 1:00 PM. Roll was called. This is an advisory panel to the Health Evidence Review Commission (HERC). All documents discussed during this meeting were materials prepared by the HERC Medical Director for deliberation by the Value-based Benefits Subcommittee at its 11/18/21 meeting. Given the advisory nature of this meeting, a quorum was not necessary as no votes were taken. The highlights from the 2020 GAP meeting were reviewed and no changes were suggested.

1) 2022 genetic-related CPT codes
    a. Staff reported that codes have not yet been released for 2022. If only a few codes relate to genetics are released, code placement may be done via an email exchange between GAP members and HERC staff. If there are a significant number of new genetic-related codes, HERC staff will arrange for a second GAP meeting in October.

2) General changes to the prenatal and non-prenatal genetic testing guidelines to remove ethnicity and family history
    a. The GAP agreed with HERC staff regarding creation of a separate section in the non-prenatal genetic testing guideline for preconception/carrier screening. There was general consensus that such testing should not be limited to "once in a lifetime" as testing is continually improving in finding new variants, new treatments are being developed that require testing for new gene mutations, and it is also difficult for CCOs and medical groups to determine if a patient has been tested in the past. It was felt to be more effective to pay for a second lifetime screen than to prior authorize to ensure that there has not been a previous test. "Once in a lifetime" was thus struck from several conditions in the new preconception/carrier screening section.
    b. NOTE: additional changes to the non-prenatal genetic testing guideline were suggested during the discussion regarding expanded carrier screening below.

3) Expanded carrier screening
    a. GAP members felt strongly that expanded carrier screening should be covered, recommending coverage of panels with genes with a carrier frequency of >1 in 200, which aligns with ACGM guidelines. The difference between panels covering genes with

a carrier frequency of >1 in 100 versus >1 in 200 includes many genes/conditions that have effective treatments and have severe consequences if untreated, such as many metabolic syndromes. These includes genes are shown in Tables 3 and 4 in the Gregg article (ACGM guideline article). Members noted that expanded carrier screening can be more cost effective in many cases than looking for gene panels that contain the smaller numbers of genes that are currently allowed in the prenatal testing guideline. There was discussion that providers can order the panel size or individual tests that they are comfortable with. Coverage of expanded carrier screening would not require a provider who is uncomfortable with this type of testing to order this test. Several of the genetics counselors stated that variants of uncertain significance are rarely reported out by companies, which should assuage some of HERC's concerns regarding this type of testing. The panel requested that the proposed staff suggestion that expanded carrier screening be of similar or lower cost than the individual gene testing be struck as this is logistically almost impossible to do. The group also suggested changes to the staff-suggested wording regarding that genetic counseling "is required" to instead be "must be offered" as more in line with ACMG and ACOG guidelines. Requiring testing would be too great a strain on the current genetic counselor workforce in Oregon. It was also pointed out that it would be operationally difficult to determine if genetic counseling had been done prior to authorizing the test.

The group then discussed the structure of the rest of the prenatal genetic testing guideline. The current layout of the guideline has the covered genetic tests in various areas. The group suggested consolidating them together in one section. It was also pointed out that the current coverage is the minimum testing that ACOG requires. The panel suggested that the section with the individual tests be labeled "ACOG-required screening" or similar. The grouping should be mirrored in the non-prenatal genetic testing guideline preconception/carrier screening section (see item #2 above). The group noted that the male partner should not have testing limited to just the genes that the female partner is found to carry. Such a limitation is impractical and could actually increase costs as panel testing is typically much less expensive than testing for individual genes.

Public testimony

i. Devki Nagar, genetic counselor with Myriad Genetics: Ms. Nagar testified as a representative of the Access to Equitable Carrier Screening Coalition. She thanked the committee for multiple reviews of this topic and reiterated support of covering carrier screening with options for other testing to align with provider and patient values. She supports the >1 in 200 gene prevalence cutoff for a panel. She noted that access to genetic counseling is limited, making required genetic counseling a barrier to screening. She also noted that patients prefer to get information from their primary maternity care provider.

4) Whole genome sequencing (WGS)
   a. The staff recommendation was for continued non-coverage. However, GAP members unanimously felt that some coverage should be allowed. It was noted that the cost of WGS has fallen dramatically, and is now similar to whole exome sequencing (WES) that is currently covered. Harding noted that WGS replaces microarray and whole exome

testing, allowing for a much more rapid diagnosis. This is particularly important for critically ill newborns in the NICU.

It was pointed out by members that WGS should be at least as effective as WES, as WGS includes all of WES as well as additional genetic material. Therefore, the lack of published studies on WGS does not mean it is not effective—its effectiveness can be extrapolated from the effectiveness of WES.

The group felt that WGS should be covered with a diagnostic guideline that allowed coverage for 1) critically ill newborns with likely genetic conditions and 2) older children if the test replaces whole exome sequencing or if the child had whole exome sequencing done at least 5 years ago that was non-diagnostic. Smits will work with Stevens and Harding on actual wording of such a guideline.

Public testimony

i. Christin Coffeen, genetic counselor employed by Illumina: Ms. Coffeen testified regarding use of WGS in the care of pediatric patients. Optimal patient care begins with a diagnosis and 80% of rare diseases have a genetic basis. Most children with rare syndromes spend many years and see many experts prior to receiving a diagnosis. WGS is the most comprehensive testing approach. WGS has been studied in over 25 peer-reviewed publications that demonstrate WGS has a 48% improved diagnostic yield compared to other diagnostic approaches. Up to 82% of patients diagnosed by WGS have improved clinical management. California Medicaid will begin covering WGS in 2022 and Michigan Medicaid already covers. ACGM published an evidence-based clinical practice guideline for WES and WGS in June 2021.

GAP members requested that Ms. Coffeen obtain the coverage criteria from other Medicaid programs that cover WGS and forward to HERC staff for consideration as they draft a coverage guideline.

5) Hereditary cancer genetic testing guideline
   a. There was no discussion regarding updating the NCCN guideline references.

6) The meeting adjourned at 3:15pm.

HIGHLIGHTS

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

Virtual Meeting
October 6, 2021
1:00-3:00 PM

Members Present: Gary Allen, DMD, Chair; Dayna Steringer; Laura McKeane; Karen Nolon; Deborah Loy

Members Absent: Alison Noble

Staff Present: Ariel Smits, MD, MPH; Jason Gingerich; Liz Walker; Daphne Peck, Kaz Rafia DMD.

Also Attending: Teri McClain (Oregon Health Authority); Manu Chaudhry, MS, DDS (Capital Dental); Amberwo, Elizabeth McCarthy (OHA); nolonk; dawnl; Sherry Edwards; Alyssa Franzen; conniew; Kathy Ganung; Beth Englander (Oregon Law Center); Christian Moller-Andersen.

Roll Call/Highlights Approval/Staff Report

The meeting was called to order at 1:05 PM and roll was called. Highlights from the 2020 OHAP meeting were approved without any changes. Staff noted that Dr. Allen's term on the HERC is ending. He is not seeking reappointment and an active recruitment process for his replacement is happening. Dr. Allen was thanks for his considerable contributions to OHAP and HERC.

- **Topic:** New Codes--2022 CDT code placement

There was minimal discussion on the 2022 CDT code placement.

- **Topic**: Coverage of porcelain crowns

Coverage of D2948 was briefly discussed. The decision was to keep on line 541. This code is not being asked for by dentists.

- **Topic**: Non-restorative caries treatment

  The group expressed concerns over confusion regarding when fluoride varnish would be covered. There is a guideline that allows up to four treatments a year in high-risk patients

for preventive care. There were questions about the use of the fluoride varnish CDT code (CDT D1206) to the caries line. The DCOs would have a hard time administering a benefit in which this code could be used for both prevention and treatment. It was pointed out that D1206 and D1208 were mouth level codes, and would not be appropriate for treatment of a specific tooth. The group generally agreed that the CDT code D1354 (Interim caries arresting medicament application – per tooth) could be used for any of the treatments in the new proposed guideline. The group requested that no codes be moved to the caries line, and that the new proposed guideline just use D1354.

There was support around the general idea of using medicaments and other non-restorative caries treatments. This type of treatment would reduce the problem of having to get into a pediatric dentist, and having kids needing to go to the OR for treatment.

- **Topic:** Expansion of orthodontia to handicapping malocclusion

The group agreed in general that handicapping malocclusion should be moved to the covered portion of the Prioritized List. There was some discussion about which score or index should be used; the general consensus was that California had a good index which other states are using and thus is a ready made index that is acceptable. Rafia noted that the Salzman Index is not used anymore.

There was vigorous discussion about the difficulty of implementation of an expansion of orthodontia. There was discussion about whether a dentist could do the evaluation, or whether it needed to be an orthodontist. There was discussion about the need for a review body to look at each request and make an individual determination on coverage. OHA would need to create such a review body, which should include orthodontists. There was concern about an inadequate orthodontist network to provide the services of such an expansion. There was considerable concern about the cost of such an expansion: the cost of additional imaging needed for evaluation, of orthodontic consultations, of the review body to look at cases at each DCO as well as HSD, extractions required for orthodontia treatment plans, the cost of any needed orthognathic surgery, and the cost of the actual orthodontic treatments.

HERC staff reflected that the issues brought up were all implementation issues that would need to be worked out by OHA before such an expansion in benefits could be accomplished. This benefit expansion would not be implementable on January 1, 2022. The benefit will need to be reviewed by the Office of Actuarial and Financial Analytics, which needs to consider the additional rate increases required for both CCOs to implement the medical benefit such as orthognathic surgery and the DCOs for all the pieces required for evaluation and treatment of handicapping malocclusion.

- **Topic**: D0190 dental screening

  The group noted that this code was not to be used for mass screenings. Loy noted that DCOs don't credential providers other than dentists, hygienists, etc. Therefore, it would be problematic for DCOs to cover this code that would be billed by pediatricians, family physicians, etc. If covered, would need to be covered under the medical (CCO) side. The group unanimously agreed that D0190 would be difficult for a DCO to administer and does not add value to care. The recommendation was continued non-coverage.

- **Public Comment:**

No public comment was received.

- **Issues for next meeting:**

- **Next meeting:**
  - TBD

Section 2.0

VBBS Report

Consent Agenda Issues—November 2021

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
20680	Removal of implant; deep (eg, buried wire, pin, screw, metal band, nail, rod or plate)	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	20680 is currently on multiple lines. HSD is requesting it be added to line 359 to allow removal of acromial clavicular hook plate	Add 20680 to line 359

November 2021
Straightforward Guideline Note Changes

We received a request to clarify whether patients who are being considered for an artificial disc in Guideline Note 101 need to meet the criteria for fusion surgery in Guideline Note 37. Guideline Note 101 currently states that "Artificial disc replacement (CPT 22856-22865) is included on Line 346 as an alternative to fusion." Guideline Note 37 contains all the criteria for qualifying for a fusion. Per GN37: "Spinal fusion procedures are included on Line 346 for patients with MRI evidence of moderate or severe central spinal stenosis only when one of the following conditions are met: 1) spinal stenosis in the cervical spine (with or without spondylolisthesis) which results in objective neurologic impairment as defined above OR 2) spinal stenosis in the thoracic or lumbar spine caused by spondylolisthesis resulting in signs and symptoms of neurogenic claudication and which correlate with xray flexion/extension films showing at least a 5 mm translation OR 3) pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of facet joints per level expected to be resected)". A CCO asked for clarification on how these two guidelines relate to one another.

As part of this review, HERC staff noted that GN37 could be clarified to improve its usability

1) HERC staff recommendations:
    a. Modify GN 101 as shown below
    b. Modify GN37 as shown below

GUIDELINE NOTE 101, ARTIFICIAL DISC REPLACEMENT

Lines 346,529

Artificial disc replacement (CPT 22856-22865) is included on Line 346 as an alternative to fusion for patients who meet criteria for spinal fusion procedures as defined in Guideline Note 37 only when all of the following criteria are met:

Lumbar artificial disc replacement

A) Patients must first complete a structured, intensive, multi-disciplinary program for management of pain, if covered by the agency;
B) Patients must be 60 years or under;
C) Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:
    - Failure of at least six months of conservative treatment
    - Skeletally mature patient
    - Replacement of a single disc for degenerative disc disease at one level confirmed by patient history and imaging

Cervical artificial disc replacement

D) Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:
    - Skeletally mature patient
    - Reconstruction of a single disc following single level discectomy for intractable symptomatic cervical disc disease (radiculopathy or myelopathy) confirmed by patient findings and imaging.

Otherwise, artificial disc replacement is included on Line 529.
Artificial disc replacement combined with fusion in a single procedure (hybrid procedure) is not covered.

November 2021
Straightforward Guideline Note Changes

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

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

Lines 346,529

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

1) Decompressive surgery is included on Line 346 to treat debilitating symptoms due to central or foraminal spinal stenosis, and only when the patient meets the following criteria:
    1) Has MRI evidence of moderate or severe central or foraminal spinal stenosis AND either
        a) Has neurogenic claudication OR
        b) Has objective neurologic impairment consistent with the MRI findings. Neurologic impairment is defined as objective evidence of one or more of the following:
            i) Markedly abnormal reflexes
            ii) Segmental muscle weakness
            iii) Segmental sensory loss
            iv) EMG or NCV evidence of nerve root impingement
            v) Cauda equina syndrome
            vi) Neurogenic bowel or bladder
            vii) Long tract abnormalities

    Foraminal or central spinal stenosis causing only radiating pain (e.g. radiculopathic pain) is included only on Line 529.

2) Spinal fusion procedures are included on Line 346 for patients with MRI evidence of moderate or severe central spinal stenosis only when one of the following conditions are met:
    1) spinal stenosis in the cervical spine (with or without spondylolisthesis) which results in objective neurologic impairment as defined above OR
    2) spinal stenosis in the thoracic or lumbar spine caused by spondylolisthesis resulting in signs and symptoms of neurogenic claudication and which correlate with xray flexion/extension films showing at least a 5 mm translation OR
    3) pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of facet joints per level expected to be resected)

For all other indications, spine surgery is included on Line 529.

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

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

- corticosteroid injections for cervical pain

Corticosteroid injections for low back pain with or without radiculopathy are only included on Line 529. Diagnostic anesthetic injections for selective nerve root blocks are included on Line 529 for lumbar or sacral symptoms.

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

COVID-19 Related Codes
November 2021

Issues:

1) Multiple new codes were added for COVID vaccines effective September 3, 2021, October 6, 2021, or October 20, 2021. These codes are for booster shots for Pfizer (standard dose), Moderna (low dose), Janssen (J&J) vaccines, a new formulation of the Pfizer vaccine (tris-sucrose), and lower dose pediatric Pfizer (age 5-11) vaccines. These codes will become active with FDA EUA or approval.

HERC staff recommendations:

CPT Code	Code Description	Recommended Placement
0004A	Pfizer-Biontech Covid-19 Vaccine Administration – Booster	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
91307	Pfizer COVID-19 vaccine pediatric (age 5-11) dosage	3
0071A	Pfizer COVID-19 vaccine pediatric dosage 1ST dose	3
0072A	Pfizer COVID-19 vaccine pediatric dosage 2ND dose	3
91305	Pfizer-Biontech Covid-19 Vaccine (Ready to Use) tris-sucrose formulation	3
0051A	Pfizer-Biontech Covid-19 Vaccine (Ready to Use) Administration tris-sucrose formulation - First dose	3
0052A	Pfizer-Biontech Covid-19 Vaccine (Ready to Use) Administration tris-sucrose formulation - Second dose	3
0053A	Pfizer-Biontech Covid-19 Vaccine (Ready to Use) Administration tris-sucrose formulation – third dose	3
0054A	Pfizer-Biontech Covid-19 Vaccine (Ready to Use) Administration tris-sucrose formulation – Booster	3
91306	Moderna Covid-19 Vaccine (Low Dose) –Booster dose	3
0064A	Moderna Covid-19 Vaccine (Low Dose) Administration – Booster dose	3
0034A	Janssen Covid-19 Vaccine (Low Dose) Administration - Booster dose	3

Expanded Carrier Screening
VBBS November 2021

Question: Should expanded carrier screening be readdressed by HERC for coverage?

Question source: PowersLaw, Inc/Access to Equitable Carrier Screening Coalition

Issue: Coverage of expanded carrier screening was discussed by GAP at their 2018 and 2020 meetings. The GAP recommended that it be covered at both of these prior meetings. Subsequently, VBBS/HERC review resulted in continued non-coverage. The major concerns of VBBS/HERC included:

1) Coverage for partners. Partners should only be tested for the few genes that mom tested positive for.
2) There was general concern about how to interpret the results. The VBBS members felt that the interpretation would be difficult for most maternity care providers, and that patients should have genetic counseling with this test, which is a limited resource. There was discussion about unintended harm of too much genetic information being given to patients with an unclear idea of how to deal with this information.
3) There was concern over interventions that might be done that might not be needed, or additional testing done that might not be needed. Medicaid is a vulnerable population and needs protections in place.
4) There was also concern about how to control the quality of which genes are included in the panel, to ensure that all include genes are recommended by ACOG guidelines.
5) At the 2020 and 2021 discussion of expanded carrier screening, various maternity care providers were surveyed. General obstetricians and certified nurse midwives indicated that they did not want to provide expanded carrier screening as they felt uncomfortable interpreting the test results. In contrast, high-risk OBs and geneticists felt that expanded carrier screening was desirable.

Of note, expanded carrier screening was reviewed in 2014 as part of a coverage guidance on prenatal testing. It received a weak recommendation for non-coverage.

Based on the 2020/2021 VBBS and HERC discussions on this topic, multiple changes were made to the prenatal and the non-prenatal genetic testing guidelines to remove ethnicity requirements for carrier screening, partially as a response to the concerns raised by the Access to Expanded Carrier Screening Coalition (not the Access to Equitable Carrier Screening Coalition).

The PowersLaw firm and the Access to Equitable Carrier Screening Coalition have requested a re-review of the VBBS/HERC decisions from 2018 and 2020/2021. This group notes:

> "Since the October 2020 GAP meeting and the 2021 VbBS and HERC meetings, the American College of Medical Genetics and Genomics (ACMG) released their updated Practice Resource on carrier screening for autosomal recessive and X-linked conditions. ACMG guidance specifically no longer recommends an initial approach to carrier screening focused solely on cystic fibrosis, spinal muscular atrophy, or ethnicity because it does not provide equitable evaluation. Instead, ACMG recommends all pregnant patients and those planning pregnancy should be offered carrier screening for conditions with a carrier frequency of >1/200, which encompasses 100+ inheritable autosomal recessive and X-linked conditions, and that payers should provide coverage for this level of carrier screening. This recommendation replaces ACMG's previous guidance and position statements on prenatal/preconception expanded carrier screening from more than a decade ago."

Expanded Carrier Screening
VBBS November 2021

Current Prioritized List status:
CPT **81443** (Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes)

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
81443	Expanded carrier screening	Insufficient evidence of effectiveness	November, 2018

DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

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

A) Genetic counseling (CPT 96040, HPCPS S0265) for high-risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect.
B) Genetic counseling (CPT 96040, HPCPS S0265) prior to consideration of chorionic villus sampling (CVS), amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening
C) Validated questionnaire to assess genetic risk in all pregnant women
D) Screening for hemoglobinopathies (CPT 83020, 83021)
E) Screening for aneuploidy with any of six screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, contingency, and cell free fetal DNA testing] (CPT 76813, 76814, 81508, -81510, 81511, 81420, 81507, 81512, 82105, 82677,84163)
F) Ultrasound for structural anomalies between 18 and 20 weeks gestation (CPT 76811, 76812)
G) CVS or amniocentesis (CPT 59000, 59015, 76945,76946, 82106, 88235, 88261-88264, 88267, 88269, 88280, 88283, 88285, 88289,88291) for a positive aneuploidy screen, maternal age >34, fetal structural anomalies, family history of inheritable chromosomal disorder or elevated risk of neural tube defect.
H) Array CGH (CPT 81228, 81229) when major fetal congenital anomalies are apparent on imaging, or with normal imaging when array CGH would replace karyotyping performed with CVS or amniocentesis in (H) above.
I) FISH testing (CPT 88271, 88272, 88274, 88275, 81171, 81172) only if karyotyping is not possible due a need for rapid turnaround for reasons of reproductive decision-making (i.e. at 22w4d gestation or beyond)
J) Screening for cystic fibrosis carrier status once in a lifetime (CPT 81220-81224)
K) Screening for fragile X status (CPT 81243, 81244, 81171. 81172) once in a lifetime
L) Screening for spinal muscular atrophy (CPT 81329) once in a lifetime
M) Screening for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255) once in a lifetime. Ashkenazi Jewish carrier panel testing (CPT 81412)

is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing.

N) Expanded carrier screening only for those genetic conditions identified above

The following genetic screening tests are not covered:

A) Serum triple screen
B) Expanded carrier screening which includes results for conditions not explicitly recommended for coverage

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

Expert guidelines

1) **ACMG 2021** Screening for autosomal recessive and X-linked conditions during pregnancy and preconception: a practice resource of the American College of Medical Genetics and Genomics
    a. Carrier screening enables those screened to consider their reproductive risks, reproductive options, and to make informed decisions.
    b. Published evidence supports clinical utility for carrier screening of multiple conditions simultaneously
    c. Carrier screening paradigms should be ethnic and population neutral and more inclusive of diverse populations to promote equity and inclusion
    d. All pregnant patients and those planning a pregnancy should be offered Tier 3 carrier screening.
        i. Tier 3 screening includes testing for all genes with ≥ 1/200 carrier frequency including X-linked conditions
    e. ACMG does not recommend: Offering Tier 1 [cystic fibrosis and spinal muscle atrophy and risk based screening] and/or Tier 2 screening [≥1/100 carrier frequency], because these do not provide equitable evaluation of all racial/ethnic groups.
    f. All pregnant patients and those planning a pregnancy should be offered Tier 3 carrier screening for autosomal recessive and X-linked conditions.
    g. Reproductive partners of pregnant patients and those planning a pregnancy may be offered Tier 3 carrier screening for autosomal recessive conditions when carrier screening is performed simultaneously with their partner.
    h. Regarding variants of uncertain significant (VUS)
        i. Only pathogenic and likely pathogenic variants should be routinely reported
        ii. The reporting of a VUS only in the partners of identified carriers and only with consent of the patient.
    i. Education and counseling are critical in carrier screening. Informed decision making with carrier screening is complex and ideally should be a part of preconception care to allow any of the reproductive decision-making options. Health-care professionals should inform patients of the risks, benefits, and consequences of carrier screening. Carrier screening counseling should be provided by knowledgeable and appropriately trained health-care professionals and should be performed pre- and post-test.
2) **ACOG 2017** committee opinion **690** (reaffirmed in 2020) **https://www.acog.org/-/media/Committee-Opinions/Committee-on-Genetics/co690.pdf?dmc=1&ts=20181029T1555151910**
    a. Ethnic-specific, panethnic, and expanded carrier screening are acceptable strategies for prepregnancy and prenatal carrier screening.
    b. The disorders selected for inclusion should meet several of the following consensus-determined criteria: have a carrier frequency of 1 in 100 or greater, have well-defined phenotype, have a detrimental effect on quality of life, cause cognitive or physical impairment, require surgical or medical intervention, or have an onset early in life. Additionally, screened conditions should be able to be diagnosed prenatally and may afford opportunities for antenatal intervention to improve outcomes, changes to delivery management to optimize newborn and infant outcomes, and education of the parents about special needs after birth.
    c. Carrier screening panels should not include conditions primarily associated with a disease of adult onset
    d. Carrier screening panels have largely replaced more specific screening because of its efficacy and economy

3) **ACOG 2017 committee opinion 691** https://www.acog.org/-/media/Committee-Opinions/Committee-on-Genetics/co691.pdf?dmc=1&ts=20170808T1020526802
    a. The cost of carrier screening for an individual condition may be higher than the cost of testing through commercially available expanded carrier screening panels

Other carrier policies

1) **Cigna 2021**
    1. A multigene reproductive carrier screening panel with ≥15 genes to predict the risk of severe inherited disease is considered not medically necessary.
2) **MODA 2021**
    1. Pregnancy related (or those planning to become pregnant, as applicable) for 1 or more of the following (a, b, or c):
        a) Pregnant woman or couples planning pregnancy with a personal or family history of genetic disorder;
        b) Pregnant woman or couples planning pregnancy with ancestry with high risk of genetic disorder that meet the specific criteria for the test (refer to Clinical Care Guidelines for specific conditions);
        c) Testing of both parents (i.e. chromosome analysis, karyotype) after previous unexplained stillbirth, repeated (two or more) first trimester miscarriages, or previous child with abnormality.
        d) Testing for Cystic Fibrosis (CF) and Spinal Muscular Atrophy (SMA) will be covered as part of standard care
        e) The requested procedure or services are considered investigational if they are requested in a quantity or panel of services that may be individually proven but when performed as a group or panel, the evidence-based literature does not support the requested procedures or services.

GAP discussion:

GAP members felt strongly that expanded carrier screening should be covered. They recommended covering panels with genes with a carrier frequency of >1 in 200, which aligns with ACGM guidelines. The difference between panels covering genes with a carrier frequency of >1 in 100 vs 1 in 200 includes many genes/conditions that have effective treatments and have severe consequences if untreated, such as many metabolic syndromes. Members noted that expanded carrier screening can be more cost effective in many cases that looking for gene panels that contain the smaller numbers of genes that are currently allowed in the prenatal testing guideline. There was discussion that providers can order the panel size or individual tests that they are comfortable with. Coverage of expanded carrier screening would not require a provider who is uncomfortable with this type of testing to order this test. Variants of uncertain significance are rarely reported out by companies according to several of the genetic counselors on GAP. The group also suggested changed the staff suggested wording regarding genetic counseling "is required" to "must be offered" as more in line with ACMG and ACOG guidelines and that requiring testing would be too great a strain on the current genetic counselor workforce. It was also pointed out that it would be operationally difficult to determine if genetic counseling had been done prior to authorizing the test.

The group also discussed the structure of the rest of the prenatal genetic testing guideline. The current layout of the guideline puts the covered genetic tests in various areas. The group suggested putting

them together in one section. It was also pointed out that the current coverage is the minimum testing that ACOG requires. The panel suggested that the section with the individual tests be labeled "ACOG required screening" or similar. The grouping should be mirrored in the non-prenatal genetic testing guideline preconception/carrier screening section.

GAP members requested striking the "once in a lifetime" requirement for testing similar to their request for this change with the preconception testing section of the non-prenatal genetic testing guideline. The group noted that the male partner should not have testing limited to just the genes that the female partner is found to carry. Such a limitation is impractical and could actually increase costs as panel testing is typically much less expensive than testing for individual genes.

Expanded Carrier Screening
VBBS November 2021

HERC staff summary

Since the January 2021 VBBS/HERC review, the American College of Medical Genetics has come out with an updated guideline which recommends expanded carrier screening. The guideline recommends pre- and post-test genetic counseling, which can be done by any appropriately trained health care professional. The guideline also recommends against reporting variants of uncertain significance. ACOG recommends ECS as one screening option, with inclusion only of genes with significant childhood disease potential. Private insurers with policies that could be identified by HERC staff do not cover expanded carrier screening; however, GAP members noted that most carriers in Oregon are actually covering this test.

HERC staff/GAP recommendation

1) Add expanded carrier screening (CPT 81443) with a requirement to offer for pre- and posttest genetic counseling.
    a) Add CPT 81443 to the Diagnostic Procedures File and remove from line 662/GN173
    b) Modify the prenatal and non-prenatal genetic testing guidelines as shown below

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

Line 662

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

Procedure Code	Intervention Description	Rationale	Last Review
~~81443~~	~~Expanded carrier screening~~	~~Insufficient evidence of effectiveness~~	~~November, 2018~~

DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

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

A) Genetic counseling (CPT 96040, HPCPS S0265) for high-risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect.
B) Genetic counseling (CPT 96040, HPCPS S0265) prior to consideration of chorionic villus sampling (CVS), amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening
C) Validated questionnaire to assess genetic risk in all pregnant women
D) ~~Screening for hemoglobinopathies (CPT 83020, 83021)~~
E) Screening for aneuploidy with any of six screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, contingency, and cell free fetal DNA testing] (CPT 76813, 76814, 81508, ~~-~~81510, 81511, 81420, 81507, 81512, 82105, 82677,84163)
F) Ultrasound for structural anomalies between 18 and 20 weeks gestation (CPT 76811, 76812)
G) CVS or amniocentesis (CPT 59000, 59015, 76945,76946, 82106, 88235, 88261-88264, 88267, 88269, 88280, 88283, 88285, 88289,88291) for a positive aneuploidy screen, maternal age >34,

fetal structural anomalies, family history of inheritable chromosomal disorder or elevated risk of neural tube defect.

H) Array CGH (CPT 81228, 81229) when major fetal congenital anomalies are apparent on imaging, or with normal imaging when array CGH would replace karyotyping performed with CVS or amniocentesis in (H) above.

I) FISH testing (CPT 88271, 88272, 88274, 88275, 81171, 81172) only if karyotyping is not possible due a need for rapid turnaround for reasons of reproductive decision-making (i.e. at 22w4d gestation or beyond)

J) ~~Screening for cystic fibrosis carrier status once in a lifetime (CPT 81220-81224)~~

K) ~~Screening for fragile X status (CPT 81243, 81244, 81171. 81172) once in a lifetime~~

L) ~~Screening for spinal muscular atrophy (CPT 81329) once in a lifetime~~

M) ~~Screening for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255) once in a lifetime. Ashkenazi Jewish carrier panel testing (CPT 81412) is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing.~~

N) Screening for genetic carrier status with the minimum testing recommended by the American College of Obstetrics and Gynecology:
   a. Screening for cystic fibrosis carrier status (CPT 81220-81224)
   ~~b.~~ Screening for fragile X status (CPT 81243, 81244, 81171. 81172)
   c. Screening for spinal muscular atrophy (CPT 81329)
   d. Screening for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255)~~.~~ Ashkenazi Jewish carrier panel testing (CPT 81412) is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing.
   e. Screening for hemoglobinopathies (CPT 83020, 83021)

O) Expanded carrier screening (CPT 81443): ~~for those genetic conditions identified above~~ A genetic counseling/geneticist consultation must be offered prior to ordering test and after results are reported. Expanded carrier testing is ONLY covered when all of the following are met:
   a. the panel includes only genes with a carrier frequency of ≥ 1 in 200 or greater, AND
   b. the included genes have well-defined phenotype, AND
   c. the included genes result in conditions have a detrimental effect on quality of life OR cause cognitive or physical impairment OR require surgical or medical intervention, AND
   d. the included genes result in conditions have an onset early in life, AND
   e. the included genes result in conditions that must be diagnosable prenatally to inform antenatal interventions and/or changes in delivery management and/or education of parents about special needs after birth.

The following genetic screening tests are not covered:

A) Serum triple screen

B) ~~Expanded carrier screening which includes results for conditions not explicitly recommended for coverage~~

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

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.

D) 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.

E) Related to preconception testing/carrier screening:
   1) The following tests are covered for a pregnant patient or patient contemplating pregnancy as well as the male reproductive partner:
      i. Screening for genetic carrier status with the minimum testing recommended by the American College of Obstetrics and Gynecology:
         1. Screening for cystic fibrosis carrier status (CPT 81220-81224)
         2. Screening for fragile X status (CPT 81243, 81244, 81171. 81172)
         3. Screening for spinal muscular atrophy (CPT 81329)

4. Screening for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255). Ashkenazi Jewish carrier panel testing (CPT 81412) is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing.
5. Screening for hemoglobinopathies (CPT 83020, 83021)

i. Expanded carrier screening (CPT 81443): A genetic counseling/geneticist consultation must be offered prior to ordering test and after test results are reported. Expanded carrier testing is ONLY covered when all of the following are met:
   1. the panel includes only genes with a carrier frequency of ≥ 1 in 200 or greater, AND
   2. the included genes have well-defined phenotype, AND
   3. the included genes result in conditions have a detrimental effect on quality of life OR cause cognitive or physical impairment OR require surgical or medical intervention, AND
   4. the included genes result in conditions have an onset early in life, AND
   5. the included genes result in conditions that must be diagnosable prenatally to inform antenatal interventions and/or changes in delivery management and/or education of parents about special needs after birth.

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

d) CPT 81224, CFTR (cystic fibrosis transmembrane conductance regulator) (eg. cystic fibrosis) gene analysis; introm 8 poly-T analysis (eg. male infertility): Covered only after genetic counseling.
e) CPT 81225-81227, 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 in the FDA labeling (e.g. psychiatric, anticoagulant, opioids).
f) CPT 81240. F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant: Factor 2 20210G>A testing should not be covered for adults with idiopathic venous thromoboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.
g) CPT 81241. F5 (coagulation Factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant: Factor V Leiden testing should not be covered for: adults with idiopathic venous thromoboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.
h) CPT 81247. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; common variant(s) (eg, A, A-) should only be covered
    i) After G6PD enzyme activity testing is done and found to be normal; AND either
        (a) There is an urgent clinical reason to know if a deficiency is present, e.g. in a case of acute hemolysis; OR
        (b) In situations where the enzyme activity could be unreliable, e.g. female carrier with extreme Lyonization.
i) CPT 81248. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; known familial variant(s) is only covered when the information is required for genetic counseling.
j) CPT 81249. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; full gene sequence is only covered
    i) after G6PD enzyme activity has been tested, and
    ii) the requirements under CPT 81247 above have been met, and
    iii) common variants (CPT 81247) have been tested for and not found.
k) CPT 81256, HFE (hemochromatosis) (eg, hereditary hemochromatosis) gene analysis, common variants (eg, C282Y, H63D): Covered for diagnostic testing of patients with elevated transferrin saturation or ferritin levels. Covered for predictive testing ONLY when a first degree family member has treatable iron overload from HFE.
l) CPT 81332, SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (eg, alpha-1-antitrypsin deficiency), gene analysis, common variants (eg, *S and *Z): The alpha-1-antitrypsin protein level should be the first line test for a suspected diagnosis of AAT deficiency in symptomatic individuals with unexplained liver disease or obstructive lung disease that is not asthma or in a middle age individual with unexplained dyspnea. Genetic testing of the anpha-1 phenotype test is appropriate if the protein test is abnormal or borderline. The genetic test is appropriate for siblings of people with AAT deficiency regardless of the AAT protein test results.
~~m) CPT 81329, Screening for spinal muscular atrophy: is covered once in a lifetime for preconception testing or testing of the male partner of a pregnant female carrier~~

n) CPT 81415-81416, exome testing: A genetic counseling/geneticist consultation is required prior to ordering test
o) CPT 81430-81431, Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel: Testing for mutations in GJB2 and GJB6 need to be done first and be negative in non-syndromic patients prior to panel testing.
p) CPT 81440, 81460, 81465, mitochondrial genome testing: A genetic counseling/geneticist or metabolic consultation is required prior to ordering test.
~~q) CPT 81412 Ashkenazi Jewish carrier testing panel: panel testing is only covered when the panel would replace and would be similar or lower cost than individual gene testing including CF carrier testing.~~

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

Whole Genome Sequencing
VBBS November 2021

Question: Should whole genome sequencing (WGS) be covered for testing children with clinical genetic abnormalities with no specific diagnosis?

Question source: Jim Gajewsky, MD; Illumina

Issue: Whole genome sequencing (WGS) is a laboratory test utilized to determine the arrangement (sequence) of an individual's entire genome at a single time. WGS allows the identification of mutations in the genome without having to target a gene or chromosome region based upon an individual's personal or family history. WGS is an alternative to whole exome sequencing (WES), in which only the part of the genome that codes for known transcribed genes is done. WES is currently covered as long as genetic counseling is done prior to testing.

Recently, Illumina contacted HERC staff to request a review of coverage of WGS. The company noted that WGS had not been reviewed since 2014, the science has advanced, and the costs have fallen over the past 7 years.

HERC history
Whole genome sequencing (CPT 81425-81427) was first reviewed as new CPT codes in 2014. At that time, GAP recommended placing on the Excluded List (later GN173) as the test was expensive and its clinical utility had not been established

Current Prioritized List status
CPT 81425 (Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis) and 81426 (Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (eg, parents, siblings) (List separately in addition to code for primary procedure)) are on line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

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
81425-81427	Genome sequence analysis	Insufficient evidence of effectiveness	November, 2014

Evidence

1) **ACMG 2021,** Systematic Evidence Review on whole exome (WES) and whole genome sequencing (WGS)
    a. N=167 studies
        i. Majority of studies were case reports or case series with small populations (N<20 patients)
        ii. N=36 studies with sample size >20 patients (N ranged from 22 to 278)
            1. 27 studies on WES
            2. 7 studies on WGS
            3. 2 studies used both WES and WGS
    b. Of the 167 included studies, 95% reported a change to patient or family clinical management
    c. included studies documented a change in clinical management as a result of ES/GS, including change in medications, procedures, or referral to specialists. When considering the types of medical management decisions, more than half of patients experienced a reported clinical impact related to the ES/GS diagnosis. Likewise, more than half of larger included studies reported an impact of ES/ GS relating to the reproductive planning or decisions of patients' families, further expanding the usefulness of ES/GS beyond the patient. However, few studies describe beneficial health outcomes or improved quality of life resulting from ES/ GS for patients... Nonetheless, despite little direct evidence that ES/GS improved mortality or ameliorated morbidity, the studies included in this review provide indirect evidence of the clinical and personal utility of ES/GS for patients and their family members.
2) **MED 2018,** rapid review of whole genome sequencing
    a. Clinical Validity and Utility
        i. A good methodological quality systematic review concluded that there is no evidence on the clinical utility of WGS.
            1. No study compared health outcomes in patients who received WGS to patients who received other genetic testing or no testing
        ii. A poor methodological quality study compared the diagnostic yield of WGS to other genetic testing methods in 103 children with symptoms suggestive of a chromosomal disorder but no genetic diagnosis.
        iii. WGS identified diagnostic variants in 41% of children vs. 24% with conventional testing (p = .01).
        iv. WGS also detected all variants detected by other methods, including whole exome sequencing (WES).
    b. Harms
        i. Center researchers identified no studies of the harms of WGS, but incidental or secondary findings (i.e., genetic variants unrelated or of unknown significance to the condition under suspicion) are a major concern.
    c. Policies and Reimbursement
        i. None of the private or public payer policies allowed coverage for WGS. CMS has not listed or provided guidance on a reimbursement rate for CPT code 81425.
2) **Costain 2020**, cohort study of whole genome sequencing for children with unexplained medical necessity
    a. N=49 families with children with complex medical needs

b. Genome sequencing detected all genomic variation previously identified by conventional genetic testing. A total of 15 probands (30.6%; 95%CI 19.5%-44.6%) received a new primary molecular genetic diagnosis after genome sequencing. Three individuals had novel diseases and an additional 9 had either ultrarare genetic conditions or rare genetic conditions with atypical features. At least 11 families received diagnostic information that had clinical management implications beyond genetic and reproductive counseling
c. The median number of conventional genetic tests per proband was 4 (range, 1-13), and a total of 232 tests were performed in this patient cohort
    i. All 49 patients had had chromosomal microarray testing and 33 (67.3%) had undergone whole exome sequencing
d. Trio genome-wide sequencing is associated with a higher diagnostic yield than only the proband undergoing sequencing
a. Conclusions: Genome sequencing is a potentially first-tier genetic test for complex medical children

Other payer policies
Private payers (Cigna 2021, Wellmark BCBS 2021, Aetna 2021) did not cover WGS

Other Medicaid policies identified for WGS

1) **Michigan Medicaid** (August 2021 policy change)
    a. The Medicaid program covers medically necessary rapid whole genome sequencing (rWGS) for the evaluation of critically ill infants up to one year of age admitted to an inpatient intensive care unit including, but not limited to, a neonatal/pediatric intensive care unit (NICU/PICU), with a complex illness of unknown etiology.
    b. rWGS is medically necessary when **all** the following apply:
        i. The beneficiary's signs or symptoms suggest a rare genetic condition that cannot be diagnosed by a standard clinical work-up;
        ii. The beneficiary's signs and symptoms suggest a broad, differential diagnosis that could require multiple genetic tests if rWGS was not performed;
        iii. Timely identification of a molecular diagnosis is necessary in order to guide clinical decision making, and the rWGS results will guide the treatment and/or management of the beneficiary's condition; and
        iv. At least **one** of the following clinical criteria apply to the beneficiary:
            1. Multiple congenital anomalies,
            2. Specific malformations highly suggestive of a genetic etiology
            3. An abnormal laboratory test suggests the presence of a genetic disease or complex metabolic phenotype (e.g., abnormal newborn screen, hyperammonemia, or lactic acidosis not due to poor perfusion),
            4. Refractory or severe hypoglycemia,
            5. Abnormal response to therapy related to an underlying medical condition affecting vital organs or bodily systems,
            6. Severe hypotonia,
            7. Refractory seizures,

8. A high-risk stratification on evaluation for a Brief Resolved Unexplained Event (BRUE) with any of the following features:
    a. Recurrent events without respiratory infection,
    b. Recurrent witnessed seizure-like events, or
    c. Required cardiopulmonary resuscitation (CPR),
9. Abnormal chemistry levels (e.g., electrolytes, bicarbonate, lactic acid, venous blood gas, glucose) suggestive of inborn error of metabolism,
10. Abnormal cardiac diagnostic testing results suggestive of possible channelopathies, arrhythmias, cardiomyopathies, myocarditis, or structural heart disease, or
11. Family genetic history related to beneficiary's condition.

c. rWGS must be ordered by the beneficiary's treating physician. Prior to ordering rWGS, the beneficiary must be evaluated by a medical geneticist or other physician sub-specialist including, but not limited to, a neonatologist or pediatric Intensivist with expertise in the conditions and/or genetic disorder for which testing is being considered. The consultation must be documented in the beneficiary's medical record and if performed via telemedicine, should follow all the requirements specified in Medicaid's telemedicine policy.
d. Pre- and post-test genetic counseling by an appropriate provider is also recommended.

2) **California Medicaid** **note: this is a bill from the California Legislature** December 2020
    a. Whole Genome Sequencing Pilot Project
        i. Rapid Whole Genome Sequencing, including individual sequencing, trio sequencing for a parent or parents and their baby, and ultra-rapid sequencing, is a covered benefit for any Medi-Cal beneficiary who is one year of age or younger and is receiving inpatient hospital services in an intensive care unit

<u>GAP discussion</u>
GAP members unanimously felt that some coverage of WGS should be allowed. It was noted that the cost of WGS has fallen dramatically, and is now similar to whole exome sequencing (WES) which is currently covered. Harding noted that WGS replaces microarray and whole exome testing, and allows much more rapid diagnosis. This is particularly important for critically ill newborns in the NICU.

It was pointed out by GAP members that WGS should be at least as effective as WES, as WGS includes all of WES as well as additional genetic material. Therefore, the lack of published studies on WGS does not mean it is not effective—its effectiveness can be extrapolated from the effectiveness of WES.

The group felt that WGS should be covered with a diagnostic guideline that allowed coverage for 1) critically ill newborns with likely genetic conditions and 2) older children if the test replaces whole exome sequencing or if the child had whole exome sequencing done at least 5 years ago that was non-diagnostic. Staff was directed to work with Stevens and Harding on actual wording of such a guideline.

Staff from Illumina, the company what does WGS, offered to forward other state Medicaid coverage policies to HERC staff.

After the meeting, staff obtained Medicaid coverage criteria for Michigan and California. Based on an email follow up exchange, the decision was to recommend coverage only for critically ill children under the age of 1 in the NICU/PICU.

HERC staff summary

A recent MED review did not find evidence to support the use of whole genome sequencing. One small cohort study not included in the MED review found that 30% of medically complex children received a diagnosis using WGS when no diagnosis had been reached with chromosomal microarray testing or, in many cases, with whole exome sequencing. No private payer surveyed covered WGS.

The GAP was unanimously in favor of coverage of WGS in certain situations. GAP members felt the efficacy could be extrapolated from findings from WES, and that WGS had better diagnostic ability in certain circumstances. Two other state Medicaid programs were found that cover WGS, both of which limit coverage to critically ill children under the age of 1. This is the group that GAP felt most strongly about covering for this benefit.

HERC staff/GAP recommendation

1) Add coverage for whole genome sequencing (CPT 81425-81427)
    a. Remove CPT 81425-81427 from line 662 and delete the entry from GN173
    b. Add CPT 81425-81427 to DIAGNOSTIC PROCEDURES file
    c. Add a clause to the non-prenatal genetic testing guideline as shown below
        i. The clause alone is shown first for review; the entire guideline is shown second for completeness. Wording in purple is from changes suggested in the expanded carrier screening topic

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
~~81425-81427~~	~~Genome sequence analysis~~	~~Insufficient evidence of effectiveness~~	~~November, 2014~~

Added clause to Diagnostic Guideline D1

~~a)~~ CPT 81425-81427, whole genome sequencing: testing is only covered when:

i) The testing is for a critically ill infant up to one year of age admitted to an inpatient intensive care unit (NICU/PICU) with a complex illness of unknown etiology; AND

ii) Whole genome sequencing is recommended by a medical geneticist or other physician sub-specialist, including but not limited to a neonatologist or pediatric intensivist with expertise in the conditions and/or genetic disorder for which testing is being considered

DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE

B) 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

C) 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.

D) 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.

E) 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.

F) Related to preconception testing/carrier screening:
   1) The following tests are covered for a pregnant patient or patient contemplating pregnancy as well as the male reproductive partner:
      i. Screening for genetic carrier status with the minimum testing recommended by the American College of Obstetrics and Gynecology:
         1. Screening for cystic fibrosis carrier status (CPT 81220-81224)
         2. Screening for fragile X status (CPT 81243, 81244, 81171. 81172)
         3. Screening for spinal muscular atrophy (CPT 81329)
         4. Screening for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255)- Ashkenazi Jewish carrier panel testing (CPT 81412) is covered if the panel would replace

and would be of similar or lower cost than individual gene testing including CF carrier testing.

5. Screening for hemoglobinopathies (CPT 83020, 83021)

i. Expanded carrier screening (CPT 81443): A genetic counseling/geneticist consultation must be offered prior to ordering test and after test results are reported. Expanded carrier testing is ONLY covered when all of the following are met:
   1. the panel includes only genes with a carrier frequency of ≥ 1 in 200 or greater, AND
   2. the included genes have well-defined phenotype, AND
   3. the included genes result in conditions have a detrimental effect on quality of life OR cause cognitive or physical impairment OR require surgical or medical intervention, AND
   4. the included genes result in conditions have an onset early in life, AND
   5. the included genes result in conditions that must be diagnosable prenatally to inform antenatal interventions and/or changes in delivery management and/or education of parents about special needs after birth.

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

e) CPT 81225-81227, 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 in the FDA labeling (e.g. psychiatric, anticoagulant, opioids).

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

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

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

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

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

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

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

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

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

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

p) CPT 81440, 81460, 81465, mitochondrial genome testing: A genetic counseling/geneticist or metabolic consultation is required prior to ordering test.

~~q) CPT 81412 Ashkenazi Jewish carrier testing panel: panel testing is only covered when the panel would replace and would be similar or lower cost than individual gene testing including CF carrier testing.~~

~~r)~~ CPT 81425-81427, whole genome sequencing: testing is only covered when:

i) The testing is for a critically ill infant up to one year of age admitted to an inpatient intensive care unit (NICU/PICU) with a complex illness of unknown etiology; AND

ii) Whole genome sequencing is recommended by a medical geneticist or other physician sub-specialist, including but not limited to a neonatologist or pediatric Intensivist with expertise in the conditions and/or genetic disorder for which testing is being considered.

* 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

NCCN Updates to the Hereditary Cancer Genetic Guideline

Issue: The NCCN references need to be updated in the hereditary cancer genetic testing guideline and the high risk breast cancer treatment guideline.

HERC staff recommendations:

1) Update the NCCN references as shown below in Guideline Note 3 and Diagnostic Guideline D25

GUIDELINE NOTE 3, PROPHYLACTIC TREATMENT FOR PREVENTION OF BREAST CANCER IN HIGH-RISK WOMEN

Line 191

Bilateral prophylactic breast removal and/or salpingo-oophorectomy are included on Line 191 for women without a personal history of invasive breast cancer who meet the criteria in the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic V1.2022 (8/11/21) ~~Breast Cancer Risk Reduction. V.1.2020 (12/4/19).~~ www.nccn.org. Prior to surgery, women without a personal history of breast cancer must have a genetics consultation as defined in section A2 of the DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE.

Contralateral prophylactic mastectomy is included on Line 191 for women with a personal history of breast cancer.

Hysterectomy is only included on Line 191 for women with a BRCA1 pathogenic/likely pathogenic variant who undergo the procedure at the time of risk reducing salpingo-oophrectomy.

DIAGNOSTIC GUIDELINE D25, HEREDITARY CANCER GENETIC TESTING

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

A) Lynch syndrome (hereditary colorectal, endometrial and other cancers associated with Lynch syndrome) services (CPT 81288, 81292-81300, 81317-81319, 81435, 81436) and familial adenomatous polyposis (FAP) services (CPT 81201-81203) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Colorectal V1.2021 (5/11/21) ~~V1.2020 (7/21/20).~~ www.nccn.org.

B) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81212, 81215-81217) for patients without a personal history of breast, ovarian and other associated cancers should be provided to high-risk patients as defined by the US Preventive Services Task Force or according to the NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic V1.2022 (8/11/21) ~~V1.2021 (9/8/20)~~ www.nccn.org.

C) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81212, 81215-81217)) for women with a personal history of breast, ovarian, or other associated cancers and for men with breast or other associated cancers should be provided according to the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic V1.2022 (8/11/21)) ~~V1.2021 (9/8/20)~~ www.nccn.org.

D) PTEN (Cowden syndrome) services (CPT 81321-81323) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Ovarian and Pancreatic. V1.2022 (8/11/21) ~~V1.2021 (9/8/20)~~ or Genetic/Familial High-Risk Assessment: Colorectal V1.2021 (5/11/21) ~~V1.2020 (7/21/20).~~ www.nccn.org.

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

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

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

If the mutation in the family is known, only the test for that mutation is covered. For example, if a mutation for BRCA 1 has been identified in a family, a single site mutation analysis for that mutation is covered (CPT 81215), while a full sequence BRCA 1 and 2 (CPT 81163) analyses is not. There is one exception, for individuals of Ashkenazi Jewish ancestry with a known mutation in the family, the panel for Ashkenazi Jewish BRCA mutations is covered (CPT 81212).

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

Hereditary breast cancer-related disorders genomic sequence analysis panels (CPT 81432, 81433, 81479) are only included for patients meeting the criteria for hereditary cancer syndrome testing per NCCN guidelines.

CDT code	Code Description	Suggested Placements	Comments
D3911	intraorifice barrier	**384** DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT ANTERIOR TOOTH) Treatment: BASIC ENDODONTICS (I.E., ROOT CANAL THERAPY) **411** DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT BICUSPID/PREMOLAR TOOTH) Treatment: BASIC ENDODONTICS (I.E., ROOT CANAL THERAPY) **444** DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT MOLAR TOOTH) Treatment: BASIC ENDODONTICS (I.E., ROOT CANAL THERAPY) **456** DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT ANTERIOR TOOTH) Treatment: ADVANCED ENDODONTICS (E.G., RETREATMENT OF PREVIOUS ROOT CANAL THERAPY) **507** DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT BICUSPID/PREMOLAR TOOTH) Treatment: ADVANCED ENDODONTICS (E.G., RETREATMENT OF PREVIOUS ROOT CANAL THERAPY) **538** DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT MOLAR TOOTH) Treatment: ADVANCED ENDODONTICS (E.G., RETREATMENT OF PREVIOUS ROOT CANAL THERAPY)	From the American Association of Endodontics: A permanent restorative material is placed over the root canal obturation material... A temporary restoration is subsequently placed over the intraorifice barrier. The intraorifice barrier prevents ingress of bacterial contaminants into the canal if the coronal temporary restoration is dislodged or placement of the permanent restoration is delayed. The intraorifice barrier does not take the place of the final restoration. All lines with root canal therapy are suggested for placements.
D3921	decoronation or submergence of an erupted tooth	384, 411, 444, 456, 507, 538 See proposed new guideline below	From the American Association of Endodontics: The requested endodontic code will address the intentional removal of the coronal tooth structure when preserving the root will facilitate maintenance or continued development of the bone around ankylosed or fractured teeth. Decoronation is also used following endodontic treatment when extraction is contraindicated
D4322	splint – intra-coronal; natural teeth or prosthetic crowns	**492** DENTAL CONDITIONS (E.G., PERIODONTAL DISEASE) Treatment: ADVANCED PERIODONTICS (E.G., SURGICAL PROCEDURES AND SPLINTING)	Replacing D4321 (Provisional splinting-extracoronal) which was on line 492

CDT code	Code Description	Suggested Placements	Comments
D4323	splint – extra-coronal; natural teeth or prosthetic crowns	**492** DENTAL CONDITIONS (E.G., PERIODONTAL DISEASE) Treatment: ADVANCED PERIODONTICS (E.G., SURGICAL PROCEDURES AND SPLINTING)	Replacing D4321 (Provisional splinting-extracoronal) which was on line 492
D5227	immediate maxillary partial denture - flexible base (including any clasps, rests and teeth)	**646** DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT Treatment: ELECTIVE DENTAL SERVICES	Other flexible base dentures (D5225, D5226) are on line 646
D5228	immediate mandibular partial denture - flexible base (including any clasps, rests and teeth)	**646** DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT Treatment: ELECTIVE DENTAL SERVICES	Other flexible base dentures (D5225, D5226) are on line 646
D5725	rebase hybrid prosthesis	**619** DENTAL CONDITIONS (E.G., MISSING TEETH) Treatment: IMPLANTS (I.E., IMPLANT PLACEMENT AND ASSOCIATED CROWN OR PROSTHESIS)	Related to dental implants, which are on line 619
D5765	soft liner for complete or partial removable denture – indirect	**454** DENTAL CONDITIONS (E.G., MISSING TEETH, PROSTHESIS FAILURE) Treatment: REMOVABLE PROSTHODONTICS (E.G., FULL AND PARTIAL DENTURES, RELINES)	Note from DCO dental directors: should be covered with same limitations as other liners
D6198	remove interim implant component	**619** DENTAL CONDITIONS (E.G., MISSING TEETH) Treatment: IMPLANTS (I.E., IMPLANT PLACEMENT AND ASSOCIATED CROWN OR PROSTHESIS)	Related to dental implants, which are on line 619
D7298	removal of temporary anchorage device [screw retained plate], requiring flap	**42** CLEFT PALATE WITH AIRWAY OBSTRUCTION **256** DEFORMITIES OF HEAD **300** CLEFT PALATE AND/OR CLEFT LIP **618** DENTAL CONDITIONS (E.G., MALOCCLUSION) Treatment: ORTHODONTIA	Orthodontics related. Orthodontics are currently on lines 42,256,300,618.
D7299	removal of temporary anchorage device, requiring flap	**42,256,300,618**	See D7298
D7300	removal of temporary anchorage device without flap	**42,256,300,618**	See D7298
D9912	pre-visit patient screening	**Diagnostic Procedure File**	From the ADA: Capture and documentation of a patient's health status prior to or on the scheduled

CDT code	Code Description	Suggested Placements	Comments
			date of service to evaluate risk of infectious disease transmission if the patient is to be treated within the dental practice. This is a COVID related screening code. The DCO group felt that this code should be bundled with the visit code
D9947	custom sleep apnea appliance fabrication and placement	**202** SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER	From the sleep apnea guideline: Mandibular advancement devices (oral appliances) are covered for those for whom CPAP fails or is contraindicated.
D9948	adjustment of custom sleep apnea appliance	**202** SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER	See D9947
D9949	repair of custom sleep apnea appliance	**202** SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER	See D9947

Proposed new guideline

GUIDELINE NOTE XXX DECORONATION OR SUBMERGENCE OF AN ERUPTED TOOTH

Lines 384, 411, 444, 456, 507, 538

Decoronation or submergence of an erupted tooth (CDT D3921) is only included on these lines for teeth that would otherwise qualify for endodontic services included on these lines but for which endodontics cannot be performed due to high-risk circumstances (e.g. certain medications or radiation related osteonecrosis).

Porcelain Crowns

Question: Should porcelain crowns (CDT D2740) be moved to a covered line?

Question source: OHA Dental Rules Advisory Committee (RAC)

Issue: Currently porcelain crowns (D2740) are on line 592 ADVANCED RESTORATIVE-ELECTIVE (INLAYS, ONLAYS, GOLD FOIL AND HIGH NOBLE METAL RESTORATIONS. Currently, by OAR, crowns are limited to children and pregnant women and the type of crown is limited to porcelain fused to metal (CDT D2751 and D2752). D2751 (Crown-porcelain fused to predominantly base metal) and D2752 (Crown-porcelain fused to noble metal) are on line 469 ADVANCED RESTORATIVE (I.E., BASIC CROWNS). The RAC also suggested consideration of moving D2928 (Prefabricated porcelain/ceramic crown – permanent tooth) from line 592 to line 469.

From Gary Allen, OHAP and dental RAC member

> When this limitation was decided years ago, porcelain fused to metal crowns were less expensive but technology has changed and porcelain crowns (D2740) are now more widely used. RAC members suggested this also be referred to OHAP to discuss moving code D2740 to Line 468. RAC members would also like to reconsider placement of code D2928 which was a new code discussed last year. It was recommended for addition to Line 591.

From Kaz Rafia, OHA dental director

> Zirconia crowns are significantly less costly to manufacture, are clinically a better fit, and with a longer lifespan.
> **D2928 belongs to Line 592, should not be covered.**

OHAP discussion: no significant discussion

HERC staff/OHAP recommendation:

1) Add CDT D2740 (Crown - porcelain/ceramic) to line 469 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH) Treatment: ADVANCED RESTORATIVE (I.E., BASIC CROWNS)
    a. Remove CDT D2740 from line 592 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH) Treatment: ADVANCED RESTORATIVE-ELECTIVE (INLAYS, ONLAYS, GOLD FOIL AND HIGH NOBLE METAL RESTORATIONS

Non-Restorative Caries Treatment

Question: Should a new guideline be adopted regarding non-restorative caries treatment?

Question source: Gary Allen, DMD

Issue: Most early dental decay is treated with invasive treatment such as drillings and fillings. Such invasive treatment can lead to future problems with the tooth. There are alternative treatments supported by the American Dental Association for non-restorative treatment of caries lesions. Such treatment can consist of fluoride varnish, fluoride gel, sealants, resins, silver diamine fluoride, and other options. The goal of nonrestorative or microinvasive caries treatment (fluoride- and non-fluoride-based interventions) is to manage the caries disease process at a lesion level and minimize the loss of sound tooth structure. Dr. Allen requested a review of the effectiveness of non-restorative treatment of dental caries and consideration of a new guideline regarding such treatment for the Prioritized List.

From Dr. Allen

> I would be interested in discussion about a guideline for nonrestorative treatment of dental caries. Many dental providers default to the most invasive treatment for early dental decay (restorative treatment) which can be traumatic for young children and irreversibly damage a permanent tooth. A few years ago, the American Dental Association published evidence-based guideline for nonrestorative treatment of carious lesions (attached) but the guidelines have been slow to be adopted in our profession. Possible reasons are lack of awareness, disbelief in nonrestorative therapy for early caries and financial incentive to use the most costly treatment option (restoration). In the spirit of HERC and the OHP Prioritized List to educate providers on the evidence and to encourage the least invasive treatment options, I would like to propose a Prioritized List guideline be developed for nonrestorative treatment of dental caries

Prioritized List history

Silver diamine fluoride (SDF) was added to line 343 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH) Treatment: BASIC RESTORATIVE (E.G., COMPOSITE RESTORATIONS FOR ANTERIOR TEETH, AMALGAM RESTORATIONS FOR POSTERIOR TEETH) in October 2015 with a new guideline. Good evidence based on several MED reports and other systematic reviews was found for the use of silver diamine fluoride for caries arrest. There is controversy, however, about the adverse effects of SDF, including darkening of the teeth.

Non-Restorative Caries Treatment

Evidence

1) **Urquhart 2019**, systematic review and network meta-analysis of nonrestorative treatments for caries https://journals.sagepub.com/doi/pdf/10.1177/0022034518800014
    a. N=44 trials (7,378 patients)
    b. Active intervention compared to placebo or another active intervention
        i. 22 interventions: sodium fluoride (NaF), stannous fluoride toothpaste or gel, acidulated phosphate fluoride (APF), difluorsilane, ammonium fluoride, polyols, chlorhexidine, calcium phosphate, amorphous calcium phosphate (ACP), casein phosphopeptide–ACP (CPP-ACP), nano hydroxyapatite, tricalcium phosphate, prebiotics and/or 1.5% arginine, probiotics, silver diamine fluoride (SDF), silver nitrate, lasers, resin infiltration, sealants, sodium bicarbonate, calcium hydroxide, and carbamide peroxide.
    c. Four network meta-analyses suggested that sealants + 5% sodium fluoride (NaF) varnish, resin infiltration + 5% NaF varnish, and 5,000-ppm fluoride (F)(1.1% NaF) toothpaste or gel were the most effective for arresting or reversing noncavitated occlusal, approximal, and noncavitated and cavitated root carious lesions on primary and/or permanent teeth, respectively (low- to moderate-certainty evidence). Study-level data indicated that 5% NaF varnish was the most effective for arresting or reversing noncavitated facial/lingual carious lesions (low certainty) and that 38% silver diamine fluoride solution applied biannually was the most effective for arresting advanced cavitated carious lesions on any coronal surface (moderate to high certainty).
    d. Relative risks of treatment vs no treatment for the arrest or reversal of noncavitated carious lesions on occulusal services
        i. 0.2% NaF mouthrinse + supervised toothbrushing: RR 1.95 (1.54 to 2.46), moderate certainty evidence
        ii. 1.23% AFP gel: RR 2.13 (1.79 to 2.54) moderate certainty of evidence
        iii. 5% NaF varnish: RR 1.97 (1.63 to 2.40), moderate certainty evidence
        iv. Resin infiltration + 5% NaF varnish: RR 3.20 (2.24 to 4.56), moderate certainty evidence
        v. Sealant: RR 1.98 (1.61 to 2.44), moderate certainty evidence

Expert guidelines

1) **Slayton 2018**: Evidence-based clinical practice guideline on nonrestorative treatments for carious lesions: A report from the American Dental Association https://jada.ada.org/action/showPdf?pii=S0002-8177%2818%2930469-0
    a. Expert panel recommendations
    b. Bottom line: Although the recommended interventions are often used for caries prevention, or in conjunction with restorative treatment options, these approaches have shown to be effective in arresting or reversing carious lesions. Clinicians are encouraged to prioritize use of these interventions based on effectiveness, safety, and feasibility.
    c. Recommendations:
        i. To arrest advanced cavitated carious lesions on any coronal surface of primary teeth, the expert panel recommends clinicians prioritize the use of 38% SDF solution (biannual application) over 5% NaF varnish (application once per week for 3 weeks). (Moderate-certainty evidence, strong recommendation.)

ii. To arrest advanced cavitated carious lesions on any coronal surface of permanent teeth, the expert panel suggests clinicians prioritize the use of 38% SDF solution (biannual application) over 5% NaF varnish (application once per week for 3 weeks). (Low-certainty evidence, conditional recommendation.)
iii. To arrest or reverse noncavitated carious lesions on occlusal surfaces of primary teeth, the expert panel recommends clinicians prioritize the use of sealants plus 5% NaF varnish (application every 3-6 months) or sealants alone over 5% NaF varnish alone (application every 3-6 months), 1.23% APF gel (application every 3-6 months), resin infiltration plus 5% NaF varnish (application every 3-6 months), or 0.2% NaF mouthrinse (once per week). (Moderate-certainty evidence, strong recommendation.)
iv. To arrest or reverse noncavitated carious lesions on occlusal surfaces of permanent teeth, the expert panel recommends clinicians prioritize the use of sealants plus 5% NaF varnish (application every 3-6 months) or sealants alone over 5% NaF varnish alone (application every 3-6 months), 1.23% APF gel (application every 3-6 months), or 0.2% NaF mouthrinse (once per week). (Moderate-certainty evidence, strong recommendation.)
v. To arrest or reverse noncavitated carious lesions on approximal surfaces of primary and permanent teeth, the expert panel suggests clinicians use 5% NaF varnish (application every 3-6 months), resin infiltration alone, resin infiltration plus 5% NaF varnish (application every 3-6 months), or sealants alone. (Low- to very-low-certainty evidence, conditional recommendation.)
vi. To arrest or reverse noncavitated carious lesions on facial or lingual surfaces of primary and permanent teeth, the expert panel suggests clinicians use 1.23% APF gel (application every 3-6 months) or 5% NaF varnish (application every 3-6 months). (Moderate- to low-certainty evidence, conditional recommendation.)
vii. To arrest or reverse noncavitated carious lesions on coronal surfaces of primary and permanent teeth, the expert panel suggests clinicians do not use 10% CPP-ACP if other fluoride interventions, sealants, or resin infiltration is accessible. (Low-certainty evidence, conditional recommendation.)
viii. To arrest or reverse noncavitated and cavitated carious lesions on root surfaces of permanent teeth, the expert panel suggests clinicians prioritize the use of 5,000 ppm fluoride (1.1% NaF) toothpaste or gel (at least once per day) over 5% NaF varnish (application every 3-6 months), 38% SDF plus potassium iodide solution (annual application), 38% SDF solution (annual application), or 1% chlorhexidine plus 1% thymol varnish (application every 3-6 months). (Low-certainty evidence, conditional recommendation.)

Current Prioritized List status

CDT code	Code description	Code placement
D1206	Topical application of fluoride varnish	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS 53 PREVENTIVE DENTAL SERVICES Treatment: CLEANING, FLUORIDE AND SEALANTS
D1208	Topical application of fluoride - excluding varnish	53
D1351	Sealant-per tooth	53
D1352	Preventive resin restoration in a moderate to high caries risk patient - permanent tooth	Excluded
D1354	Interim caries arresting medicament application – per tooth [used for silver diamine fluoride]	343 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH) Treatment: BASIC RESTORATIVE (E.G., COMPOSITE RESTORATIONS FOR ANTERIOR TEETH, AMALGAM RESTORATIONS FOR POSTERIOR TEETH)
D1355	Caries preventive medicament application – per tooth [used for silver diamine fluoride, silver nitrate, thymol-CHS varnish, topical providone iodine]	53
D2990	Resin infiltration of incipient smooth surface lesions	646 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT Treatment: elective dental services

GUIDELINE NOTE 17, PREVENTIVE DENTAL CARE

Lines 3,53

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

Fluoride varnish (99188) is included on Line 3 for use with children 18 and younger during well child preventive care visits. Fluoride treatments (D1206 and D1208) are included on Line 53 PREVENTIVE DENTAL SERVICES for use with adults and children during dental visits. The total number of fluoride applications provided in all settings is not to exceed four per twelve months for a child at high risk for dental caries and two per twelve months for a child not at high risk. The number of fluoride treatments is limited to once per 12 months for average risk adults and up to four times per 12 months for high-risk adults.

GUIDELINE NOTE 91, CARIES ARRESTING MEDICAMENT APPLICATION

Line 343

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

OHAP discussion:
The group expressed concerns over confusion regarding when fluoride varnish would be covered. There is a guideline that allows up to four treatments a year in high risk patients for preventive care. There were questions about the use of the fluoride varnish CDT code (CDT D1206) to the caries line. The DCOs would have a hard time administering a benefit in which this code could be used for both prevention and treatment. It was pointed out that D1206 and D1208 were mouth level codes, and would not be appropriate for treatment of a specific tooth. The group generally agreed that the CDT code D1354 (Interim caries arresting medicament application – per tooth) could be used for any of the treatments in the new proposed guideline. The group requested that no codes be moved to the caries line, and that the new proposed guideline just use D1354.

There was support around the general idea of using medicaments and other non-restorative caries treatments. This type of treatment would reduce the problem of having to get into a pediatric dentist, and having kids needing to go to the OR for treatment.

HERC staff/OHAP recommendations:
1) Modify GN91 as shown below

GUIDELINE NOTE 91, CARIES ARRESTING MEDICAMENT APPLICATION
Line 343

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

D1354 is also included on this line to
1) arrest or reverse noncavitated carious lesions on occlusal surfaces using sealants plus 5% fluoride varnish (application every 3-6 months) or sealants alone (application every 3-6 months), 1.23% fluoride gel (application every 3-6 months), resin infiltration plus 5% fluoride varnish (application every 3-6 months), or 0.2% fluoride mouthrinse (once per week).
2) arrest or reverse noncavitated carious lesions on approximal surfaces using 5% fluoride varnish (application every 3-6 months), resin infiltration alone, resin infiltration plus 5% fluoride varnish (application every 3-6 months), or sealants alone.
3) arrest or reverse noncavitated carious lesions on facial or lingual surfaces using 1.23% fluoride gel (application every 3-6 months) or 5% fluoride varnish (application every 3-6 months).

Orthodontia for Handicapping Malocclusion

Question: Should the limited coverage for orthodontia be expanded to include handicapping malocclusion?

Question source: OHA Dental Rules Advisory Committee

Issue: Currently, orthodontia coverage on the Prioritized List is limited to craniofacial anomalies. The OHA dental rules RAC requested consideration of inclusion of handicapping malocclusion, similar to other state Medicaid programs. Handicapping malocclusion and/or handicapping dentofacial deformity are conditions that constitute a hazard to the maintenance of oral health and interfere with the well-being of the patient by adversely affecting dentofacial function or speech. There are scoring systems to determine when handicapping malocclusion is present, such as the Salzmann Evaluation Index or the Handicapping Labio-Lingual Deviation Index.

Orthodontia was last reviewed in 2017, and coverage was added for craniofacial anomalies with a new guideline note. Orthodontia for non-craniofacial anomalies is on an uncovered line.

Current Prioritized List status

CDT code	Code Description	Code Placement
D7298	removal of temporary anchorage device [screw retained plate], requiring flap	NEW CODE
D7299	removal of temporary anchorage device, requiring flap	NEW CODE
D7300	removal of temporary anchorage device without flap	NEW CODE
D8010	Limited orthodontic treatment of the primary dentition	42 CLEFT PALATE WITH AIRWAY OBSTRUCTION 256 DEFORMITIES OF HEAD 300 CLEFT PALATE AND/OR CLEFT LIP 618 DENTAL CONDITIONS (E.G., MALOCCLUSION) Treatment: ORTHODONTIA
D8020	Limited orthodontic treatment of the transitional dentition	42,256,300,618
D8030	Limited orthodontic treatment of the adolescent dentition	42,256,300,618
D8040	Limited orthodontic treatment of the adult dentition	42,256,300,618
D8050-D8060	Interceptive orthodontic treatment	42,256,300,618
D8070-D8090	Comprehensive orthodontic treatment	42,256,300,618
D8210	Removable appliance therapy	42,256,300,618
D8220	Fixed appliance therapy	42,256,300,618
D8660	Pre-orthodontic treatment examination to monitor growth and development	42,256,300,618
D8670	Periodic orthodontic treatment visit	42,256,300,618

Orthodontia for Handicapping Malocclusion

CDT code	Code Description	Code Placement
D8680	Orthodontic retention (removal of appliances, construction and placement of retainer(s))	42,256,300,618
D8681	Removable orthodontic retainer adjustment	42,256,300,618
D8690	Orthodontic treatment (alternative billing to a contract fee)	42,256,300,618
D8695	Removal of fixed orthodontic appliances for reasons other than completion of treatment	267 DENTAL CONDITIONS (TIME SENSITIVE EVENTS) Treatment: URGENT DENTAL SERVICES
D8696-D8697	Repair of orthodontic appliance	42,256,300,618
D8698-D8699	Re-cement/re-bond fixed retainer	42,256,300,618
D8701-D8702	Repair of fixed retainer	42,256,300,618
D8703-D8704	Replacement of lost or broken retainer	42,256,300,618

Orthodontia for Handicapping Malocclusion

ICD-10 Code	Code description	Current Placement
M26.211	Malocclusion, Angle's class I	618
M26.212	Malocclusion, Angle's class II	618
M26.213	Malocclusion, Angle's class II	618
M26.219	Malocclusion, Angle's class, unspecified	618
M26.220	Open anterior occlusal relationship	618
M26.221	Open posterior occlusal relationship	618
M26.23	Excessive horizontal overlap	618
M26.24	Reverse articulation	618
M26.25	Anomalies of interarch distance	618
M26.29	Other anomalies of dental arch relationship	618
M26.31	Crowding of fully erupted teeth	618
M26.33	Horizontal displacement of fully erupted tooth or teeth	618
M26.34	Vertical displacement of fully erupted tooth or teeth	618
M26.35	Rotation of fully erupted tooth or teeth	618
M26.36	Insufficient interocclusal distance of fully erupted teeth (ridge)	618
M26.37	Excessive interocclusal distance of fully erupted teeth	618
M26.4	Malocclusion, unspecified	618
M26.70	Unspecified alveolar anomaly	618
Z46.4	Encounter for fitting and adjustment of orthodontic device	618
K00.1	Supernumerary teeth	645 DENTAL CONDITIONS WHERE TREATMENT IS CHOSEN PRIMARILY FOR AESTHETIC CONSIDERATIONS Treatment: COSMETIC DENTAL SERVICES
K00.2	Abnormalities of size and form of teeth	645
K00.5	Hereditary disturbances in tooth structure, not elsewhere classified	645
K00.6	Disturbances in tooth eruption	645
K00.9	Disorder of tooth development, unspecified	645

GUIDELINE NOTE 169, ORTHODONTICS AND CRANIOFACIAL SURGERY FOR CRANIOFACIAL ANOMALIES

Line 256

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

Orthodontia for Handicapping Malocclusion

Other state policies

1) Washington Medicaid
    a. Orthodontic treatment is covered for persons under the age of 21 with
        1) Cleft lip and palate, cleft palate or cleft lip with alveolar process involvement, or
        2) Other craniofacial anomalies,
        3) Severe malocclusions with a Washington Modified Handicapping Labiolingual Deviation Index score of 25 or higher
2) Connecticut Medicaid
    a. Orthodontic treatment is covered for persons scoring 26 points or higher on the Salzmann Evaluation Index
3) New York State Bureau of Dental Review
    a. Orthodontic treatment is covered for persons scoring 26 or higher on the Handicapping Labiolingual Deviation Index
4) California Medicaid
    a. Orthodontic treatment is covered for
        1) Cleft palate
        2) Cranio-facial anomalies
        3) Deep impinging overbite when lower incisors are destroying the soft tissue of the palate, tissue laceration and/or clinical attachment must be present
        4) Crossbite of individual anterior teeth when clinical attachment loss and recession of the gingival margin are present
        5) Severe traumatic deviation
        6) Overjet greater than 9mm with incompetent lips or mandibular protrusion (reverse overjet) greater than 3.5mm with masticatory and speech difficulties
        7) Score of 26 or higher on the Handicapping Labio-Lingual Deviation Index California Modification

OHAP discussion:

The group agreed in general that handicapping malocclusion should be moved to the covered portion of the Prioritized List. There was some discussion about which score or index should be used; the general consensus was that California had a good index which other states are using and thus is a ready made index that is acceptable. Rafia noted that the Salzman Index is not used anymore.

There was vigorous discussion about the difficulty of implementation of an expansion of orthodontia. There was discussion about whether a dentist could do the evaluation, or whether it needed to be an orthodontist. There was discussion about the need for a review body to look at each request and make an individual determination on coverage. OHA would need to create such a review body, which should include orthodontists. There was concern about an inadequate orthodontist network to provide the services of such an expansion. There was considerable concern about the cost of such an expansion: the cost of additional imaging needed for evaluation, of orthodontic consultations, of the review body to look at cases at each DCO as well as HSD, extractions required for orthodontia treatment plans, the cost of any needed orthognathic surgery, and the cost of the actual orthodontic treatments.

Orthodontia for Handicapping Malocclusion

HERC staff reflected that the issues brought up were all implementation issues that would need to be worked out by OHA before such an expansion in benefits could be accomplished. This benefit expansion would not be implementable on January 1, 2022. The benefit will need to be reviewed by Office of Actuarial and Financial Analytics (OAFA), which needs to consider the additional rate increases required for both CCOs to implement the medical benefit such as orthognathic surgery and the DCOs for all the implementation steps required for evaluation and treatment of handicapping malocclusion. OHA's goal is to implement this benefit January 1, 2023. This topic can be brought back to the Commission prior to implementation if necessary for a successful implementation.

Orthodontia for Handicapping Malocclusion

HERC staff/OHAP recommendations (effective January 1, 2023):

1) Rename line 256 DEFORMITIES OF HEAD AND HANDICAPPING MALOCCLUSION Treatment CRANIOTOMY/CRANIECTOMY; ORTHODONTIA
2) Add the following ICD-10 codes from line 618 DENTAL CONDITIONS (E.G., MALOCCLUSION) Treatment: ORTHODONTIA and line 645 DENTAL CONDITIONS WHERE TREATMENT IS CHOSEN PRIMARILY FOR AESTHETIC CONSIDERATIONS Treatment: COSMETIC DENTAL SERVICES to line 256

ICD-10 Code	Code description
K00.1	Supernumerary teeth
K00.2	Abnormalities of size and form of teeth
K00.5	Hereditary disturbances in tooth structure, not elsewhere classified
K00.6	Disturbances in tooth eruption
K00.9	Disorder of tooth development, unspecified
M26.211	Malocclusion, Angle's class I
M26.212	Malocclusion, Angle's class II
M26.213	Malocclusion, Angle's class II
M26.219	Malocclusion, Angle's class, unspecified
M26.220	Open anterior occlusal relationship
M26.221	Open posterior occlusal relationship
M26.23	Excessive horizontal overlap
M26.24	Reverse articulation
M26.25	Anomalies of interarch distance
M26.29	Other anomalies of dental arch relationship
M26.31	Crowding of fully erupted teeth
M26.33	Horizontal displacement of fully erupted tooth or teeth
M26.34	Vertical displacement of fully erupted tooth or teeth
M26.35	Rotation of fully erupted tooth or teeth
M26.36	Insufficient interocclusal distance of fully erupted teeth (ridge)
M26.37	Excessive interocclusal distance of fully erupted teeth
M26.4	Malocclusion, unspecified
M26.70	Unspecified alveolar anomaly
Z46.4	Encounter for fitting and adjustment of orthodontic device

3) Modify GN 169 as shown below

GUIDELINE NOTE 169, ORTHODONTICS ~~AND CRANIOFACIAL SURGERY~~ FOR CRANIOFACIAL ANOMALIES AND HANDICAPPING MALOCCLUSION

Line 256

Orthodontic treatment is included on this line for persons under the age of 21 with

1) Cleft lip and palate, cleft palate or cleft lip with alveolar process involvement, OR
2) Other craniofacial anomalies resulting in significant malocclusion expected to result in difficulty with mastication, speech, or other oral function, OR
3) Deep impinging overbite when lower incisors are destroying the soft tissue of the palate, tissue laceration and/or clinical attachment must be present, OR
4) Crossbite of individual anterior teeth when clinical attachment loss and recession of the gingival margin are present, OR

5) Severe traumatic deviation, OR
6) Overjet greater than 9mm with incompetent lips or mandibular protrusion (reverse overjet) greater than 3.5mm with masticatory and speech difficulties; OR
7) Severe malocclusions with a Handicapping Labiolingual Deviation Index California Modification score of 26 or higher.

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

Commented [JDG1]: Is advanced dental imaging needed for handicapping malocclusion as well?

Nightmare Disorder

Question: Should nightmare disorder be moved to a higher priority line?

Question source: Dr. Ben Hoffman, OHSU pediatrics

Issue: Currently, nightmare disorder (ICD10 F51.5) is on line 606 DISORDERS OF SLEEP WITHOUT SLEEP APNEA. This diagnosis has not been reviewed in the past 10 years at a minimum. Dr. Hoffman requested a review of coverage, as nightmare disorder is a distinct diagnosis which is responsive to medications and therapy.

Nightmare disorder is defined by the repeated occurrence of nightmares that cause clinically significant distress or impairment in social, occupational or other important areas of functioning, which are not attributable to the physiological effects of a substance (e.g. drug abuse or medication) and which cannot be adequately explained by coexisting mental and medical disorders.

Evidence

1) **Nadorff 2014**, review of pharmacologic and non-pharmacologic treatments for nightmare disorder
    a. prazosin has consistently shown efficacy for the treatment of nightmares and distressed awakenings based on 5 RCTs.
    b. Psychotherapeutic treatments recommended based on expert opinion (literature consists of small RCTs or case series)
        i. Lucid dreaming
        ii. Imagery rehearsal therapy
        iii. Exposure, relaxation, and rescripting therapy
        iv. Systematic desensitization
        v. Exposure therapy

Expert guidelines

1) **Morgenthaler 2018**: Position Paper for the Treatment of Nightmare Disorder in Adults: An American Academy of Sleep Medicine Position Paper
    a. Behavioral and Psychological Treatment Options
        i. Image rehearsal therapy is recommended for the treatment of PTSD-associated nightmares and nightmare disorder.
        ii. The following may be used for the treatment of PTSD-associated nightmares: cognitive behavioral therapy, cognitive behavioral therapy for insomnia, eye movement desensitization and reprocessing, and exposure, relaxation, and rescripting therapy.
        iii. The following may be used for the treatment of nightmare disorder: cognitive behavioral therapy, exposure, relaxation, and rescripting therapy, hypnosis, lucid dreaming therapy, progressive deep muscle relaxation, sleep dynamic therapy, self-exposure therapy, systematic desensitization, and testimony method
    b. Pharmacologic Treatment Options
        i. The following may be used for the treatment of PTSD associated nightmares: the atypical antipsychotics olanzapine, risperidone and aripiprazole, clonidine, cyproheptadine, fluvoxamine, gabapentin, nabilone, phenelzine, prazosin, topiramate, trazodone, and tricyclic antidepressants.

ii. The following may be used for the treatment of nightmare disorder: nitrazepam, prazosin, and triazolam.
iii. The following are not recommended for the treatment of nightmare disorder: clonazepam and venlafaxine.

BHAP input: the advisory panel unanimously agreed that nightmare disorder should be moved to a covered line.

HERC staff/BHAP recommendations:

1) Add ICD-10-CM F51.5 (nightmare disorder) to Line 173 POSTTRAUMATIC STRESS DISORDER
    a. Remove ICD-10 F51.5 from line 606 DISORDERS OF SLEEP WITHOUT SLEEP APNEA

HCPCS Codes in the SUD Waiver Requiring Review

Question: Should certain treatments be added to the substance use disorder line?

Question source: OHA SUD Waiver Team

Issue: OHA has applied to CMS for a waiver for an expansion of SUD services. As part of that process, CCOs will be asked to cover certain services for substance use disorder. Some of these services have not previously been paired with SUD diagnoses. HERC staff would like to review these services with BHAP for possible inclusion on line 4 SUBSTANCE USE DISORDER.

Code issues

1) HCPCS **H0022** Alcohol and/or drug intervention service (planned facilitation); Alcohol and drug intervention services provide treatment services and activities that assist the professionally trained interventionalist to pursue and detect alcohol and or drug addictions and to intercede to halt the progress of the addictions. These services also include early interventions.
    a. Current placement: "Never Reviewed"
    b. BHAP/HSC/HERC history: no prior review of this code found
    c. Description: HCPCS code represents a planned intervention that may assist a person to abstain from SUD use.
    d. Note: not payable by Medicare
    e. BHAP input: This code represents facilitated intervention by treatment providers to get a patient into treatment services and as such as a pre-treatment service. Dana Peterson from the OHA SUD Waiver Team stated the team hoped to use this code to reimburse for services to get a person to reengage in SUD treatment. This code might be used by outreach co-ordinators to reach out to a person who might not have an SUD diagnosis. Savicki noted that adding coverage of this code would be a huge expansion of services. Lindsay noted that there might not be enough information to make a diagnosis of a patient at the point of using this code. All felt that this would be a valuable service. Savicki noted that this service would often be done by a peer support specialist. There were questions about how to bill for a patient who might not have medical insurance or other identification. The end decision was that this was a valuable service, and should be added to line 4; however, there are significant implementation issues that will need to be worked out by HSD prior to opening this code for use.
    f. HERC staff/BHAP recommendation
        i. Option 1: Add H0022 to line 4 SUBSTANCE USE DISORDER
        ii. Option 2: Advise HSD to add H0022 to the DIAGNOSTIC PROCEDURE file
            1. may be more appropriate since a SUD diagnosis may not be present.

2) HCPCS **H0039** Assertive community treatment, face-to-face, per 15 minutes; Assertive community treatment uses a team based, multidisciplinary approach. The goal is to reduce the extent of hospital admissions, to improve the individual's quality of life, and to function in social situations by providing focused, proactive treatments. These services are most appropriate for individuals with severe and persistent mental illness and the greatest level of functional impairment.
    a. Current placement: 7,22,26,96,149,173,201,203 and 16 other lines
    b. BHAP/HSC/HERC history: no prior review of this code found
    c. Description: Assertive community treatment (ACT) is an intensive and highly integrated approach for community mental health service delivery. ACT teams serve individuals with the most serious forms of mental illness, predominantly but not exclusively the schizophrenia spectrum disorders

d. Evidence for use in SUD
    i. **Penzenstadler 2019**, Systematic Review of Assertive Community Treatment (ACT) for SUD
        1. N=11 articles
            a. 5 studies (N=741 patients)
            b. Control group was standard addiction treatment
        2. No significant difference in substance use found between ACT and standard SUD treatment
        3. Data on hospitalization rates and incarceration rates varies between studies
        4. One study found higher quality of life with ACT
        5. No difference was found in cost-effectiveness between ACT and standard SUD therapy
        6. Conclusion: Overall, ACT is a promising approach that may be useful for promoting treatment engagement for patients with SUD
e. BHAP input: Members felt that this code should be reserved for patients with chronic mental illness. There might be a dual diagnosis, but SUD alone should not be the only diagnosis.
f. HERC staff/BHAP recommendation: do not add H0039 to line 4. Keep on chronic mental illness lines and will be available for use with patients with dual diagnoses.

3) HCPCS **H0043** Supported housing, per diem
    a. Current placement: "Never Reviewed"
    b. BHAP/HSC/HERC history: no prior review of this code found
    c. Description: non-residential treatment housing
    d. Note: not payable by Medicare.
    e. BHAP input: Davis felt that this was an important service to cover. Dallia from the SUD Waiver Team stated that the team wanted to use this code to pay for follow up visit with a patient who was discharged to a subsidized housing to see how the person is doing, how community integration is progressing, etc. Members felt that the SUD Waiver Team should be using a case management code for this type of service. This code is per day, and implies a service being given. Members felt that a case management type service could be done with case management with a modifier to try to get at the Waiver Team purpose
    f. HSD input: HSD staff plans to use a H2014 (skills training and development, per 15 minutes) with a modifier to represent this service.
    g. HERC staff/BHAP recommendation
        i. Advise HSD to add HCPCS H0043 to the Excluded File

4) HCPCS **H2023** Supported employment/education; Supported employment services are available to individuals with serious mental illness. Employment specialists assist in obtaining and maintaining employment in the community and in continuing treatment for the client to ensure rehabilitation and productive employment.
    a. Current placement: 7,22,26,96,149,173,201,203 and 19 other lines
    b. BHAP/HSC/HERC history: BHAP voted to removed H2023 from all lines on the Prioritized List and place on the Ancillary List in 2016. However, in 2017 based on OHA testimony: "This change is causing difficulties with the Oregon Performance Plan and their compliance with requirements of the US Department of Justice. This type of

employment has strict rules from the US DOJ and can only be used by a very limited number of serious mental health disorders. Making these codes ancillary opened them up to any diagnosis, which is in violation of US DOJ rules."

c. OHA received federal CMS waiver to cover this for SUD treatment. Unsure if there is a waiver of US DOJ rules
d. BHAP input: Members felt that addition of this code to line 4 would be appropriate if OHA has a CMS waiver allowing use for SUD. Donny Jardine from the SUD team felt that OAR could be written that would satisfy US DOJ requirements. CCO representatives noted that there are very strict criteria that behavioral health providers are required to adhere to and that SUD providers would also have to adhere to these strict criteria. HERC staff was directed to work with Waiver Team to see if this is implementable on line 4 with discussions with CMS regarding specific waiver language.
e. HSD input: HSD staff plans to use a H2014 (skills training and development, per 15 minutes) with a modifier to represent this service.
f. HERC staff/BHAP recommendation:
    i. Make no changes to current H2023 placement

5) HCPCS **H2032** Activity therapy, per 15 min; Activity therapy such as music, dance, creative art, or any type of play, not for recreation, but related to the care and treatment of the patient's disabling mental health problems is reported for services per 15 minutes.
    a. Current placement: 7,22,26,96,121,149,173,193 and 30 other lines
    b. BHAP/HSC/HERC history: no prior review of this code found
    c. Description: activity therapy encompasses a wide range of activities with seek to engage the individual in creative endeavors that help to alter the thought processes of the patient in a positive manner. This may include art, music, movement, journaling, etc.
    d. Evidence: difficult to search for evidence as activity therapy encompasses such a wide range of interventions. However, activity therapy appears to be commonly used in community treatment programs for SUD
    e. BHAP input: Members agreed on addition to line 4
    f. HERC staff/BHAP recommendation:
        i. Add HCPCS H2032 to line 4 SUBSTANCE USE DISORDER

6) HCPCS **H2036** Alcohol and/or other drug treatment program, per diem; Outpatient services for alcohol and chemical dependency are structured to promote sobriety and independent living and to assist with continued treatment. Outpatient services allow patients to present for prescribed treatments and therapy and to maintain an otherwise routine home life.
    a. Current placement: "Never Reviewed"
    b. BHAP/HSC/HERC history: no prior review of this code found
    c. Description: SUD treatment
    d. Note: not payable by Medicare. Appears to be a bundled code for a hospitalization for SUD treatment
    e. BHAP input: The Waiver Team indicated that this code would be use for day treatment programs. Day treatment programs are billing as outpatient programs. The Waiver teams wants to use this code as a bundled fee for all the services (counseling, drug testing, etc.) that are provided in one day. Panel members felt that addition to line 4 was reasonable.
    f. HERC staff/BHAP recommendation:
        i. Add HCPCS H2036 to line 4 SUBSTANCE USE DISORDER

2024 Biennial Review
Selective Mutism

Question: Should the selective mutism line be merged into either the social phobia or the anxiety line?

Question source: HERC staff; Dr. Ben Hoffman, pediatrician; other pediatric advocates

Issue: Selective mutism is a severe anxiety disorder in which a patient is unable to speak in certain social situations despite fluent speech in other situations. It usually starts in childhood but can persist into adulthood if untreated. Treatment is generally psychotherapy and/or speech therapy, but some anxiety medications have been shown to be helpful in some cases. Selective mutism is co-occurring with severe anxiety in most cases, particularly with social anxiety disorder. Selective mutism can have a profound effect on a patient's life. Selective mutism is a relatively rare disorder. Estimates on its point prevalence have been obtained in clinic or school samples in various countries and typically range between 0.03% and 1.9% depending on the setting.

Selective mutism (ICD-10-CM F94.0) is currently the only diagnosis on line 473 SELECTIVE MUTISM. Review of HSC and HERC minutes could not find information on why this diagnosis was prioritized to this position. At one point, this diagnosis was on line 426 Avoidant Disorder of Childhood or Adolescence; Elective Mutism, and it is unclear when this line was changed.

Similar diagnoses are on line 458 SIMPLE PHOBIAS AND SOCIAL ANXIETY DISORDER (social phobia, ICD-10-CM F40.1) and Line 414 OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED (generalized anxiety disorder, ICD-10-CM F41.1).

Evidence

1) **Steains 2021**, meta-analysis of RCTS of psychological interventions for selective mutism
    a. N=5 RCTs (233 patients)
    b. The results of the analyses showed psychological interventions to be more effective than no treatment, with the overall weighted effect size of g = 0.87, indicating a large mean treatment effect
    c. Conclusion: this meta-analysis provides support for the efficacy of treatment for selective mutism
2) **Muris 2021**, review of diagnosis and management of selective mutism in children
    a. There is a clear link between selective mutism and fear and anxiety, particularly social anxiety.
    b. cognitive-behavioral therapy (CBT) is generally recognized as the most feasible intervention for children with this disorder
    c. There may be a role in SSRI's for treatment option
    d. Conclusion: SM is a rare but debilitating disorder that has puzzled researchers and clinicians for a long time. Empirical insights indicate that SM is mainly fear- and anxiety-driven and as such clinicians need to approach the condition as an anxiety disorder.

Claims review

In 2019, 40 unique recipients had claims for ICD-10-CM F94.0 (Selective mutism). These recipients had a variety of other ICD-10-CM codes in their claims, including social phobia, other disorders of psychological development, conduct disorders, acute stress reaction). The most common procedures billed with F94.0 were psychotherapy and speech/hearing therapy.

2024 Biennial Review
Selective Mutism

BHAP input

The panel members strongly felt that selective mutism was a form of severe anxiety and should be covered like any other anxiety disorder. Marshall noted that this is quite a disabling disorder which is a long term condition unless treated. Keith Cheng, a child psychiatrist, gave verbal testimony that this condition prevents children from attending school.

The group felt that waiting for the 2024 biennial review to move the line to a covered position was too long. HERC staff proposed moving the only ICD-10 code on that line ((ICD-10-CM F94.0) to the generalized anxiety line and having line 473 SELECTIVE MUTISM simply show as a struck out line on the Prioritized List until the 2024 biennial review list.

BHAP rescored line 473, recommended that suffering be changed from a 1 to a 3, due to high level of suffering of the patient and the family, and that need for treatment be changed from 0.8 to 1.

BHAP members did not feel that speech therapy needed to be paired with this diagnosis.

2024 Biennial Review
Selective Mutism

HERC staff summary:
Selective mutism is similar to anxiety disorder or social anxiety disorder. Cognitive behavioral therapy appears to be effective for treatment, and the disorder is debilitating when untreated. BHAP strongly feels that this diagnosis should be covered similarly to other anxiety disorders.

HERC staff/BHAP recommendations:

1) For implementation on January 1, 2022 Prioritized List:
    a. Add ICD-10-CM F94.0 (Selective mutism) to Line 414 OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED
        i. Remove F94.0 from line 473
    b. Strike through line 473 SELECTIVE MUTISM
2) For implementation on January 1, 2024 Prioritized List:
    a. Merge line 473 into line 414
    b. See scoring of those lines below for comparison

~~**Line: 473**~~
~~Condition: SELECTIVE MUTISM~~
~~Treatment: MEDICAL/PSYCHOTHERAPY~~
~~ICD-10:~~
~~CPT: 90785,90832-90840,90846-90853,90882,90887,98966-98972,99051,99060,99202-99215, 99224,99324-99355,99366-99368,99415-99423,99439-99449,99451,99452,99487-99491, 99495-99498,99605-99607~~
~~HCPCS: G0068,G0071,G0088-G0090,G0176,G0177,G0248-G0250,G0425-G0427,G0459,G0463-G0467,G0469,G0470,G0511,G2012,G2064,G2065,G2211,G2212,G2214,G2251,G2252, H0004,H0023,H0032-H0038,H2010,H2012,H2014,H2021,H2022,H2027,H2032,H2033, S9484~~

Line 473 SELECTIVE MUTISM (staff/BHAP proposed scores shown first, then current scoring in paracenteses)
Category: 7 (7)
Healthy life years: 1 (1)
Suffering: 3 (1)
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 1
Effectiveness: 4
Need for treatment: 1 (0.8)
Net cost: 4
Score: 400 (192)
Line placement: 409 (473)

Line 414 OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED
Category: 7
Healthy life years: 2
Suffering: 2
Population effects: 0
Vulnerable population: 1

Tertiary prevention: 1
Effectiveness: 3
Need for treatment: 1
Net cost: 4
Score: 360
Line placement: 414

Code	Code Description	Similar Codes
00100	Anesthesia for procedures on salivary glands, including biopsy	All anesthesia codes are Ancillary
01937	Anesthesia for percutaneous image-guided injection, drainage or aspiration procedures on the spine or spinal cord; cervical or thoracic	All anesthesia codes are Ancillary
01938	Anesthesia for percutaneous image-guided injection, drainage or aspiration procedures on the spine or spinal cord; lumbar or sacral	All anesthesia codes are Ancillary
01939	Anesthesia for percutaneous image-guided destruction procedures by neurolytic agent on the spine or spinal cord; cervical or thoracic	All anesthesia codes are Ancillary
01940	Anesthesia for percutaneous image-guided destruction procedures by neurolytic agent on the spine or spinal cord; lumbar or sacral	All anesthesia codes are Ancillary
01941	Anesthesia for percutaneous image-guided neuromodulation or intravertebral procedures (eg, kyphoplasty, vertebroplasty) on the spine or spinal cord; cervical or thoracic	All anesthesia codes are Ancillary
01942	Anesthesia for percutaneous image-guided neuromodulation or intravertebral procedures (eg, kyphoplasty, vertebroplasty) on the spine or spinal cord; lumbar or sacral	All anesthesia codes are Ancillary
33509	Harvest of upper extremity artery, 1 segment, for coronary artery bypass procedure, endoscopic	Coronary artery bypass with arterial graft procedures (CPT 33517-33536) are on lines 69,98,189,285
33894	Endovascular stent repair of coarctation of the ascending, transverse, or descending thoracic or abdominal aorta, involving stent placement; across major side branches	Coarctation of the aorta is on line 44

Code	Code Description	Similar Codes
33895	Endovascular stent repair of coarctation of the ascending, transverse, or descending thoracic or abdominal aorta, involving stent placement; not crossing major side branches	Coarctation of the aorta is on line 44
33897	Percutaneous transluminal angioplasty of native or recurrent coarctation of the aorta	Coarctation of the aorta is on line 44
63052	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single vertebral segment (List separately in addition to code for primary procedure)	Similar code 63047 (Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar) is on line 47,150,254,346,361,529 Posterior interbody arthrodesis (CPT 22630) is on lines 47,150,200,254,346,361,401,478, 529, 558

Code	Code Description	Similar Codes
63053	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s] [eg, spinal or lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each additional segment (List separately in addition to code for primary procedure)	See above
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	Both cataract removal codes (CPT 66982-66988) and the code for insertion of anterior segment aqueous drainage devices (CPT 66183) are on line 139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	Both cataract removal codes (CPT 66982-66988) and the code for insertion of anterior segment aqueous drainage devices (CPT 66183) are on line 139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE

Code	Code Description	Similar Codes
69716	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor	Similar codes 69714 and 69715 (Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with/without mastoidectomy) are on lines 311 and 445
69719	Revision or replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor	See above
69726	Removal, osseointegrated implant, skull; with percutaneous attachment to external speech processor	See above
69727	Removal, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor	See above
80220	Hydroxychloroquine	Drug level
80503	Pathology clinical consultation; for a clinical problem, with limited review of patient's history and medical records and straightforward medical decision making When using time for code selection, 5-20 minutes of total time is spent on the date of the consultation.	
80504	Pathology clinical consultation; for a moderately complex clinical problem, with review of patient's history and medical records and moderate level of medical decision making When using time for code selection, 21-40 minutes of total time is spent on the date of the consultation.	

Code	Code Description	Similar Codes
80505	Pathology clinical consultation; for a highly complex clinical problem, with comprehensive review of patient's history and medical records and high level of medical decision making When using time for code selection, 41-60 minutes of total time is spent on the date of the consultation.	
80506	Pathology clinical consultation; prolonged service, each additional 30 minutes (List separately in addition to code for primary procedure)	
91303	Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, DNA, spike protein, adenovirus type 26 (Ad26) vector, preservative free, 5x1010 viral particles/0.5 mL dosage, for intramuscular use	Already placed on line 3 in January 2021 Represents the Janssen (J&J) vaccine

Code	Code Description	Similar Codes
93593	Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; normal native connections	Congenital heart disease lines 45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653
93594	Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; abnormal native connections	See above

Code	Code Description	Similar Codes
93595	Left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone, normal or abnormal native connections	See above
93596	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); normal native connections	See above
93597	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); abnormal native connections	See above
93598	Cardiac output measurement(s), thermodilution or other indicator dilution method, performed during cardiac catheterization for the evaluation of congenital heart defects (List separately in addition to code for primary procedure)	See above

Code	Code Description	Similar Codes
99424	Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes provided personally by a physician or other qualified health care professional, per calendar month.	Similar codes G2064 and G2065 (Comprehensive care management services) are on all lines with E&M codes

Code	Code Description	Similar Codes
99425	Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care; each additional 30 minutes provided personally by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)	See above

Code	Code Description	Similar Codes
99426	Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care; first 30 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month.	See above

Code	Code Description	Similar Codes
99427	Principal care management services, for a single high-risk disease, with the following required elements: one complex chronic condition expected to last at least 3 months, and that places the patient at significant risk of hospitalization, acute exacerbation/decompensation, functional decline, or death, the condition requires development, monitoring, or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen and/or the management of the condition is unusually complex due to comorbidities, ongoing communication and care coordination between relevant practitioners furnishing care; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)	See above
99437	Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; each additional 30 minutes by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)	Similar chronic care management codes (CPT 99490-99491) are on all lines with E&M codes

Recommended Placement
ANCILLARY PROCEDURES
ANCILLARY PROCEDURES
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ANCILLARY PROCEDURES
69 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 98 CARDIOMYOPATHY 189 CHRONIC ISCHEMIC HEART DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
44 COARCTATION OF THE AORTA

Recommended Placement
44 COARCTATION OF THE AORTA
44 COARCTATION OF THE AORTA
47 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS 150 CERVICAL VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR CLOSED; OTHER VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR UNSTABLE; SPINAL CORD INJURIES WITH OR WITHOUT EVIDENCE OF VERTEBRAL INJURY 200 CANCER OF BONES 254 CHRONIC OSTEOMYELITIS 346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS 361 SCOLIOSIS 478 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT NEUROLOGIC INJURY OR STRUCTURAL INSTABILITY 529 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS 558 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT NEUROLOGIC INJURY OR STRUCTURAL INSTABILITY

Recommended Placement
47,150,200,254,346,361,401,478, 529, 558
139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE
139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE

Recommended Placement
311 HEARING LOSS - AGE 5 OR UNDER 445 HEARING LOSS - OVER AGE OF FIVE
311, 445
285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 311, 445
285, 311, 445
DIAGNOSTIC PROCEDURES
DIAGNOSTIC PROCEDURES
DIAGNOSTIC PROCEDURES

Recommended Placement
DIAGNOSTIC PROCEDURES
DIAGNOSTIC PROCEDURES
3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

Recommended Placement
45 CORONARY ARTERY ANOMALY 67 VENTRICULAR SEPTAL DEFECT 70 CONGENITAL PULMONARY VALVE ANOMALIES 76 PATENT DUCTUS ARTERIOSUS; AORTIC PULMONARY FISTULA/WINDOW 84 ENDOCARDIAL CUSHION DEFECTS 85 CONGENITAL PULMONARY VALVE ATRESIA 88 DISCORDANT CARDIOVASCULAR CONNECTIONS 89 CONGENITAL MITRAL VALVE STENOSIS/INSUFFICIENCY 104 TETRALOGY OF FALLOT (TOF); CONGENITAL VENOUS ABNORMALITIES 105 CONGENITAL STENOSIS AND INSUFFICIENCY OF AORTIC VALVE 110 CONGENITAL HEART BLOCK; OTHER OBSTRUCTIVE ANOMALIES OF HEART 118 ATRIAL SEPTAL DEFECT, SECUNDUM 128 COMMON TRUNCUS 130 TOTAL ANOMALOUS PULMONARY VENOUS CONNECTION 134 INTERRUPTED AORTIC ARCH 138 EBSTEIN'S ANOMALY 176 COMMON VENTRICLE 188 CONGENITAL TRICUSPID ATRESIA AND STENOSIS 232 HYPOPLASTIC LEFT HEART SYNDROME 264 CONGESTIVE HEART FAILURE,
45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653

Recommended Placement
45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653
45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653
45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653
45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653

Recommended Placement
All lines with E&M codes

Recommended Placement
All lines with E&M codes

Recommended Placement
All lines with E&M codes

Recommended Placement
All lines with E&M codes
All lines with E&M codes

1) **81523** Oncology (breast), mRNA, next-generation sequencing gene expression profiling of 70 content genes and 31 housekeeping genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk to distant metastasis
    a. Per the oncology genetic counselor on GAP, this code represents a form of Mammaprint, which is a covered test in GN148
        i. Mammaprint is also coded with CPT 81521 (Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes, utilizing fresh frozen or formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk of distant metastasis) or HCPCS S3854 (Gene expression profiling panel for use in the management of breast cancer treatment)
        ii. These codes are both on line 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
    b. Next generation sequencing is the use of ultra-high throughput massively parallel RNA sequencing. The advantage of NGS compared to microarrays is that is does not require the probes used for microarray testing and reduces cross-hybridization.
    c. HERC staff recommendations:
        i. Place CPT 81523 on line 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
        ii. Update GN148 as shown below

GUIDELINE NOTE 148, BIOMARKER TESTS OF CANCER TISSUE

Lines 157,184,191,229,262,271,329

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

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

- Oncotype DX Breast Recurrence Score (CPT 81519) for breast tumors that are estrogen receptor positive, HER2 negative, and either lymph node negative, or lymph node positive with 1-3 involved nodes.
- EndoPredict (CPT 81522) and Prosigna (CPT 81520 or PLA 0008M) for breast tumors that are estrogen receptor positive, HER2 negative, and lymph node negative.
- MammaPrint (using CPT 81521, 81523 or HCPCS S3854) for breast tumors that are estrogen receptor or progesterone receptor positive, HER2 negative, lymph node negative, and only in those cases categorized as high clinical risk.

For early stage breast cancer that is estrogen receptor positive, HER2 negative, and either lymph node negative or lymph node positive with 1-3 involved nodes, Breast Cancer Index (CPT 81518) is included on Line 191 when the patient is willing to use the test results in a shared decision-making process regarding prolonged adjuvant endocrine therapy.

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

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

For melanoma, BRAF gene mutation testing (CPT 81210) is included on Line 229. DecisionDx-Melanoma (CPT 81529) is included on Line 662.

For lung cancer, epidermal growth factor receptor (EGFR) gene mutation testing (CPT 81235) is included on Line 262 only for non-small cell lung cancer. KRAS gene mutation testing (CPT 81275) is not included on this line.

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

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

For prostate cancer, Oncotype DX Genomic Prostate Score, Prolaris Score Assay (CPT 81541), and Decipher Prostate RP (CPT 81542) are included on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

For thyroid cancer, Afirma gene expression classifier (CPT 81546) is included on Line 662.

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

2) 91113 Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon
    a. VBBS/HERC reviewed in October 2021 and reaffirmed lack of coverage
    b. Staff summary from the October review: Major evidence sources (NICE, AHRQ) and specialty society guidelines (ASGE) do not find strong evidence for use of wireless capsule endoscopy for evaluation of gastroparesis or intestinal motility issues. The American Society for Gastrointestinal Endoscopy finds limited application for the use of capsule endoscopy in the esophagus or colon.
    c. HERC staff recommendations:
        i. Place CPT 91113 on line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
        ii. Update the 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 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
91113	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon	Insufficient evidence of effectiveness	November 2021

3) **93319** 3D echocardiographic imaging and postprocessing during transesophageal echocardiography, or during transthoracic echocardiography for congenital cardiac anomalies, for the assessment of cardiac structure(s) (eg, cardiac chambers and valves, left atrial appendage, interatrial septum, interventricular septum) and function, when performed
    a. Similar codes:
        i. On line 662/Gn173
            1. 76376: 3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation
            2. 76377: 3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation
            3. Note: per CMS, these codes are to be added to the ECHO CPT code to represent to work in 3D rendering and interpretation
    b. Other codes
        i. 93355: Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg, TAVR, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure)

(peri-and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D

c. HERC staff summary: no other 3D rendering codes are currently covered on the Prioritized List. 3D is listed as one aspect of CPT 93355
d. HERC staff recommendation:
    i. Place CPT 99319 on line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
    ii. Update the GN173 entry for 3D image rendering as shown below

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS
Line 662
The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
76376-76377 99319	3D rendering of imaging studies	No additional proven benefit beyond the standard study, therefore not reimbursed separately	~~November 2019~~ November 2021

4) **94625** Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; without continuous oximetry monitoring (per session) and **94626** Physician or other qualified health care professional services for outpatient pulmonary rehabilitation; with continuous oximetry monitoring (per session)
    a. Similar code: HCPCS G0424 (Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day) is on lines 9,58,222,233,240,283
    b. COVID and long term post-COVID conditions are on line 399
    c. HERC staff recommendation:
        i. Add CPT 94625 and 94626 to the lines below
            1. 9 ASTHMA
            2. 58 BRONCHIECTASIS
            3. 222 OCCUPATIONAL LUNG DISEASES
            4. 233 ADULT RESPIRATORY DISTRESS SYNDROME; ACUTE RESPIRATORY FAILURE; RESPIRATORY CONDITIONS DUE TO PHYSICAL AND CHEMICAL AGENTS
            5. 240 CONDITIONS REQUIRING HEART-LUNG AND LUNG TRANSPLANTATION
            6. 283 CHRONIC OBSTRUCTIVE PULMONARY DISEASE; CHRONIC RESPIRATORY FAILURE
            7. 399 INFLUENZA, NOVEL RESPIRATORY VIRUSES
        ii. Add HCPCS G0424 (Pulmonary rehab) to line 399 INFLUENZA, NOVEL RESPIRATORY VIRUSES

2022 CPT Code Review

Exclusion of Left Atrial Appendage

Codes: **33267, 33268, 33269** Exclusion of left atrial appendage

1) **33267:** Exclusion of left atrial appendage, open, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)
2) **33268**: Exclusion of left atrial appendage, open, performed at the time of other sternotomy or thoracotomy procedure(s), any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)
3) **33269**: Exclusion of left atrial appendage, thoracoscopic, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)

Similar codes: **33340** Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation.

This code was reviewed in 2016 as part of the 2017 CPT code review. Based on a 2012 and a 2016 systematic review as well as a 2014 NICE review, this procedure was determined to be experimental and added to line 662/GN173.

Description: The left atrial appendix (LAA) is the most common place of thrombosis in patients with atrial fibrillation, and it can be excluded from the systemic circulation at the time of cardiac surgery by excision, ligation, suturing, or stapling. LAA exclusion has been proposed as a method to reduce stroke risk in patients with atrial fibrillation, as an alternative to anti-coagulation medications.

Evidence

Percutaneous closure devices

1) **MED 2017:** percutaneous transcatheter closure of the left atrial appendage with endocardial implant (CPT Code 33340)
    1. There are data on the efficacy of the WATCHMAN, the only implanted device currently approved by the Food and Drug Administration (FDA) for percutaneous closure of the left atrial appendage, from two randomized controlled trials (RCTs):
        a. WATCHMAN Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation (PROTECT AF)
        b. Prospective Randomized Evaluation of the WATCHMAN Left Atrial Appendage Closure Device in Patients with Atrial Fibrillation (PREVAIL)
    2. The risk of ischemic strokes appears to be similar for those undergoing WATCHMAN placement or continuing with anticoagulation with warfarin, according to direct comparisons.
    3. Indirect comparisons through the use of network meta-analysis estimate a similar risk of ischemic stroke with novel oral anticoagulants (e.g., direct thrombin inhibitors, factor Xa inhibitors).
    4. The first RCT of the WATCHMAN device observed increased risk of serious procedural harms, notably pericardial tamponade necessitating percutaneous drainage or surgery and periprocedural stroke. Subsequent RCTs and clinical registries demonstrate decreased rates of these events compared to the original studies, possibly resulting from increased operator experience.

5. Conclusions: Estimates of the effect of the WATCHMAN device for percutaneous left atrial appendage closure demonstrate non-inferiority to warfarin therapy for ischemic stroke, mortality, and major bleeding. Current studies have not been designed to provide information of superiority for any of these outcomes. The data providing the estimates from meta-analyses arise from two RCTs with a total of 1,114 individuals. The older study, PROTECT AF, found increased rates of procedure-related complications that appeared to improve in the more recent PREVAIL study, but still include potential for significant morbidity and mortality from complications such as procedure-related stroke and pericardial effusion/tamponade requiring surgery or prolonged hospitalization. Procedure-related risks are balanced by the potential for major bleeding events caused by warfarin or other novel oral anticoagulants. Direct comparisons between the WATCHMAN, warfarin, and newer agents do not exist in the literature, but several network meta-analyses estimated similar risk of major bleeding for WATCHMAN, warfarin, and novel oral anticoagulant agents.

2) **Ontario Health Technology Assessment 2017:** Left atrial appendage closure device with delivery system
    1. N=2 studies comparing the LAAC device with warfarin
        a. PREVAIL and PROTECT AF trials (7000+ patients each)
    2. LAAC device was comparable to novel oral anticoagulants in reducing stroke (odds ratio [OR] 0.85; credible interval [Cr.I] 0.63–1.05). Similarly, the reduction in the risk of all-cause mortality was comparable between the LAAC device and novel oral anticoagulants (OR 0.71; Cr.I 0.49–1.22). The LAAC device was found to be superior to novel oral anticoagulants in preventing hemorrhagic stroke (OR 0.45; Cr.I 0.29–0.79), whereas novel oral anticoagulants were found to be superior to the LAAC device in preventing ischemic stroke (OR 0.67; Cr.I 0.24–1.64).
    3. The body of clinical evidence was found to be of moderate quality as assessed by the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group criteria
    4. Results from the economic evaluation indicate that the LAAC device is cost-effective compared with aspirin in patients with contraindications to oral anticoagulants. In patients without contraindications to oral anticoagulants, we found that the LAAC device is not cost-effective compared with novel oral anticoagulants.

Peri-operative closure

3) **Mohamed 2021**, meta-analysis of surgical left atrial appendage occlusion during cardiac surgery
    1. N=5 RCTs (2,580 patients randomized to LAAO and 2,548 patients randomized to conservative management
        a. Median follow up 3.7 yrs
    2. Patients who underwent S-LAAO had significantly lower rates of thromboembolic events after surgery compared to the control group (RR 0.67, 95% CI [0.53, 0.84]; p <0.01;
    3. All-cause mortality, major bleeding/blood transfusion, and myocardial infarction were all similar between the groups (RR 1.0, 95% CI [0.9, 1.11]; p = 0.97), (RR 0.93, 95% CI [0.79, 1.10]; p = 0.41), and (RR 0.88, 95% CI [0.61, 1.28]; p = 0.51), respectively
    4. No adverse events related to the procedure were reported
4) **Kheiri 2020**, meta-analysis of left atrial appendage closure vs anticoagulation in patients with atrial fibrillation
    1. N=2 RCTs (1516 patients) of oral anticoagulation vs LAAO

2. Early procedural complications (within 7 days) included 3.1% pericardial effusion, 0.6% device embolization 0.5% major bleeding, 0.5% stroke, and 0.1% death (combined risk of serious complications 5.0%).
3. Compared with OAC, LAAC was associated with a statistically significant reduction of all-cause death (incident- rate-ratio = 0.74, 95% CI 0.56 to 0.99, p = 0.02; HR 0.73, 95% CI 0.56 to 0.97, p = 0.03; absolute-risk-difference = 2.6%) and cardiovascular death (HR 0.63, 95% CI 0.42 to 0.94, p = 0.02). There were no significant differences between groups in terms of all stroke or systemic embolism (HR 0.99, 95% CI 0.65 to 1.50, p = 0.96) or overall bleeding (HR 0.88, 95% CI 0.65 to 1.20, p = 0.43).
4. Although serious early procedure related complications were not infrequent (5.0%) these complications occurred predominantly in earlier RCTs, with more contemporary data demonstrating a lower complication risks and higher success rates, perhaps due in part to improvements in patient selection and/or operator experience

5) **Whitlock 2021,** RCT of left atrial appendage occlusion during cardiac surgery to prevent stroke
    1. N=2379 patients in the occlusion group and N=2391 patients in the no-occlusion group
        i. Patients scheduled to undergo cardiac surgery for another indication with atrial fibrillation and at least a score of 2 on the CHADS-VASc scale
        ii. Follow up 3.8 years
    2. Ischemic stroke or systemic embolism occurred in 114 participants (4.8%) in the occlusion group and in 168 (7.0%) in the no-occlusion group (hazard ratio, 0.67; 95% confidence interval, 0.53 to 0.85; P = 0.001). The incidence of perioperative bleeding, heart failure, or death did not differ significantly between the trial groups.
    3. No difference seen in hospitalization for heart failure, myocardial infarction, or death between groups
    4. Adverse events: Re-exploration for bleeding within the first 48 hours after surgery occurred in 94 participants (4.0%) in the occlusion group and in 95 (4.0%) in the no-occlusion group. The 30-day mortality was 3.7% in the occlusion group and 4.0% in the no-occlusion group.
    5. At hospital discharge, 83.4% of the participants in the occlusion group and 81.0% of those in the no-occlusion group were receiving oral anticoagulation, and the corresponding values were 79.6% and 78.9% at the 1-year visit and 75.3% and 78.2% at the 3-year visit.
    6. Conclusion: Among participants with atrial fibrillation who had undergone cardiac surgery, most of whom continued to receive ongoing antithrombotic therapy, the risk of ischemic stroke or systemic embolism was lower with concomitant left atrial appendage occlusion performed during the surgery than without it.

6) **Friedman 2018**, retrospective cohort study of left atrial appendage occlusion during concomitant cardiac surgery with readmission for thromboembolism
    1. N=10,524 patients (3,892 underwent LAAO)
        a. Mean follow up 2.6 yrs
        b. Claims data study with no clinical verification
    2. S-LAAO, compared with no S-LAAO, was associated with lower unadjusted rates of thromboembolism (4.2% vs 6.2%), all-cause mortality (17.3% vs 23.9%), and the composite end point (thromboembolisms, hemorrhagic stroke and all cause mortality at 3 years) (20.5% vs 28.7%) but no significant difference in rates of hemorrhagic stroke (0.9% vs 0.9%). After inverse probability–weighted adjustment, S-LAAO was

associated with a significantly lower rate of thromboembolism (subdistribution hazard ratio [HR], 0.67; 95% CI, 0.56-0.81; P < .001), all-cause mortality (HR, 0.88; 95% CI, 0.79-0.97; P = .001), and the composite end point (HR, 0.83; 95% CI, 0.76-0.91; P < .001) but not hemorrhagic stroke (subdistribution HR, 0.84; 95% CI, 0.53-1.32; P = .44). S-LAAO, compared with no S-LAAO, was associated with a lower risk of thromboembolism among patients discharged without anticoagulation (unadjusted rate, 4.2% vs 6.0%; adjusted subdistribution HR, 0.26; 95% CI, 0.17-0.40; P < .001), but not among patients discharged with anticoagulation (unadjusted rate, 4.1% vs 6.3%; adjusted subdistribution HR, 0.88; 95% CI, 0.56-1.39; P = .59).

3. Conclusions: Among older patients with AF undergoing concomitant cardiac surgery, S-LAAO, compared with no S-LAAO, was associated with a lower risk of readmission for thromboembolism over 3 years. These findings support the use of S-LAAO, but randomized trials are necessary to provide definitive evidence.

Expert guidelines

1) **ACC/AHA 2019,** management of patients with atrial fibrillation https://reader.elsevier.com/reader/sd/pii/S0735109719302098?token=E9BC269822C4EAEAE6973C13F2F98F1B173251DB348D095EBBDEDAF974274746737A4A65ABEC446C168E350A9CF7740D&originRegion=us-east-1&originCreation=20211014142627
    a. Percutaneous LAA occlusion may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation
        i. Level of evidence B-NR (moderate quality evidence from 1 or more well designed, well executed non-randomized studies, observations studies or registry studies)
        ii. Strength of recommendation: IIB (weak)
        iii. Noted to be a focus of ongoing research
    b. Surgical occlusion of the LAA may be considered in patients with AF undergoing cardiac surgery, as a component of an overall heart team approach to the management of AF.
        i. Level of evidence B-NR (moderate quality evidence from 1 or more well designed, well executed non-randomized studies, observations studies or registry studies)
        ii. Strength of recommendation: IIB (weak)
        iii. New recommendation based on the Friedman article above

Other policies

1) **NICE 2021,** management of atrial fibrillation https://www.nice.org.uk/guidance/ng196/resources/atrial-fibrillation-diagnosis-and-management-pdf-66142085507269
    a. Consider left atrial appendage occlusion (LAAO) if anticoagulation is contraindicated or not tolerated and discuss the benefits and risks of LAAO with the person
        i. This is device occlusion, not surgical occlusion
    b. Do not offer LAAO as an alternative to anticoagulation unless anticoagulation is contraindicated or not tolerated.
    c. No recommendation/policy found on operative LAAO
2) **CMS**
    a. Only covers left atrial appendage occlusion devices as part of a study
    b. No policy found on operative LAAO

Other payer policies

1) **Aetna 2020:**
    a. No policy was found on left atrial appendage occlusion during other cardiac surgery
    b. Aetna considers left atrial appendage closure (LAAC) devices medically necessary for non-valvular atrial fibrillation (NVAF) when the device has received U.S. Food and Drug Administration (FDA) Premarket Approval (PMA) for that device's FDA-approved indication and meet all of the conditions specified below
    c. The member must have: A CHADS2 score ≥ 2
    d. Shared decision making documented
    e. suitability for short-term warfarin (i.e., the member is able to take short-term warfarin) and long-term aspirin but deemed unable to take long term oral anticoagulation due to
        i. Member has thromboembolism while on an oral anticoagulant (i.e., while INR is in therapeutic range); *or*
        ii. Member has major bleed (intracranial bleed, significant gastrointestinal bleeding (not just guaiac positive stools) while on an oral anticoagulant (i.e., while INR is in therapeutic range); *or*
        iii. Member has elevated risk of bleeding on oral anticoagulant with a HAS-BLED score of 3 or more; *or*
        iv. Member has other absolute contraindication to long-term anticoagulation;
    f. The member (preoperatively and postoperatively) is under the care of a cohesive, multidisciplinary team (MDT) of medical professionals; *and*
    g. The procedure must be furnished in a hospital with an established structural heart disease (SHD) and/or electrophysiology (EP) program; *and*
    h. The procedure must be performed by an interventional cardiologist(s), electrophysiologst(s) or cardiovascular surgeon(s) that meet certain criteria

2) Cigna 2020
    a. Percutaneous transcatheter closure of the left atrial appendage (CPT code 33340) for non-valvular atrial fibrillation using a U.S. Food and Drug Administration (FDA) approved device is considered medically necessary for the prevention of stroke when ALL of the following criteria are met:
        i. There is an increased risk of stroke and systemic embolism based on CHADS2* ≥ 2 or CHA2DS2-VASc** score ≥ 3 and systemic anticoagulation therapy is recommended.
        ii. Attestation that for this individual the long-term risk of systemic anticoagulation outweighs the risk of the device implantation.
    b. Surgical closure of the left atrial appendage, including use of a clip, (CPT code 33999) for the prevention of stroke in conjunction with other cardiac surgical procedures is considered experimental, investigational or unproven.

Exclusion of Left Atrial Appendage

HERC staff summary: Left atrial appendage occlusion, either with a device or with surgical closure as part of another cardiac surgery, is an active area of investigation for preventing stroke in patients with atrial fibrillation.

In regard to percutaneous LAAO procedures, no significant new data has been published since the 2016 EGBS review which found them to be experimental. Private payers and the UK health system appear to cover the transcatheter closure device, and Medicare covers it with evidence development for patients who are not candidates for long term anticoagulation.

In regard to surgical occlusion of the left atrial appendage during other cardiac surgery, this procedure is thought to be non-inferior to anticoagulation but has a significant rate of complications based on limited evidence. The studies on surgical occlusion are confounded by the fact that most studies appear to have patients continue anticoagulation, making the effect of surgical LAA occlusion difficult to discern. Private payers do not cover surgical LAAO and no policies were found for NICE or CMS.

Expert guidelines say that both types of procedures "may be considered" as a weak recommendation.

Overall, both procedures appear to be experimental. The LAAO procedure during other cardiac procedures may be reasonable to coverage for patients who have contraindications to anticoagulation.

HERC staff recommendations:

1) Update date of last review in GN173 to November 2021 regardless of which option below is selected
2) Add the codes below to Line 662 and make the updates to the GN173 entry shown below
    a. **33267:** Exclusion of left atrial appendage, open, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)
    b. **33268**: Exclusion of left atrial appendage, open, performed at the time of other sternotomy or thoracotomy procedure(s), any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)
    c. **33269**: Exclusion of left atrial appendage, thoracoscopic, any method (eg, excision, isolation via stapling, oversewing, ligation, plication, clip)

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
33267, 33268, 33269 33340	Exclusion of left atrial appendage Percutaneous transcatheter closure of the left atrial appendage with endocardial implant	Insufficient evidence of effectiveness	~~November, 2016~~ November 2021

2022 CPT Code Review

Cerebral Embolic Protection Devices

Code**: 33370** Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catheterization, imaging, and radiological supervision and interpretation, percutaneous

Similar codes: None

Description: Cerebral embolic protection devices are filters designed to capture or deflect emboli traveling to the brain during transcatheter aortic valve replacement procedures in order to protect the supra-aortic vessels from embolic debris. These filters are normally positioned across the origin of supra-aortic vessels before the advancement of the TAVR system across the aortic valve and is retrieved at the end of the procedure. If emboli can be deflected using these devices, then stroke could be reduced as a complication of this type of procedure. There are several such devices on the market, including the Embrella, Claret, and Triguard devices.

Evidence

1) **Lansky 2021**, REFLECT I trial
    1. Triguard device
    2. Prospective single-blind study 2:1 randomization (N=141 device vs N=63 control, plus 54 "roll in" patient)
    a. Roll in patients defined as proctored cases performed when investigators did not have prior experience with the device
    b. Patients undergoing transcatheter aortic valve replacement
    c. Study stopped early by the data safety monitoring board
    3. The primary safety outcome (defined as composite of all-cause death, stroke, life-threatening or disabling bleeding, stage 2–3 acute kidney injury (AKI), coronary artery obstruction requiring intervention, major vascular complications, and valve-related dysfunction requiring repeat procedure) at 30 days occurred in 21.8% (95% CI 15.1–29.8%) of subjects in the TG group, meeting the primary safety endpoint compared with the pre-specified performance goal of 34.4% (P<0.001)
    4. The primary hierarchical efficacy endpoint was not significantly different between groups, with a mean score (higher is better) of -5.3± 99.8 for TG and 11.8± 96.4 for controls (P= 0.314)
2) **Nazif 2021**, REFLECT II trial
    1. TriGuard 3 device
    2. Prospective single-blind study 2:1 randomization (N=121 device vs N=58 control, plus 41 "roll in" patient)
    a. Roll in patients defined as proctored cases performed when investigators did not have prior experience with the device
    b. Patients undergoing transcatheter aortic valve replacement
    c. Study stopped early by the data safety monitoring board
    d. primary hierarchical composite efficacy endpoint (including death or stroke at 30 days, National Institutes of Health Stroke Scale score worsening in hospital, and cerebral ischemic lesions on diffusion weighted magnetic resonance imaging at 2 to 5 days)
    e. The trial met its primary safety endpoint compared with the PG (15.9% vs. 34.4% (p < 0.0001). The primary hierarchal efficacy endpoint at 30 days was not met (mean scores [higher is better]: -8.58 TG3 vs. 8.08 control; p = 0.857).

3) **Butala 2020**, Transcatheter valve therapy registry study
    1. Cohort registry study using the Society for Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry.
    2. N=126,186 patients from 599 sites
    3. In our primary analysis using the instrumental variable model, there was no association between EPD use and in-hospital stroke (adjusted relative risk, 0.90 [95% CI, 0.68–1.13]; absolute risk difference, −0.15% [95% CI, −0.49 to 0.20]). However, in our secondary analysis using the propensity score–based model, EPD use was associated with 18% lower odds of in-hospital stroke (adjusted odds ratio, 0.82 [95% CI, 0.69–0.97]; absolute risk difference, −0.28% [95% CI, −0.52 to −0.03]).
    4. CONCLUSIONS: In this nationally representative observational study, we did not find an association between EPD use for TAVR and in-hospital stroke in our primary instrumental variable analysis, and found only a modestly lower risk of in-hospital stroke in our secondary propensity-weighted analysis. These findings provide a strong basis for large-scale randomized, controlled trials to test whether EPDs provide meaningful clinical benefit for patients undergoing TAVR.

HERC staff summary: Cerebral embolic protection devices are actively being studied as a way to reduce the risk of stroke during transcatheter aortic valve replacement surgeries. However, the studies to date have not found a reduction in stroke, death, or other important outcomes.

HERC staff recommendation:

1) Place CPT 33370 (Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, catheterization, imaging, and radiological supervision and interpretation, percutaneous) on line 662 and place entry in 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 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
33370	Transcatheter placement and subsequent removal of cerebral embolic protection device(s)	Insufficient evidence of effectiveness	November 2021

2022 CPT Code Review
Drug-Induced Sleep Endoscopy

Code: **42975** Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic

Similar codes: none

Description: Drug-induced sleep endoscopy (DISE), also known as sleep nasoendoscopy or nasopharyngoscopy, is an upper airway evaluation technique which uses a flexible fiberoptic endoscope to examine the site of airway obstruction while individuals are in a sedative-induced sleep designed to mimic the natural sleep state. The purpose of DISE is to determine what causes site of airway obstruction during sleep and help surgeons determine and plan appropriate surgical procedures for their patients with OSA who have failed, or were unable to tolerate, positive airway pressure (e.g., CPAP or BIPAP).

The DISE procedure is currently listed as one of the criteria for evaluation of medical necessity for the FDA-approved hypoglossal nerve neurostimulation. Note: hypoglossal nerve stimulation is not a covered therapy for OSA on the Prioritized List

Evidence

1) **Cheong 2021**, review of drug-induced sleep endoscopy for management of obstructive sleep apnea
    a. Utilization for determining possible benefit from mandibular advancement devices (MAD)
        i. Many of the published studies on DISE and MAD are retrospective. Selection bias is also a major issue as those recruited for MAD tended to have less severe OSA, and patients deemed not likely to benefit were not recruited for MAD use in the first place. Nonetheless, based on the currently available information, it appears that most patients who have improved airway dimensions with mandibular advancement during DISE will benefit from an MAD. Conclusion: More studies are required to demonstrate the efficacy of DISE in the management of OSA.
    b. Utilization in prescribing positional therapy
        i. Positional maneuvers during DISE can assess the feasibility of combination therapy (e.g., MAD or limited surgery with positional therapy) for multilevel collapse, potentially reducing the number of invasive interventions required
    c. Role in planning surgical intervention
        i. Further multicenter prospective randomized trials with control groups who do not undergo DISE are sorely needed to investigate the true clinical impact of DISE in patients undergoing OSA surgery.
    d. Role in planning upper airway stimulation (e.g. hypoglossal nerve stimulation)
        i. DISE was incorporated as a mandatory screening investigation in the landmark Stimulation Therapy for Apnea Reduction (STAR) trial following earlier studies that showed CCCp during DISE to be associated with poor results after upper airway stimulation
    e. Conclusions: High-quality clinical evidence supporting the value of DISE in guiding alternative treatments for OSA is limited

Other payer policies

1) **Aetna 2021**
    a. *Drug-Induced Sleep Endoscopy (DISE):* Aetna considers the use of DISE medically necessary to evaluate appropriateness of FDA-approved hypoglossal nerve stimulation when all of the criteria for hypoglossal nerve stimulation are met. Aetna considers DISE experimental and investigational for all other indications because of insufficient evidence in the peer-reviewed published medical literature of its safety and effectiveness
2) **Cigna 2021** only covers DISE for evaluation for hypoglossal nerve stimulation

HERC staff summary

Drug induce sleep endoscopy appears to be an experimental procedure. It is only covered by private payers when used for evaluation for hypoglossal nerve stimulation, which is not a covered procedure on the Prioritized List. Please see discussion on hypoglossal nerve stimulation later in the 2022 CPT code review.

HERC staff recommendations:

1) Place **42975 (**Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic) on line 662 and add an entry to 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 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
42975	Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic	Insufficient evidence of effectiveness	November 2021

2022 CPT Code Review
Per-oral Endoscopic Myotomy

Code: **43497** Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [POEM])

Similar code: this procedure was previously billed with CPT 43499 Unlisted procedure, esophagus

Description: Peroral endoscopic myotomy (POEM) is a procedure in which a scope is passed through the mouth and into the esophagus. Part of the muscle layer of the lower part of the esophagus, the sphincter, and the upper part of the stomach is removed. POEM has been proposed as a treatment for a variety of esophageal and gastric conditions, including achalasia, diverticula, gastroparesis, and congenital hypertrophic pyloric stenosis.

Achalasia is a rare condition in which the lower esophageal sphincter loses inhibitory neural input making it fail to relax after swallowing. Treatments include Botox injections, laparoscopic Heller myotomy, and pneumatic dilation.

Gastroparesis is a condition in which the stomach does not empty normally. It is commonly associated with diabetes. Treatments for gastroparesis include medications, better diabetic control, and lifestyle changes such as eating small frequent meals.

Diverticula of the esophagus are pouches that form because the muscles of the esophagus fail to relax after swallowing. This can cause pain, and food can be caught in the diverticula. Serious cases are treated with various types of surgery.

Evidence

Achalasia

1) **Zhong 2021,** systematic review and meta-analysis of peroral endoscopic myotomy for achalasia in children
    a. N=11 studies (389 children)
        i. 3 prospective cohort, 8 retrospective cohort
        ii. Clinical success was defined as a decrease in Eckardt score to ≤3 during follow-up.
    b. Pooled clinical success was achieved in 343 children (92.4%; 95% CI, 89.0%–94.8%, I2 =0%)
    c. After POEM, the Eckardt score was significantly decreased by 6.76 points (95% CI, 6.18–7.34, *P*<0.00001, I2 =84%), and the LES pressure was significantly reduced by 19.38 mmHg (95% CI, 17.54–21.22, *P*<0.00001, I2 =33%)
    d. The pooled major adverse events rate was 12.8% (95% CI, 4.5%– 31.5%, I2 =87%). Specifically, the pooled occurrence rate of mucosal injury was 4.6% (95% CI, 1.9%–10.5%, I2 =48%), the rate of pneumothorax was 3.0% (95% CI, 1.4%–6.3%, I2 =0%), the rate of pneumonitis was 4.4% (95% CI, 1.1%–16.6%, I2 =80%), and the rate of pneumoperitoneum was 5.3% (95% CI, 2.1%–13.1%, I2 =56%)
    e. Conclusion: Our current study demonstrated that the POEM was an effective and safe technique for treating achalasia in children. Further randomized comparative studies of POEM and other therapeutic methods are warranted to determine the most effective treatment modality for achalasia in children.

2) **Zhong 2020,** systematic review and meta-analysis of peroral endoscopic myotomy vs pneumatic dilation for achalasia
    a. N=7 studies (619 patients: 298 POEM and 321 pneumatic dilation)
        i. Follow-up 2 to 70 months
        ii. "clinical success" was not defined
    b. At 3 months' follow-up, the clinical success was achieved in 151 of 155 patients (96.9%, 95% CI, 92.3–98.7%) in the POEM group, while in 136 of 155 patients (80.8%, 95% CI, 73.5–86.5%) in the pneumatic dilation group, giving a risk ratio of 1.13 (95% CI, 0.99–1.28, *P* = 0.06, *I*2 = 67%). At 6 months' follow-up, the clinical success was achieved in 122 of 127 patients (95.6%, 95% CI, 90.3–98.1%) in the POEM group compared to 198 of 236 patients (83.8%, 95% CI, 78.5–88.0%) in the pneumatic dilation group, with a risk ratio of 1.14 (95% CI, 1.06–1.22, *P* = 0.0002, *I*2 = 0%) At 12 months' follow-up, treatment success was achieved in 202 of 212 patients (94.9%, 95% CI, 90.9–97.2%) in the POEM group compared to 246 of 340 patients (71.9%, 95% CI, 66.8–76.5%) in the pneumatic dilation group, with a risk ratio of 1.34 (95% CI, 1.24–1.45, *P* < 0.00001, *I*2 = 17%) (Fig. 2c). At 24 months' follow-up, the clinical success was achieved in 161 of 175 patients (91.7%, 95% CI, 86.5–95.0%) in the POEM group compared to 194 of 297 patients (63.8%, 95% CI, 52.4–73.9%) in the pneumatic dilation group, with a risk ratio of 1.35 (95% CI, 1.10–1.65, *P* = 0.004, *I*2 = 70%)
    c. The posttreatment mean Eckardt scores was significantly different in patients undergoing POEM (1.166, 95% CI, 0.709–1.622) versus those receiving pneumatic dilation (2.024, 95% CI, 1.518–12.531), with a mean difference of −0.88 (95% CI, −1.54 to −0.23, *P* = 0.008, *I*2 = 93%)
    d. The gastroesophageal reflux (GER) rate for POEM was significantly higher than pneumatic dilation, with a risk ratio of 4.17 (95% CI, 1.52–11.45, *P* = 0.006, *I*2 = 61%)
    e. other complications in the POEM group, such as subcutaneous emphysema, mucosal injuries and bleeding, were significantly higher than in the pneumatic dilation group, with a risk ratio of 3.78 (95% CI, 1.41–10.16, *P* = 0.008, *I*2 = 0%)
    f. Conclusion: The long-term efficacy of POEM was superior to that of pneumatic dilation, but accompanied by higher complications. More randomized controlled studies are warranted to determine the optimal method for achalasia in the future
3) **Tan 2020,** systematic review and meta-analysis of peroral endoscopic myotomy in achalasia in patients with failed previous interventions
    a. N=15 studies (2,276 patients)
        i. All cohort studies, 6 prospective, 9 retrospective
        ii. 1261 patients had undergone previous procedures, 1015 patients were treatment naïve
        iii. Clinical success was defined as an Eckardt score ≤3 during the study follow-up period
    b. Ten studies with 1,095 patients reported the clinical success of POEM for patients with prior endoscopic or/ and surgical treatment. Clinical success was achieved in 999 patients (91.2%) at 3-month follow-up. The pooled clinical success in patients with greater than three months' follow-up was 90.8% (95% CI, 88.8% to 92.4%).
    c. Four studies reported clinical success with 1-year follow-up. Two studies reported 2- and 3-year follow-ups. The pooled results of clinical success rates for 1-, 2-, and 3-year followups were 89.9% (95% CI, 86.9% to 92.3%), 85.8% (95% CI, 81.7% to 89.1%) and 81.2% (95% CI, 76.2% to 85.4%), respectively

d. Fourteen studies with 1,195 patients reported the adverse events of POEM for patients with prior endoscopic or/and surgical treatment. A total of 83 (6.9%) adverse events occurred. The pooled adverse events rate was 10.3% (95% CI, 6.6% to 15.8%)
    i. Major adverse events included mediastinitis, esophageal leak, pneumothorax, pleural effusion, bleeding requiring transfusion or re-intervention, hydrothorax, mucosal tear
e. Conclusion: POEM appears to be a safe, effective and feasible treatment for those who have undergone previous failed endoscopic or surgical intervention. It has similar outcomes in previously treated and treatment-naive achalasia patients. It may be an attractive option for the treatment of patients with this difficult condition. However, further studies with a long-term follow-up to determine the durability of rescue POEM are still warranted.

4) **Awaiz 2017,** systematic review and meta-analysis of peroral endoscopy myotomy and laparoscopic Heller myotomy for achalasia
    a. N=7 trials comparing laparoscopic Heller myotomy (LHM) to peroral endoscopic myotomy (POEM) reported in 20 publications
        i. N=250 patients undergoing LHM, 233 patients undergoing POEM
        ii. All grades and subtypes of achalasia were included
        iii. No requirement for prior treatment with pneumatic balloon dilation, Botox injection or other treatment
    b. There was a comparable overall complication rate (OR, 1.25; 95% CI, 0.56-2.77; P=0.59), postoperative GERD rate (OR, 1.27; 95% CI, 0.70-2.30; P=0.44), length of hospital stay (WMD, 0.30; 95% CI, -0.24 to 0.85; P=0.28), postoperative pain score (WMD, -0.26; 95% CI, -1.58 to 1.06; P=0.70), and long-term GERD (WMD, 1.06; 95% CI, 0.27-4.1; P=0.08) for both procedures. There was a significantly higher short-term clinical treatment failure rate for LHM (OR, 9.82; 95% CI, 2.06-46.80; P<0.01).
    c. Conclusions: POEM compares favorably to LHM for achalasia treatment in short-term perioperative outcomes. However, there was a significantly higher clinical treatment failure rate for LHM on short-term postoperative follow-up. Presently long-term postoperative follow-up data for POEM beyond 1 year are unavailable and eagerly awaited.

Gastroparesis

1) **Li 2021**, meta analysis of gastric per-oral endoscopy myotomy for refractory gastroparesis
    a. N=8 studies (272 patients)
        i. 2 prospective and 6 retrospective cohort studies
    b. The pooled clinical response rate was 84% (95% CI, 77–89%). The gastric emptying scintigraphy (GES) improvement rate and GES normal rate were also analyzed, and the results were 84% (95% CI, 77–90%) and 53% (95% CI, 39–66%), respectively. Finally, the pooled adverse events rate was 12% (95% CI, 6–19%).
        i. "Clinical response rate" was defined as whatever the article used for response rate
    c. Conclusion: POEM was shown to be feasible and safe for the treatment of gastroparesis with various etiologies, which could be a potential first-line therapy for certain patients. Future studies are needed to investigate the appropriate patients for POEM to explore the "most beneficial" subgroup of patients.

Esophageal diverticula

1) **Facciorusso 2021**, systematic review and meta-analysis of peroral endoscopic myotomy for the treatment of esophageal diverticula
    a. N=12 studies (300 patients) with Zenker's diverticulum (ZD) or epiphrenic diverticula
        i. 4 studies were retrospective case-control studies comparing POEM to flexible endoscopic treatment
        ii. 7 studies were retrospective cohort studies
        iii. 1 study was a prospective case series
    b. Pooled rate of technical success was 95.9% (93.4%-98.3%) in ZD patients and 95.1% (88.8%-100%) in patients with epiphrenic diverticula. Pooled rate of treatment success was similar for ZD (90.6%, 87.1%-94.1%) and epiphrenic diverticula (94.2%, 87.3%-100%). Rates of treatment success were maintained at 1 year (90%, 86.4%-97.4%) and 2 years (89.6%, 82.2%-96.9%) in ZD patients. Pooled rate of symptom recurrence was 2.6% (0.9%-4.4%) in ZD patients and 0% in patients with epiphrenic diverticula. Pooled rates of adverse events and severe adverse events were 10.6% (4.6%- 16.6%) and 3.5% (0%-7.4%) in ZD and 8.4% (0%-16.8%) and 8.4% (0%-16.8%) in epiphrenic diverticula, respectively.
    c. Conclusion: POEM represents an effective and safe therapy for the treatment of esophageal diverticula.

<u>Expert guidelines</u>

1) **Society of American Gastrointestinal and Endoscopic Surgeons (SAGE) 2021**, guidelines for the use of peroral endoscopic myotomy for the treatment of achalasia
    a. POEM vs Heller myotomy
        i. The Guideline panel suggests that adult and pediatric patients with type I and II achalasia may be treated with either POEM or laparoscopic Heller myotomy based on surgeon and patient's shared decision-making (conditional recommendation, very low certainty evidence).
        ii. Based on their collective experience, the panel suggests POEM over laparoscopic Heller myotomy for type III adult or pediatric achalasia. (expert opinion)
    b. POEM vs pneumatic dilation
        i. The Guideline panel recommends peroral endoscopic myotomy over pneumatic dilatation in patients with achalasia (strong recommendation, moderate certainty evidence)
        ii. For the subgroup of patients who are particularly concerned about the continued use of PPI post-operatively, the panel suggests that either POEM or pneumatic dilatation can be used based on joint patient and surgeon decision-making (conditional recommendation, very low certainty evidence).

1) **American College of Gastroenterology (AGC) 2020,** guideline on the diagnosis and management of achalasia
    a. Based on current data, we recommend tailored POEM or laparoscopic Heller myotomy (LHM) for type III achalasia
        i. Moderate level of evidence, strong recommendation
    b. POEM compared with LHM with fundoplication or pneumatic dilation is associated with a higher incidence of GERD.
    c. We recommend that POEM or pneumatic dilation result in comparable symptomatic improvement in patients with types I or II achalasia

i. Low level of evidence, conditional recommendation

d. We recommend that POEM and LHM result in comparable symptomatic improvement in patients with achalasia
    i. Moderate level of evidence, strong recommendation

Other payer policies

1) **Aetna 2021**:
    a. Aetna considers per-oral endoscopic myotomy (POEM) medically necessary for the treatment of type III (spastic) achalasia. Aetna considers POEM experimental and investigational for other types of achalasia.
    b. Aetna considers gastric per-oral endoscopic myotomy (G-POEM) experimental and investigational for the following indications because its effectiveness for these indications has not been established (not an all-inclusive list):
        i. Treatment of congenital hypertrophic pyloric stenosis
        ii. Treatment of gastroparesis.
        iii. Aetna considers diverticular peroral endoscopic myotomy (D-POEM) experimental and investigational for the treatment of esophageal diverticulum because its effectiveness has not been established.
        iv. Aetna considers Zenker per-oral endoscopic myotomy (Z-POEM) diverticulotomy experimental and investigational for closing defect due to Zenker's diverticulum because its effectiveness has not been established.

2) **CMS NCD 2021**
    a. POEM may be considered medically necessary for treatment of symptomatic, monometrically proven primary idiopathic achalasia, types I, II, or III.

3) **Premara BCBS 2021**
    a. POEM is investigational. More and larger studies are needed to compare POEM with standard surgery to treat esophageal achalasia

4) **PacificSource 2020**
    a. PacificSource considers the POEM procedure medically necessary when ALL the following criteria are met:
        i. A diagnosis of esophageal achalasia type III (spastic) is established by the following:
            1. Twenty percent (20%) or more of swallows have premature spastic contractions as indicated by esophageal manometry; and
            2. Non-relaxing lower esophageal sphincter pressure (LES) indicated by a barium esophagogram with fluoroscopy and esophageal manometry.
        ii. Failure of a previous treatment for achalasia (e.g. Botox, pneumatic dilation); and
        iii. None of the following contraindications are present:
            1. Severe pulmonary disease; or
            2. Esophageal irradiation; or
            3. Esophageal malignancy; or
            4. Bleeding disorder, including coagulopathy; or
            5. Recent esophageal surgery; and endoscopic intervention

Current Prioritized List status
ICD-10-CM K22.0 (Achalasia of cardia) is on line 378 ESOPHAGEAL STRICTURE; ACHALASIA

Line 378 includes CPT codes for pneumatic dilation of the esophagus, and CPT 43279 (Laparoscopy, surgical, esophagomyotomy (Heller type), with fundoplasty, when performed)

HERC staff summary
Peroral endoscopic myotomy [POEM]) is a relatively established procedure that has been studied as treatment for a variety of conditions of the stomach and esophagus, including achalasia, esophageal diverticula, and gastroparesis. The literature to date on POEM as a treatment for esophageal diverticula and gastroparesis consists of small cohort studies. There is a more robust literature on POEM for treatment of achalasia, with trials comparing POEM to laparoscopic Heller myotomy (LHM) and multiple cohort studies comparing POEM to pneumatic dilation. Studies tend to be small as achalasia is a rare condition. POEM appears to have similar outcomes to LHM for achalasia for improvement of achalasia symptoms at least in the short term, but has some significant adverse events including pneumothorax, esophageal rupture, and significant bleeding, as well as increased rates of GERD. The ACG expert recommendation is for POEM as one option for treatment of achalasia of all types. SAGE recommends POEM over LHM only for type III achalasia (expert recommendation), and private payers and CMS appear to generally align with this recommendation. Achalasia is a rare condition which currently is paired with multiple treatments, including pneumatic dilation and LHM. Staff recommendation for coverage of type III achalasia is based mainly on expert recommendation.

HERC staff recommendations:
1) Add CPT **43497** Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [POEM]) to line 378 ESOPHAGEAL STRICTURE; ACHALASIA
2) Adopt a new guideline as shown below for line 378

GUIDELINE NOTE XXX PERORAL ENDOSCOPIC MYOTOMY (POEM)
Line 378
Peroral endoscopic myotomy (POEM; CPT 43497) is included on this line only for treatment of symptomatic, monometrically proven primary idiopathic achalasia, type III.

2022 CPT Code Review
Periurethral Transperinenal Adjustable Balloon Continence Device

Codes

1) **53451**: Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance
2) **53452**: Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance
3) **53453**: Periurethral transperineal adjustable balloon continence device; removal, each balloon
4) **53454**: Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume

Description: The periurethral transperinenal adjustable balloon continence devices consists of two small, adjustable, silicone balloons each connected with tubing to a port. The balloons are placed where the prostate was removed or resected. The fluid-filled balloons apply pressure to and support the bladder neck, which helps prevent accidental leakage of urine. The only device currently on the market is the ProACT device from Uromedica.

Many other devices and procedures exist for treatment of post-prostate treatment urinary incontinence. These include artificial urinary sphincters, sling procedures, and injection of bulking agents.

Evidence

1) **Larson 2019,** systematic review and meta-analysis of ProACT for the treatment of male stress urinary incontinence
    a. N=19 studies (1264 patients)
        i. Mean follow up 3.6 years
        ii. Postprostatectomy incontinence in 92.3% of patients
        iii. All cohort studies
        iv. 10 good quality, 7 fair quality, and 2 poor quality studies
    b. At baseline, patients on average were using 4.0 pads per day (PPD) (95% confidence interval [CI]: 2.6-5.4), which was reduced to an average of 1.1 PPD (95% CI: 0.5-1.7) after

ProACT implantation. The number of patients that were considered "dry" was 60.2% (95% CI: 54.2%-65.9%) and the number of patients who were found to be either "dry" or improved greater than 50% was 81.9% (95% CI: 74%-87.8%).

c. The meta-analysis estimate for intraoperative perforation of the bladder or urethra is 5.3% (95% CI: 3.4%-8%). Estimates for infection and urinary retention were 2.2% (95% CI: 1.1%-4.3%) and 1.5% (95% CI: 0.7%-3.4%), respectively. The estimated overall revision rate for all causes is 22.2% (95% CI: 15.2%-31.2%) with a mean followup of 3.6 years (range 12-118 months).

a. Conclusions: Implantation of adjustable balloon devices is efficacious and safe for the treatment of male SUI. Given the minimal invasiveness of the therapy, adjustable balloon devices may be a serious option as a first-line treatment in nonirradiated patients with SUI who are not ideal candidates for the artificial urinary sphincter.

Expert guidelines

1) **American Urologic Association 2019,** guideline on incontinence after prostate treatment
    a. Adjustable balloon devices may be offered to patients with mild stress urinary incontinence after prostate treatment. (Moderate Recommendation; Evidence Level: Grade B)
        i. While the adjustable balloon devices have been shown to improve incontinence, providers should be aware of an increased incidence of intraoperative complications and need for explanation within the first two years compared to the male sling and AUS. Given the limited clinical experience of implanters across the United States, providers should obtain specialty training prior to device implantation.

Other payer policies

1) **Wellmark BCBS 2021**: Considers Transperineal Implantation of Permanent Adjustable Balloon Continence Device (ProACT) to be experimental
2) **Aetna 2021:** Aetna considers transperineal implantation of a permanent adjustable balloon continence device (e.g., ACT, ProACT Therapy System, Uromedica, Inc.) for the treatment of urinary incontinence experimental and investigational because its effectiveness has not been established.
3) **Providence Health Plans 2021**: Transperineal periurethral balloon continence devices are listed as not covered

HERC staff summary:
Transperineal periurethral balloon continence devices are a new treatment with a limited evidence base (only non-comparative cohort studies). There is a high rate of reported complications and need for explantation. No private payer surveyed is currently covering these devices and the AUA notes that it "may be offered to patients with mild stress urinary incontinence after prostate treatment" but that there are concerns about complication rates and need for specialty training prior to implantation.

HERC staff recommendation

1) Place CPT **53453** (Periurethral transperineal adjustable balloon continence device; removal, each balloon) on line 424 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
2) Place the following CPT codes on line 662 and place entry in GN173 as shown below
    a. **53451**: Periurethral transperineal adjustable balloon continence device; bilateral insertion, including cystourethroscopy and imaging guidance
    b. **53452**: Periurethral transperineal adjustable balloon continence device; unilateral insertion, including cystourethroscopy and imaging guidance
    c. **53454**: Periurethral transperineal adjustable balloon continence device; percutaneous adjustment of balloon(s) fluid volume

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
53451, 53452, 53454	Periurethral transperineal adjustable balloon continence device	Insufficient evidence of effectiveness	November 2021

2022 CPT Code Review

Laser Interstitial Thermal Therapy (LITT)

Codes**:**
61736: Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion
61737: Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesion(s)

Description: Laser interstitial thermal therapy (LITT) is a minimally invasive treatment using a focused beam of electromagnetic radiation emitted from a laser that is stereotactically placed into a targeted location. The laser then induces hyperthermia to ablate the target minimizing injury to the surrounding tissues while magnetic resonance imaging (MRI) thermography is used to monitor tissue temperatures. The use of laser interstitial thermal therapy (LITT) is currently being researched to include but not limited to the following indications, brain tumors and breast tumors, prostate cancer, osteoid osteoma (bone tumor), lung cancer, liver cancer, radiation necrosis and epilepsy. The best studied use of LITT is in treatment of epilepsy and brain tumors.

Evidence

1) **CADTH 2019:** evidence review on laser interstitial therapy for epilepsy and/or brain tumors https://cadth.ca/sites/default/files/pdf/htis/2019/RC1140%20LITT%20Final.pdf
    a. N=5 publications
        i. 2 systematic reviews
            1. N=404 with intractable temporal lobe epilepsy
                a. 239 LITT vs 165 stereotactic radiosurgery
                b. Authors of one systematic review reported that across 18 retrospective chart reviews, case studies and case reports and one RCT that followed patients for 12 to 36 months, there was no statistically significant difference in the mean incidence of seizure freedom in patients with drug-resistant, medically-intractable TLE treated with MR-guided LITT compared with those treated with SRS
                    i. Mean incidence of seizure freedom: 50% (CI, 44% to 56%; range, 35% to 71%) vs. 42% (CI, 27% to 59%; range, 0% to 73%); *P* = 0.39; indicating that the difference between the groups was not statistically significant
                c. Complications: Mean incidence of complications: 20% (CI, 14% to 26%) vs. 32% (20% to 46%); *P* = 0.06; indicating no statistically significant difference between the groups with a trend in favor of LITT
                    i. LITT complications: gait abnormalities (n = 9), cranial nerve deficits (n = 8), cerebral hemorrhage (n = 4), headache and nausea (n = NR)
                    ii. SRS complications: cerebral edema (n = 11), psychotic and cognitive symptoms (n = 7), and nerve deficits (n = 2)

Laser Interstitial Thermal Therapy (LITT)

d. Conclusions*:* On the basis of current literature, we found that whereas seizure outcome rates … may be similar between the 2 procedures, [MR-guided] LITT may be associated with lower complication rates. However, more largescale comparative studies are required to validate our findings.

2. N=589 patients with high grade tumors in or near areas of eloquence
    a. 67 LITT vs 522 with open craniotomy
    b. Examined only adverse events
    c. Mean major neurocognitive complication rates (lasting >3 months): 5.7% (CI, 1.8% to 11.6%; I2 = 0%) vs. 13.9% (CI, 10.3% to 17.9%; I2 = 65%)
        i. Absolute risk difference: -0.10 (CI, -0.15 to -0.05; *P* < 0.0001); in favor of LITT
    d. Conclusions: LITT … may reduce major neurocognitive complications compared to open craniotomy in patients with high-grade gliomas.

ii. 2 prospective cohort studies
1. N=100 patients with brain tumors, epilepsy or unspecified indications
    a. Conclusion: Analysis of the first 100 patients from the registry suggests that SLA is a safe, minimally invasive procedure for the treatment of intracranial pathologies. The morbidity and hospitalization time profiles compare favorably to those previously reported for conventional craniotomies.
2. N=20 patients with recurrent tumors following stereotactic radiosurgery for brain metastases
    a. The overall survival rate was 71% at three months of follow-up among 13 patients and 64.5% at six and a half months of follow-up in an undisclosed number of patients
    b. Conclusions: In summary, this prospective study confirmed that LITT is a low-risk surgical procedure that can control radiographic lesion growth after SRS in patients with brain metastases and should be considered in those who are surgically eligible. Further studies with a control group for better characterization of possible benefits are warranted.

iii. 1 cost-effectiveness study
1. Conclusion: The use of brain LITT under magnetic resonance imaging guidance in complex craniotomies where high-grade gliomas reside in or near areas of eloquence (or where these types of tumors are deep seated) appears to be cost effective"

b. In summary, the outcomes of interest were seizure freedom, disease progression and overall survival, quality of life, hospitalization, and adverse events. Evidence of limited quality and quantity suggested that LITT proffers no advantage over stereotactic radiosurgery in inducing seizure freedom in patients with drug-resistant, medically intractable temporal lobe epilepsy. Relative to patients who were treated with stereotactic radiosurgery and craniotomy, patients treated with LITT appeared to experience fewer adverse events and complications. No comparative evidence on disease progression, overall survival, hospitalization, or quality of life was found. None

of the studies reported on the incidence of epileptic episodes, post-operative pain, use of medication, or hospital readmissions.

c. Considerable caution must be taken in interpreting the evidence presented in this report due to the paucity of comparative data and other limitations. While the systematic reviews on clinical effectiveness and safety had some noteworthy strengths, there were serious limitations related to the quality of the included primary studies, potential for patient selection, measurement, and reporting biases.

2) **Kim 2020,** LAANTERN study
   a. Prospective cohort registry study, N=223 patients
      i. Of the ablated tumors, 131 were primary and 92 were metastatic. Most patients with primary tumors had high-grade gliomas (80.9%). Nearly all metastatic lesions (92.4%) were previously treated, and the LITT procedure was indicated for tumor recurrence (50.6%), radiation necrosis (40%), or unknown (9.4%)
      ii. Median follow up 223 days
   b. The 1-yr estimated survival rate was 73%, and this was not impacted by disease etiology. Overall survival in the total cohort of patients was consistent with prior publications in similar patient populations.
   c. Patient-reported QoL as assessed by the Functional Assessment of Cancer Therapy-Brain was stabilized postprocedure. KPS declined by an average of 5.7 to 10.5 points postprocedure; however, 50.5% had stabilized/improved KPS at 6mo.
   d. **CONCLUSION:** Results from the ongoing LAANTERN registry demonstrate that LITT stabilizes and improves QoL from baseline levels in a malignant brain tumor patient population with high rates of comorbidities. Overall survival was better than anticipated for a real world registry and comparative to published literature.

Expert guidelines

1) **NCCN 2.2021**, Central Nervous System Cancers
   a. Principles of brain tumor surgery
      i. MRI-guided laser interstitial thermal therapy (LITT) (category 2B) may be considered for patients who are not surgical candidates (craniotomy or resection). Potential indications include relapsed brain metastases and radiation necrosis
   b. Included articles from CADTH
      i. Ahluwalia 2018 (cohort study of 20 patients with brain tumors)

Other payer policies

1) **Cigna 2021**
   a. Laser Interstitial Thermal Therapy (LITT) is considered experimental, investigational or unproven for all indications.
2) **Aetna 2021**
   a. Aetna considers magnetic resonance-guided laser interstitial thermal therapy (MRgLITT) (e.g. the NeuroBlate and the Visualase Thermal Therapy System) medically necessary as an alternative to standard surgery where criteria in section I on epilepsy surgery are met.
3) **Wellmark BCBS 2020**:
   a. The treatment of medically refractory epilepsy using MRI-guided laser interstitial thermal therapy (MRIgLITT) is considered medically necessary when ALL of the following criteria are met:

Laser Interstitial Thermal Therapy (LITT)

i. Documented disabling seizures despite the use of two or more tolerated antiepileptic drug regiments; and
ii. Documented (i.e. imaging or EEG) presence of well-defined epileptogenic foci accessible by laser interstitial thermal therapy (LITT).

b. MRI-guided laser interstitial thermal therapy (MRIgLITT) when the above criteria is not met and for all other indications, including but not limited to the following is considered investigational because the evidence is insufficient to determine the effects of the technology on health outcomes:
   i. Epilepsy except as indicated above
   ii. Brain tumors (primary and metastatic)
   iii. Breast cancer (benign or malignant)
   iv. Liver cancer (primary and metastatic)
   v. Lung cancer (primary and metastatic)
   vi. Osteoid osteoma
   vii. Prostate cancer
   viii. Radiation necrosis

<u>Expert input:</u>
Dr. Ahmed Raslan, OHSU neurosurgery

I don't believe these are experimental for epilepsy or brain tumors.

I will follow up with a list of publications that demonstrates the efficacy of the therapy and the relative safety and often big advantage when compared to open approaches in specific situations (hypothalamic hamartomas for example).

There hasn't been a RCT to compare against open surgery for obvious logistical reasons but there is a myriad of studies to show the beneficial effect. Will be happy to participate in any in-depth review.

2022 CPT Code Review

Laser Interstitial Thermal Therapy (LITT)

HERC staff summary:

Laser interstitial thermal therapy (LITT) is a new technology that is best studied for treatment of refractory epilepsy and brain tumors. A trusted source systematic review (CADTH 2019) found limited quality and quantity of evidence that LITT had equivalent outcomes to stereotactic radiosurgery for refractory epilepsy. No comparative evidence was found on LITT for treatment of brain tumors on disease progression, overall survival or quality of life. NCCN gives LITT a category 2 B recommendation for patients who are not surgical candidates for treatment of brain metastases or radiation necrosis. Private payer coverage of LITT is mixed, and mainly is for refractory epilepsy.

HERC staff recommendation:

1) Place the following CPT codes on line 662 and place entry in GN173 as shown below
    a. **61736:** Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion
    b. **61737:** Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesion(s)

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
61736, 61737	Laser interstitial thermal therapy (LITT) of lesion, intracranial	Insufficient evidence of effectiveness	November 2021

2022 CPT Code Review

Hypoglossal Nerve Neurostimulator

Codes**:**
64582: Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array
64583: Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator
64584: Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array

Similar code:
Previously coded with CPT 64568 (Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator) which is on lines 174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS and 441 TRIGEMINAL AND OTHER NERVE DISORDERS

Description: Hypoglossal nerve stimulation is a treatment for obstructive sleep apnea. The hypoglossal nerve is the twelfth cranial nerve and innervates all the extrinsic and intrinsic muscles of the tongue. The hypoglossal nerve stimulator is an implanted device that stimulates this nerve to stimulate the tongue to improve tongue obstruction in sleep apnea. Alternative treatments for OSA include CPAP, tonsillectomy, adenoidectomy, and mandibular advancement devices.

Current Prioritized List status

GUIDELINE NOTE 27, TREATMENT OF SLEEP APNEA
Line 202
For adults over the age of 18 years:

A) CPAP is covered initially when all of the following conditions are met:
   1) 12 week 'trial' period to determine benefit. This period is covered if apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour; or if between 5 and 14 events with additional symptoms including one or more of the following:
   2) excessive daytime sleepiness defined as either an Epworth Sleepiness Scale score>10 or daytime sleepiness interfering with ADLs that is not attributable to another modifiable sedating condition (e.g. narcotic dependence), or
   3) documented hypertension, or
   4) ischemic heart disease, or
   5) history of stroke
   6) Additionally:
      a) Providers must provide education to patients and caregivers prior to use of CPAP machine to ensure proper use; and
      b) Positive diagnosis through polysomnogram (PSG) or Home Sleep Test (HST).

B) CPAP coverage subsequent to the initial 12 weeks is based on documented patient tolerance, compliance, and clinical benefit. Compliance (adherence to therapy) is defined as use of CPAP for at least four hours per night on 70% of the nights during a consecutive 30-day period.

C) Mandibular advancement devices (oral appliances) are covered for those for whom CPAP fails or is contraindicated.
D) Surgery for sleep apnea in adults is not included on this line (due to lack of evidence of efficacy). Surgical codes are included on this line only for children who meet criteria below
E) Hypoglossal nerve stimulation for treatment of obstructive sleep apnea is not included on this line due to insufficient evidence of effectiveness and evidence of harm.

For children age of 18 years or younger:

A) Adenotonsillectomy is an appropriate first line treatment for children with OSA. Adenoidectomy without tonsillectomy is only covered when a child with OSA has previously had a tonsillectomy, when tonsillectomy is contraindicated, or when tonsillar hypertrophy is not present. More complex surgical treatments are only included on this line for children with craniofacial anomalies.
B) Intranasal corticosteroids are an option for children with mild OSA in whom adenotonsillectomy is contraindicated or for mild postoperative OSA.
C) CPAP is covered for a 3 month trial for children through age 18 who have
   1) undergone surgery or are not candidates for surgery, AND
   2) have documented residual sleep apnea symptoms (sleep disruption and/or significant desaturations) with residual
      daytime symptoms (daytime sleepiness or behavior problems)
D) CPAP will be covered for children through age 18 on an ongoing basis if:
   1) There is documentation of improvement in sleep disruption and daytime sleepiness and behavior problems with CPAP
      use, AND
   2) Annual re-evaluation for CPAP demonstrates ongoing clinical benefit and compliance with use, defined as use of CPAP
      for at least four hours per night on 70% of the nights in a consecutive 30 day period

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

Evidence

1) **NICE 2017**, review of hypoglossal nerve stimulation for moderate to severe obstructive sleep apnea https://www.nice.org.uk/guidance/ipg598/documents/overview-2;
   a. Overall recommendation: Current evidence on the safety and efficacy of hypoglossal nerve stimulation for moderate to severe obstructive sleep apnea is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research
   b. N=7 studies (1 systematic review, 4 prospective case series, 1 RCT, and 1 retrospective case series
      i. N=326 patients
   c. Effectiveness
      i. In a systematic review and meta-analysis of 200 patients
         1. there was a statistically significant decrease in the AHI (a normal AHI is less than 5 events per hour). At 3-, 6-, and 12-month follow-up the mean differences from baseline were −23.94 (95% confidence interval

[CI] −31.45 to −16.43, 34 patients), −25.60 (95% CI −31.18 to −20.01, 60 patients) and −17.51 (95% CI −20.69 to −14.34, 170 patients) respectively (p<0.001 for all time points).

2. there was a statistically significant decrease in the ODI (defined as the number of times per hour of sleep that the blood oxygen level drops by 4 or more percentage points from baseline). At 3-, 6-, and 12-month follow-up the mean differences from baseline were −10.04 (CI −16.31 to −3.78, 34 patients), −11.68 (95% CI −17.16 to −6.19, 60 patients) and −13.73 (95% CI −16.87 to −10.58, 170 patients) respectively (p<0.01 at 3 months and p<0.001 at 6 and 12 months)
3. there was a statistically significant decrease in the ESS (scores range from 0 to 24 with higher scores indicating more daytime sleepiness). At 3-, 6-, and 12-month follow-up the mean differences from baseline were -4.17 (CI −6.45 to −1.90, 34 IP 1470 [IPG598] IP overview: hypoglossal nerve stimulation for moderate to severe obstructive sleep apnea patients), −3.82 (95% CI −5.37 to −2.27, 60 patients) and −4.42 (95% CI −5.39 to −3.44, 170 patients) respectively (p

ii. In a prospective case series of 126 patients, there was a statistically significant decrease in the mean AHI ± standard deviation (SD) from 32.0±11.8 at baseline to 15.3±16.1 at 1 year (p<0.001). There was a statistically significant decrease in the mean ODI ± SD from 28.9±12.0 at baseline to 13.9±15.7 at 1 year (p<0.001). there was a statistically significant decrease in the mean ESS score ± SD from 11.6±5.0 at baseline to 7.0±4.2 at 1 year (p<0.001).

iii. In a prospective case series of 60 patients, there was a statistically significant decrease in the mean AHI ± SD from 31.2±13.2 at baseline to 13.8±14.8 at 12-month follow-up (p<0.05) The proportion of responders s (AHI<20 with at least 50% reduction) was 68% (41/60) after 12 months. there was a statistically significant decrease in the mean ODI ± SD from 27.6±16.4 at baseline to 13.7±14.9 at 12- month follow-up (p<0.05). there was a statistically significant decrease in the mean ESS score ± SD from 12.8±5.3 at baseline to 6.5±4.5 at 12-month follow-up (p<0.05).

iv. In a prospective case series of 46 patients, there was a statistically significant decrease in the mean AHI ± SD from 34.9±22.5 at baseline to 25.4±23.1 at 6-month follow-up (p=0.004). The proportion of responders (AHI<20 with at least 50% reduction) was 35% (15/43) after 6 months. There was a statistically significant decrease in the mean ODI ± SD from 32.4±22.3 at baseline to 23.6±22.3 at 6- month follow-up (p=0.006). The proportion of ODI responders (ODI with at least 50% reduction) was 40% (17/43) after 6 months. There was a statistically significant decrease in the mean ESS score ± SD from 12.0±4.8 at baseline to 8.3±4.4 at 6- month follow-up (p<0.001)

v. In a prospective case series of 31 patients, there was a statistically significant decrease in the mean AHI± SD from 32.9±11.2 at baseline to 7.1±5.9 at 1-year follow-up (p<0.001). In the prospective case series of 31 patients, there was a statistically significant decrease in the mean ODI ± SD from 30.7±14.0 at baseline to 9.9±8.0 at 1-year follow-up (p=0.004). There was a statistically significant decrease in the mean ESS score ± SD from 12.6± 5.6 at baseline to 5.9±5.2 at 1- year follow-up (p=0.006)

d. Adverse events

Hypoglossal Nerve Neurostimulator

i. Transient ipsilateral hemi-tongue paresis was reported in 15% (2/13) of patients in a prospective case series of 13 patients from a systematic review and metaanalysis of 200 patients. Temporary tongue weakness was reported in 18% (23/126) of patients in a prospective case series of 126 patients within 1 year of the procedure. Paresis was reported in 11% (5/46) of patients within 30 days of implantation in a prospective case series of 46 patients; all cases resolved spontaneously
ii. Paraesthesia was reported in 13% (6/46) of patients (within 30 days of implantation in 5 patients, and more than 30 days after implantation in 1 patient) in the prospective case series of 46 patients.
iii. Mechanical pain associated with the presence of the device was reported in 10% (12/126) of patients in the prospective case series of 126 patients within 3 years of the procedure. Discomfort due to electrical stimulation was reported in 58% (73/126) of patients in the prospective case series of 126 patients within 4 years of the procedure. In the same study, discomfort related to incisions was reported in 29% (37/126) of patients and discomfort not related to incisions was reported in 27% (34/126) of patients within 4 years of the procedure. Pain was reported in 41% (19/46) patients in the prospective case series of 46 patients (7 patients reported non-serious pain within 30 days of implantation, 12 reported it more than 30 days after implantation); 3 patients reported serious pain (1 case within 30 days and 2 cases more than 30 days after implantation).
iv. Device migration more than 30 days after implantation was reported in 1 patient in the prospective case series of 46 patients
v. Temporary internal device usability or functionality complaint was reported in 16% (20/126) of patients within 4 years of the procedure in the prospective case series of 126 patients. In the same study, temporary external device usability or functionality complaint was reported in 24% (30/126) of patients within 4 years of the procedure
vi. Leads breaking was reported in 15% (2/13) of patients in the prospective case series of 13 patients from the systematic review and meta-analysis of 200 patients

Other payer policies

1) **Aetna 2021:**
    a. Aetna considers Food and Drug Administration (FDA)-approved hypoglossal nerve neurostimulation (e.g., Inspire II System, Inspire 3028 system for Upper Airway Stimulation (UAS) Therapy) medically necessary for the treatment of moderate to severe obstructive sleep apnea when *all* of the following criteria are met:
        i. Member is 18 years of age or older; *and*
        ii. Body mass index (BMI) is less than 32 kg/m^2; *and*
        iii. A polysomnography (PSG) is performed within 24 months of first consultation for Inspire implant; *and*
        iv. Member has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); *and*
        v. Apnea hypopnea index (AHI) is 15 to 65 events per hour; *and*

vi. Member has a minimum of one month of CPAP monitoring documentation that demonstrates CPAP failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as less than 4 hours per night, 5 nights per week); *and*
vii. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; *and*
viii. No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per tonsillar hypertrophy grading scale. See Appendix).

b. Aetna considers hypoglossal nerve neurostimulation experimental and investigational for all other indications.

2) CMS LCD 2020

a. FDA-approved hypoglossal nerve neurostimulation is considered medically reasonable and necessary for the treatment of moderate to severe obstructive sleep apnea when all of the following criteria are met:
i. Beneficiary is 22 years of age or older; **and**
ii. Body mass index (BMI) is less than 35 kg/m^2; **and**
iii. A polysomnography (PSG) is performed within 24 months of first consultation for HGNS implant; **and**
iv. Beneficiary has predominantly obstructive events (defined as central and mixed apneas less than 25% of the total AHI); **and**
v. AHI is 15 to 65 events per hour; **and**
vi. Beneficiary has documentation that demonstrates CPAP failure (defined as AHI greater than 15 despite CPAP usage) or CPAP intolerance (defined as less than 4 hours per night, 5 nights per week or the CPAP has been returned) including shared decision making that the patient was intolerant of CPAP despite consultation with a sleep expert; **and**
vii. Absence of complete concentric collapse at the soft palate level as seen on a drug-induced sleep endoscopy (DISE) procedure; **and**
viii. No other anatomical findings that would compromise performance of device (e.g., tonsil size 3 or 4 per standardized tonsillar hypertrophy grading scale).

2022 CPT Code Review

Hypoglossal Nerve Neurostimulator

HERC staff summary:

Hypoglossal nerve stimulation was previously reviewed as part of a coverage guidance on treatments for sleep apnea and recommended for non-coverage. One of our highly trusted sources (NICE) found limited evidence of effectiveness and high rates of harms and recommended use only as part of research. Medicare published LCDs covering this procedure in 2020; subsequently, most payers appear to be covering in certain situations.

Note: if a decision to add coverage is made, then the topic "2022 CPT Code Review Drug Induced Sleep Endoscopy" needs to be readdressed as that test is required prior to hypoglossal nerve stimulator placement.

HERC staff recommendation:

1) Place CPT **64584** (Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array) on line 424 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
2) Place the following CPT codes on line 662 and place entry in GN173 as shown below
    a. **64582:** Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array
    b. **64583:** Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator

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
64581, 64583	Implantation, revision or replacement of hypoglossal nerve neurostimulator array	Insufficient evidence of effectiveness	November 2021

2022 CPT Code Review
Thermal Destruction of Intraosseous Basivertebral Nerve

Codes:

1) **64628**: Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral
2) **64629**: Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral

Similar codes: none

Description: The sensory nerves within the center of the vertebral body converge to form the basivertebral nerve (BVN). The BVN exits the vertebral body posteriorly via the basivertebral foramen. In patients with vertebrogenic back pain, utilizing therapeutic radiofrequency (RF) ablation of the BVN has been proposed as a method of treating low back pain.

Evidence

1) **Khalil 2019**, the INTRACEPT trial
    a. RCT of patients with low back pain
        i. N= 51 treated with BVN ablation, N=53 treated with standard care
        ii. Followed for 3 months
    b. Comparing the RF ablation arm to the standard care arm, the mean changes in Oswestry Disability Index (ODI) at 3 months were -25.3 points versus -4.4 points, respectively, resulting in an adjusted difference of 20.9 points (p<.001). Mean changes in VAS were -3.46 versus -1.02, respectively, an adjusted difference of 2.44 cm (p<.001). In the RF ablation arm, 74.5% of patients achieved a ≥10-point improvement in ODI, compared with 32.7% in the standard care arm (p<0.001).
2) **Fischgrund 2018**, SMART trial
    a. RCT of radiofrequency ablation (RA) of the basivertebral nerve vs sham
        i. N=147 patients in the RA group, N=78 patients in the sham group
        ii. 12 month follow up
    b. At 3 months, the average Oswestry Disability Index (ODI) in the treatment arm decreased 20.5 points, as compared to a 15.2 point decrease in the sham arm (p = 0.019, per-protocol population). A responder analysis based on ODI decrease ≥ 10 points showed that 75.6% of patients in the treatment arm as compared to 55.3% in the sham control arm exhibited a clinically meaningful improvement at 3 months.
        i. No ODI scores reported after 3 months
    c. The least mean squares (LSM) improvement in VAS in the treatment arm was 2.97, 3.04, and 2.84 cm at 3, 6, and 12 months, respectively. The LSM improvement in VAS in the sham arm was 2.36, 2.08, and 2.08 cm at 3, 6, and 12 months, respectively
    d. Eight procedure-related events were reported in six patients following the 225 index procedures, for a complication rate of 2.7%. Two of these six patients were in the sham arm. The events included nerve root injury (n = 1), lumbar radiculopathy (n = 2), retroperitoneal hemorrhage (n = 1), and transient motor or sensory deficits (n = 4).

Expert guideline:

1) **Lorio 2019**, ISASS guideline on intraosseous ablation of the basivertebral nerve for relief of chronic back pain
    a. Noted only two trials to date (INTRACEPT and SMART reviewed above)

b. Intraosseous ablation of the BVN is a relatively new minimally invasive treatment for the relief of CLBP that is diagnosed using well-established clinical and MRI findings. The procedure is supported by level 1 evidence including 2 RCTs demonstrating a statistically significant decrease in pain and an improvement in function with outcomes sustained to at least 24 months in a limited number of studies. BVN ablation may provide a treatment option to fill the gap in the treatment paradigm for patients that fail nonsurgical treatment.
c. Noted all studies are industry funded, short term and may be biased

Other payer policies

- Aetna 2021: Intracept System (intra-osseous basivertebral nerve ablation) for the treatment of low back pain is investigational
- Cigna 2021: intraosseous radiofrequency nerve ablation of basivertebral nerve (e.g., INTRACEPT® Intraosseous Nerve Ablation System) (CPT codes 64999, C9752, C9753) is investigational
- Anthem BCBS 2021: Intraosseous basivertebral nerve ablation is investigational

HERC staff summary

Basivertebral nerve ablation is a new treatment for chronic low back pain, with an evidence base consisting of two RCTs (N=320 patients) which reported only short term outcomes. All private payers surveyed consider it experimental.

HERC staff recommendation

1) Add the following CPT codes to line 662 and add an entry to GN173 as shown below
    a. **64628**: Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral
    b. **64629**: Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral

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
64628-64629	Thermal destruction of intraosseous basivertebral nerve	Insufficient evidence of effectiveness	November 2021

2022 CPT Code Review
Drug-Eluting Lacrimal Canaliculus Stents

Code: **68841** Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each

Similar codes: Previously coded with CPT level III code 0356T

Description: This code is for use for Ocular Therapeutix's Dextenza, with is an FDA approved device for the treatment of ocular inflammation and pain following ophthalmic surgery, such as cataract or glaucoma surgery. DEXTENZA is a corticosteroid intracanalicular insert placed in the punctum, a natural opening in the inner portion of the lower eyelid, and into the canaliculus and is designed to deliver dexamethasone to the ocular surface for up to 30 days without preservatives. DEXTENZA resorbs and exits the nasolacrimal system without the need for removal.

Similar devices are being investigated for delivery of other drugs to the ocular system, such as OTX-TP, which delivers travoprost, a corticosteroid.

Evidence:

1) **Ittoop 2019**, review of novel glaucoma devices
    a. OTX-TP (Ocular Therapeutix, Bedford, MA, USA) is a rod-shaped, punctal plug made from a polyethylene glycol hydrogel, which is embedded with microspheres that contain an encapsulated formula of travoprost. The device is placed vertically into the superior or inferior canaliculus. As the tear film fills the canaliculus, the medication is slowly released by hydrolysis of the microspheres
        i. Two studies: 17 patient feasibility study and 73 patient phase II study.
        ii. OcularTherapeutix appears to be actively enrolling patients in a phase III clinical trial
2) **Tyson 2019,** phase 3 study of sustained-release intracanalicular dexamethasone insert for treatment of ocular inflammation and pain after cataract surgery
    a. N=438 patients (216 drug eluting insert, 222 placebo insert)
    b. Study sponsored by Ocular Therapeutix
    c. At Day 14, significantly more patients had an absence of anterior chamber cells in the dexamethasone insert arm compared with the placebo arm (52.3% versus 31.1%; P< .0001). At Day 8, significantly more patients had an absence of ocular pain in the dexamethasone insert arm compared with placebo (79.6% versus 61.3%; P < .0001). The dexamethasone insert arm showed no increase compared with placebo in incidence of all adverse events or ocular adverse events. Twice as many placebo patients required rescue therapy, compared with treated patients at Day 14.
    d. The most common ocular adverse events reported in the study eye were eye inflammation, increase in IOP, and anterior chamber inflammation in the dexamethasone insert arm. In the placebo arm, the most common ocular adverse events reported were eye inflammation, increase in IOP, anterior chamber inflammation, worsened corrected distance visual acuity, and cystoid macular edema
    e. In conclusion, the efficacy and safety data presented in this study demonstrate that the sustained-release dexamethasone intracanalicular insert provides a statistically significant sustained reduction in inflammation after cataract surgery and statistically significant sustained reduction in ocular pain starting in the first few days after cataract

surgery and continuing for a month after surgery, while maintaining a favorable safety profile.

Other payer policies:

1) Cigna 2021: EACH of the following devices is considered experimental, investigational or unproven for any indication:
    a. drug-eluting ocular devices (CPT Codes® 0356T, 0444T, 0445T)
2) Aetna 2021: Aetna considers insertion of a drug-eluting implant, including punctal dilation and implant removal when performed, into the lacrimal canaliculus experimental and investigational for the treatment of glaucoma or ocular hypertension because its effectiveness has not been established.

HERC staff summary

Drug eluting stents for the lacrimal canaliculus are being actively studied as a method to delivery medications after cataract and other eye surgery. The evidence to date is very limited and no private payer surveyed is covering this procedure.

HERC staff recommendation:

1) Place CPT 68841 on line 662/GN 173

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
68841	Insertion of drug-eluting implant, including punctal dilation when performed, into lacrimal canaliculus, each	Insufficient evidence of effectiveness	November 2021

2022 Biennial Review
Trabecular bone score

Codes:

1) **77089**: Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture-risk
2) **77090:** Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical preparation and transmission of data for analysis to be performed elsewhere
3) **77091**: Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical calculation only
4) **77092**: Trabecular bone score (TBS), structural condition of the bone microarchitecture; interpretation and report on fracture-risk only by other qualified health care professional

Similar codes: DEXA scans (CPT 77080-77081) are the standard test for bone density and are on the DIAGNOSTIC PROCEDURES file

Description: Bone strength is determined by bone mineral density (BMD) and non-BMD skeletal properties, such as bone geometry, mineralization, microdamage, remodeling, and microarchitecture. Trabecular bone score is a textural index that evaluates pixel gray level variations in the lumbar spine (LS) image by dual-energy X-ray absorptiometry (DXA). It provides an indirect assessment of trabecular microarchitecture that is an independent predictor of fracture risk. TBS is included as a risk factor with the fracture risk tool, FRAX, and may influence treatment decisions by altering the estimated 10-yr fracture probability. TBS has been cleared by the US Food and Drug Administration for use as a complement to DXA analysis and clinical examination for assessment of fracture risk and monitoring the effects of therapy

Evidence:

1) **Rajan 2020:** review of trabecular bone score
    a. TBS is associated with incident vertebral, hip and major osteoporotic fractures in postmenopausal women and in men greater than 50 years of age. TBS may be used to adjust FRAX probabilities of fracture, though data available till date doesn't support any additional benefit.

   b. Though TBS predicts fracture risk independently in both genders, with the currently available data, it cannot be recommended as a standalone tool for decision regarding treatment of osteoporosis. TBS can be used as a tool to complement BMD in assessment of bone health. Additional studies are needed to assess its utility in clinical practice.

2) **Viswanathan 2018**: Screening to Prevent Osteoporotic Fractures: An Evidence Review for the U.S. Preventive Services Task Force
   a. Accuracy of Bone Measurement Tests Used to Predict Fracture:
      i. The AUCs of machine-based tests, including centrally measured DXA (areal bone mineral density and trabecular bone score) and calcaneal quantitative ultrasound, for predicting fractures ranged from 0.59 to 0.86 (21 studies).
      ii. Regarding type of bone test, AUC estimates for fracture prediction based on centrally measured DXA BMD, trabecular bone score, or a combination of both were as follows: any osteoporotic fracture (0.63 to 0.74), vertebral or spine fracture (0.61 to 0.75), and hip (0.64 to 0.85). The AUC estimate of hip fracture based on DXL was 0.61.
   b. Other Measures of Test Performance:
      i. One study evaluated reclassification arising from adding trabecular bone score to spine BMD in a sample of 665 Japanese women age 50 years or older who completed the baseline study and at least one followup survey over 10 years. The study reported no significant differences in AUC, but reported an NRI of 0.235 (95% CI, 0.15 to 0.54); no risk categories were specified for the NRI. This finding can potentially be explained by chance (given the small sample size) or miscalibration.

<u>Expert guidelines</u>:

1) **USPSTF 2016** screening for osteoporosis
   a. Among different bone measurement tests performed at various anatomical sites, bone density measured at the femoral neck by dualenergy x-ray absorptiometry (DXA) is the best predictor of hip fracture and is comparable to forearm measurements for predicting fractures at other sites. Other technologies for measuring peripheral sites include quantitative ultrasonography (QUS), radiographic absorptiometry, single energy x-ray absorptiometry, peripheral dual-energy x-ray absorptiometry, and peripheral quantitative computed tomography
   b. Trabecular bone score is not mentioned

2) **Krohn 2019,** International Society of Clinical Densitometry official position on trabecular bone score
   a. TBS should not be used alone to determine treatment recommendations in clinical practice.
   b. TBS can be used in association with FRAX and BMD to adjust FRAX-probability of fracture in postmenopausal women and older men.
   c. TBS is not useful for monitoring bisphosphonate treatment in postmenopausal women with osteoporosis.
   d. TBS is potentially useful for monitoring anabolic therapy.
   a. TBS is associated with major osteoporotic fracture risk in postmenopausal women with type II diabetes

2022 Biennial Review
Trabecular bone score

Other payer policies:

1) **Aetna 2021**
    a. Aetna considers tomosynthesis-based trabecular bone analysis for determination of bone strength in person with diabetes mellitus experimental and investigational because the effectiveness of this approach has not been established.
2) **Cigna 2021**
    a. Trabecular bone score not listed as a covered test of osteoporosis screening

Expert input

Dr. Eric Orwoll, osteoporosis expert at OHSU

I think you should give serious consideration to covering it, at least in certain situations.

From the Kennel article: "Although derived from standard DXA images, the information procured from TBS is independent from and is complementary to the information provided by both BMD assessment and the World Health Organization (WHO) Fracture Risk Assessment (FRAX) algorithm. Further, the incorporation of TBS into the FRAX algorithm generates TBS-adjusted fracture risks that have been shown to be more accurate than use of the standard FRAX tool alone. This is of significant clinical value in high risk populations in whom there has been shown to be discrepancy between the estimated risk of fracture as assessed by FRAX/BMD and the observed fracture incidence, such as occurs in patients with type 2 diabetes mellitus or chronic kidney disease."

Of course the USPSTF won't be easily ready to endorse it since they are extremely conservative and usually quite behind clinical practice

2022 Biennial Review
Trabecular bone score

HERC staff summary

Trabecular bone score has been used to screen for osteoporosis, but its use in clinical care has not yet been determined. Private payers with identified policies do not appear to be covering this test.

HERC staff recommendation:

1) Add the following CPT codes to line 662 and add an entry to GN173 as shown below
    a. **77089**: Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture-risk
    b. **77090:** Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical preparation and transmission of data for analysis to be performed elsewhere
    c. **77091**: Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical calculation only
    d. **77092**: Trabecular bone score (TBS), structural condition of the bone microarchitecture; interpretation and report on fracture-risk only by other qualified health care professional

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
77089-77092	Trabecular bone score	Insufficient evidence of effectiveness	November 2021

2022 CPT Code Review
Genetics Related Codes

1) **81349**: Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number and loss-of-heterozygosity variants, low-pass sequencing analysis
    a. Similar codes
        i. DIAGNOSTIC PROCEDURES file
            1. 81228: Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (eg, bacterial artificial chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis)
            2. 81229: Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities
            3. Note: entry in Diagnostic Guideline D1, NON-PRENATAL GENETIC TESTING GUIDELINE
                a. 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:
                    i. 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
            4. Note: entry in Diagnostic Guideline D17 PRENATAL GENETIC TESTING
                a. H) Array CGH (CPT 81228, 81229) when major fetal congenital anomalies are apparent on imaging, or with normal imaging when array CGH would replace karyotyping performed with CVS or amniocentesis in (G) above
        ii. On line 662/GN173
            1. 81277: Cytogenomic neoplasia (genome-wide) microarray analysis, interrogation of genomic regions for copy number and loss-of-heterozygosity variants for chromosomal abnormalities
                a. Note: this is an oncology test on cancer tissue
            2. 81425-81427: Whole genome sequencing
    b. GAP input:
        i. 81228 (DMAP fee $630) and 81229 (DMAP fee $812) are performed using cytogenetic microarrays, to detect copy number variants (CNVs, deletions and duplications not detectable on karyotype),and loss of heterozygosity across the whole genome. Coverage for these services is currently addressed in GN D1 for

intellectual disabilities, and in D17 for use on fetal tissue from amniocentesis or chorionic villi, when fetal anomalies are seen on ultrasound. In practice, I have not seen a request for 81228 for a few years, it seems to have been entirely replaced by the higher resolution 81229 which can detect single nucleotide polymorphisms (SNPs). I guess this is because of advances in chip design and processing hardware and software. I suppose its okay to leave both codes in place, though one is seldom used. Thermo-Fisher is a major vendor in the microarray space. Early iterations of Next Generation Sequencing could not reliably detect CNVs, so a microarray was needed in addition, usually performed first and then sequencing if the microarray did not answer the clinical question. My impression is that now the bioinformatics have evolved to the point where CNVs can be detected in genome sequence data. My question about the new 81349 code is whether it represents CNV testing using microarray, like 81228 and 81229, or if it pulls CNV, loss of heterozygosity, etc off of NGS data

ii. Despite several staff attempts to get input from the OHSU genetics lab, no input was received.

a. <u>HERC staff recommendation</u>

iii. Place CPT 81349 on the DIAGNOSTIC PROCEDURES file

iv. Modify Diagnostic Guideline D1 as shown below (note other changes to this guideline as proposed in other issues at this meeting)

v. Modify Diagnostic Guideline D17 as shown below (note other changes to this guideline as proposed in other issues at this meeting)

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.

D) 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 and 81349, 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.

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

e) CPT 81225-81227, 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 in the FDA labeling (e.g. psychiatric, anticoagulant, opioids).

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

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

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

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

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

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

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

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

n) CPT 81415-81416, exome testing: A genetic counseling/geneticist consultation is required prior to ordering test
o) CPT 81430-81431, Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel: Testing for mutations in GJB2 and GJB6 need to be done first and be negative in non-syndromic patients prior to panel testing.
p) CPT 81440, 81460, 81465, mitochondrial genome testing: A genetic counseling/geneticist or metabolic consultation is required prior to ordering test.
q) CPT 81412 Ashkenazi Jewish carrier testing panel: panel testing is only covered when the panel would replace and would be similar or lower cost than individual gene testing including CF carrier testing.

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

DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING
The following types of prenatal genetic testing and genetic counseling are covered for pregnant women:

A) Genetic counseling (CPT 96040, HPCPS S0265) for high-risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect.
B) Genetic counseling (CPT 96040, HPCPS S0265) prior to consideration of chorionic villus sampling (CVS), amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening
C) Validated questionnaire to assess genetic risk in all pregnant women
D) Screening for hemoglobinopathies (CPT 83020, 83021)
E) Screening for aneuploidy with any of six screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, contingency, and cell free fetal DNA testing] (CPT 76813, 76814, 81508, 81510, 81511, 81420, 81507, 81512, 82105, 82677, 84163)
F) Ultrasound for structural anomalies between 18 and 20 weeks gestation (CPT 76811, 76812)
G) CVS or amniocentesis (CPT 59000, 59015, 76945,76946, 82106, 88235, 88261-88264, 88267, 88269, 88280, 88283, 88285, 88289,88291) for a positive aneuploidy screen, maternal age >34, fetal structural anomalies, family history of inheritable chromosomal disorder or elevated risk of neural tube defect
H) Array CGH (CPT 81228, 81229, 81349) when major fetal congenital anomalies are apparent on imaging, or with normal imaging when array CGH would replace karyotyping performed with CVS or amniocentesis in (G) above
I) FISH testing (CPT 88271, 88272, 88274, 88275, 81171, 81172) only if karyotyping is not possible due a need for rapid turnaround for reasons of reproductive decision-making (i.e. at 22w4d gestation or beyond)
J) Screening for cystic fibrosis carrier status once in a lifetime (CPT 81220-81224)
K) Screening for fragile X status (CPT 81243, 81244, 81171, 81172) once in a lifetime
L) Screening for spinal muscular atrophy (CPT 81329) once in a lifetime
M) Screening for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255) once in a lifetime. Ashkenazi Jewish carrier panel testing (CPT 81412)

is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing

N) Expanded carrier screening only for those genetic conditions identified above

The following genetic screening tests are not covered:

A) Serum triple screen
B) Expanded carrier screening which includes results for conditions not explicitly recommended for coverage

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

2022 CPT Code Review
Laboratory Test Codes

1) **81560** Transplantation medicine (allograft rejection, pediatric liver and small bowel), measurement of donor and third-party-induced CD154+T-cytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score
    a. Similar codes: none
    b. Description: This code represents the Pleximmune test, which predicts acute cellular rejection in children with liver- or intestine transplantation and is intended to assist in the management of immunosuppression
    c. Evidence
        i. **Sindhi 2015**, profile of Pleximmune
            1. Pleximmune test sensitivity and specificity for predicting acute cellular rejection is 84% and 81% respectively in training set–validation set testing of 214 children
        ii. **Kohut 2020**, review of biomarkers for liver transplant rejection
            1. Honorable mention should be made to the development of a cell-based assay measuring allospecific CD154+T-cytotoxic memory cells expressed as an immunoreactivity index to predict ACR. This test, Pleximmune (Plexision Inc., Pittsburgh, PA), is the first cell-based test approved by the US Food and Drug Administration that predicts ACR in children who received LT or intestine transplantation. This test while holding tremendous potential has not been widely adopted into clinical practice.
    d. Other payer policies:
        i. **Aetna 2021**: Aetna considers the Pleximmune test experimental and investigational for prediction of acute cellular rejection in children with liver or intestine transplantation and all other indications because its clinical value has not been established.
    e. HERC staff summary: appears to be experimental
    f. HERC staff recommendation:
        i. Add CPT **87154:** to line 662 and add an entry to 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 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
81560	Transplantation medicine (allograft rejection, pediatric liver and small bowel), measurement of donor and third-party-induced CD154+T-cytotoxic memory cells,	Insufficient evidence of effectiveness	November 2021

	utilizing whole peripheral blood, algorithm reported as a rejection risk score		

2) **82653:** Elastase, pancreatic (EL-1), fecal; quantitative:
   a. Similar code: 82656 (Elastase, pancreatic (EL-1), fecal, qualitative or semi-quantitative) is Diagnostic
   b. Description: Measurement of the pancreatic enzyme elastase, which is a measure of exogenous pancreatic enzyme function. If low, a patient may need enzyme supplementation. This occurs frequently in diseases such as cystic fibrosis
   c. HERC staff recommendation: DIAGNOSTIC PROCEDURES

3) **83521:** Immunoglobulin light chains (ie, kappa, lambda), free, each
   a. Similar code: currently uses the genetic code 83520 (Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified)
   b. Description: test for diseases such as multiple myeloma, amyloidosis, and Waldenstrom macroglobulinemia
   c. HERC staff recommendation: DIAGNOSTIC PROCEDURES

4) **83529**: Interleukin-6 (IL-6)
   a. Similar code(s): none
   b. Description: pro-inflammatory cytokine being studied for use as an inflammatory marker for autoimmune and inflammatory diseases such as multiple sclerosis, atherosclerosis, lupus, etc. The drug tocilizumab is an interleukin-6 receptor antagonist
   c. Evidence
      i. **Franco 2019**, Cochrane review of IL-6 for diagnosis of sepsis in critically ill adults
         1. N=23 studies (4192 patients) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6490303/pdf/CD011811.pdf
         2. Using a fixed prevalence of sepsis of 50% and a fixed specificity of 74%, we found a sensitivity of 66% (95% confidence interval 60 to 72).
         3. Our evidence assessment of plasma interleukin-6 concentrations for the diagnosis of sepsis in critically ill adults reveals several limitations. High heterogeneity of collected evidence regarding the main diagnosis, setting, country, positivity threshold, sepsis criteria, year of publication, and the origin of infection, among other factors, along with the potential number of misclassifications, remain significant constraints for its implementation
      ii. **Wang 2013**, systematic review and meta-analysis of inflammatory markers and risk of type 2 diabetes
         1. N=10 prospective cohort studies (19,709 patients)
         2. detected a significant dose-response association of IL-6 levels with type 2 diabetes risk (relative risk [RR] 1.31 [95%CI 1.17–1.46]).

3. CONCLUSIONS: This meta-analysis provides further evidence that elevated levels of IL-6 and CRP are significantly associated with increased risk of type 2 diabetes.

d. Other payer policies:
   i. **Aetna 2021:** IL-6 is experimental for the diagnosis of inflammatory bowel disease and rheumatic diseases
e. HERC staff summary: IL-6 testing appears to be experimental
f. HERC staff recommendation:
   i. Add CPT 83529 to line 662 and add an entry to 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 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
83529	Interleukin-6 (IL-6)	Insufficient evidence of effectiveness	November 2021

5) **86015**: Actin (smooth muscle) antibody (ASMA), each
   a. Similar code(s): none
   b. Description: used as a diagnostic test for autoimmune hepatitis
   c. Other payer policies:
      i. Aetna 2021: ASMA is experimental for the diagnosis of inflammatory bowel disease but may be medically necessary to diagnose autoimmune hepatitis
   d. HERC staff recommendation: DIAGNOSTIC PROCEDURES

6) **86036**: Antineutrophil cytoplasmic antibody (ANCA); screen, each antibody and **86037**: Antineutrophil cytoplasmic antibody (ANCA); titer, each antibody
   a. Similar code(s): none
   b. Description: used to diagnose polyarteritis nodosa, microscopic polyangiitis, and similar autoimmune vasculitis disorders
   c. HERC staff recommendation: DIAGNOSTIC PROCEDURES

7) **86051**: Aquaporin-4 (neuromyelitis optica [NMO]) antibody; enzyme-linked immunosorbent immunoassay (ELISA); **86052**: Aquaporin-4 (neuromyelitis optica [NMO]) antibody; cell-based immunofluorescence assay (CBA), each; **86053**: Aquaporin-4 (neuromyelitis optica [NMO]) antibody; flow cytometry (ie, fluorescence-activated cell sorting [FACS]), each
   a. Similar code(s): none
   b. Description: NMO antibodies help to diagnose neuromyelitis optica, an autoimmune disease of the CNS, and to distinguish this condition from multiple sclerosis
   c. HERC staff recommendation: DIAGNOSTIC PROCEDURES

8) **86231**: Endomysial antibody (EMA), each immunoglobulin (Ig) class; **86258:** Gliadin (deamidated) (DGP) antibody, each immunoglobulin (Ig) class; **86364**: Tissue transglutaminase, each immunoglobulin (Ig) class
    a. Similar code(s): none
    b. Description: serum tests used in the diagnosis of celiac disease and to determine the adherence to a gluten free diet
    c. Expert guidelines:
        i. **American College of Gastroenterology 2013**, guideline for the diagnosis and management of celiac disease
            1. Immunoglobulin A (IgA) anti-tissue transglutaminase (TTG) antibody is the preferred single test for detection of CD in individuals over the age of 2 years. (Strong recommendation, high level of evidence)
            2. In patients in whom low IgA or selective IgA deficiency is identified, IgG-based testing (IgG DGPs and IgG TTG) should be performed. (Strong recommendation, moderate level of evidence)
            3. EMA IgG is not widely available
            4. A positive CD-specific serology (TTG, DGP, and EMA) in patients with villous atrophy confirms the diagnosis of CD
            5. Both EMA and DGP are listed in their diagnostic flowchart for evaluation of suspected celiac disease
        ii. **NICE 2015**, assessment and management of celiac disease https://www.nice.org.uk/guidance/ng20/resources/coeliac-disease-recognition-assessment-and-management-pdf-1837325178565
            1. When healthcare professionals request serological tests to investigate suspected coeliac disease in young people and adults, laboratories should:
                a. test for total immunoglobulin A (IgA) and IgA tissue transglutaminase (tTG) as the first choice
                b. use IgA endomysial antibodies (EMA) if IgA tTG is weakly positive
                c. consider using IgG EMA, IgG deamidated gliadin peptide (DGP) or IgG tTG if IgA is deficient
    d. HERC staff recommendation: DIAGNOSTIC PROCEDURES

9) **86362**: Myelin oligodendrocyte glycoprotein (MOG-IgG1) antibody; cell-based immunofluorescence assay (CBA), each; **86363**: Myelin oligodendrocyte glycoprotein (MOG-IgG1) antibody; flow cytometry (ie, fluorescence-activated cell sorting [FACS]), each
    a. Similar code(s): none
    b. Description: Myelin oligodendrocyte glycoprotein antibody disorders (MOGAD) is an idiopathic, inflammatory, demyelinating disease of the central nervous system (CNS). Diagnostic criteria for MOGAD include serum positive MOG-IgG by cell based assay, as well as clinical findings such as optic neuropathy or transverse myelitis
    c. HERC staff recommendation: DIAGNOSTIC PROCEDURES

10) **86381**: Mitochondrial antibody (eg, M2), each
    a. Similar code(s): none
    b. Description: test used to diagnostic primary biliary cholangitis
    c. HERC staff recommendation: DIAGNOSTIC PROCEDURES

11) **86596**: Voltage-gated calcium channel antibody, each
    a. Similar code(s): none
    b. Description: used to diagnose Lambert-Eaton myasthenic syndrome, a rare autoimmune disorder of the neuromuscular junction. This testing is required by many insurers prior to treatment with Firdapse or Ruzurgi
    c. HERC staff recommendation: DIAGNOSTIC PROCEDURES

12) **87154:** Culture, typing; identification of blood pathogen and resistance typing, when performed, by nucleic acid (DNA or RNA) probe, multiplexed amplified probe technique including multiplex reverse transcription, when performed, per culture or isolate, 6 or more targets
    a. Similar code(s): none
    b. Description: Several proprietary tests are on the market (e.g. FilmArray, BioFire, Sepsityper) which identify multiple pathogens and test for antibiotic resistance genes. These tests allow rapid identification of pathogens in patients with sepsis compared to the normal 2 day blood culture and sensitivity tests.
    c. Evidence
        i. **Robinson 2021,** clinical impact of rapid species identification
            1. Pre-post observational study
            2. N=514 patients
            3. Median time to antimicrobial susceptibility testing (AST) results decreased 29.4 hours ($P < .001$) post-intervention, Utilization (days of therapy [DOTs]/1000 days present) of broad-spectrum agents decreased (PRE 655.2 vs POST 585.8; $P = .043$) and narrow-spectrum beta-lactams increased (69.1 vs 141.7; $P < .001$). Discrepant results occurred in 69/250 (28%) post-intervention episodes, resulting in incorrect antibiotic stewardship program recommendations in 10/69 (14%).
            4. No significant differences in secondary clinical outcomes including in-hospital and 30-day mortality, length of stay, C difficile infection, readmission, or relapse of BSI were observed
        ii. **Ehren 2020**, clinical impact of rapid species identification
            1. Before-after observational study
            2. N=264 patients (64 conventional testing, 68 conventional testing + rapid testing, 72 rapid diagnostics)
            3. Time to identification of species significant reduced, as well as time to step-down antimicrobial therapy. However, groups did not differ in antimicrobial consumption, duration of antimicrobial therapy, mortality, length of stay, or incidence of C difficile infection.
    d. Expert guidelines

i. **Barlam 2015**, IDSA guideline on implementing an antibiotic stewardship program
   1. Should ASPs Advocate for Rapid Diagnostic Testing on Blood Specimens to Optimize Antibiotic Therapy and Improve Clinical Outcomes?
      a. We suggest rapid diagnostic testing in addition to conventional culture and routine reporting on blood specimens if combined with active ASP support and interpretation (weak recommendation, moderate-quality evidence).
      b. Comment: Availability of rapid diagnostic tests is expected to increase; thus, ASPs must develop processes and interventions to assist clinicians in interpreting and responding appropriately to results.

e. Expert input: John Townes, OHSU head of infectious disease felt that these tests might be beneficial from an infection control and antibiotic stewardship perspective

f. HERC staff summary: rapid pathogen testing appears to be a promising technology for antibiotic stewardship; however, the evidence to date does not appear to show that these tests affect clinical outcomes. These tests have a weak recommendation for coverage by the IDSA.

g. HERC staff recommendation:
   i. Add CPT **87154:** to line 662 and add an entry to GN173 as shown below
      1. Alternative: place on the Diagnostic Procedures File as likely only to be used in ICU situations where they would be covered as part of DRG

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
87154	Culture, typing; identification of blood pathogen and resistance typing, when performed, by nucleic acid (DNA or RNA) probe, multiplexed amplified probe technique including multiplex reverse transcription, when performed, per culture or isolate, 6 or more targets	Insufficient evidence of effectiveness	November 2021

Remote Therapeutic Monitoring

Codes:

1) **98975**: Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment
2) **98976**: Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days
3) **98977**: Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days
4) **98980**: Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes
5) **98981**: Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes

Similar codes:

1) Remote monitoring on lines 9,20,48,58,69,75,81,97,98,110,172,189,202,213,219,222, 223, 225, 233, 257, 264, 281, 283, 304, 341, 347,366,464,566,635,647,653,657
    a. 99453: Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment
    b. 99457: Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes
    c. 99458: Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)
2) Remote monitoring on line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS
    a. 99454: Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days

Description: CMS recently created remote therapeutic monitoring (RTM) codes, which are very similar to the remote physiologic monitoring (RPM) codes that were published in 2020.

CMS has identified some key differences between these codes.

1) RTM codes allow collection of non-physiologic data such as therapy adherence and response that are not included in the RPM codes.

2) RTM codes allow only for monitoring of respiratory and musculoskeletal system data, where RPM codes do not specify systems and could be used for cardiovascular, endocrine, and other system data
3) RTM allow data to be self-reported by the patient or reported by a device, while RPM codes require data to be reported by a device
4) Three of the RTM codes (98975-98977) are intended to be reported by nurses, speech therapists, nurse practictioners, physical therapists, and other providers who cannot report RPM codes. These are considered Practice Expense (PE) codes.

In July 2021, CMS published a proposed rule stating: "primary billers of RTM codes are projected to be nurses and physical therapists… In our review of the new codes, we identified an issue that disallows physical therapists and other practitioners, who are not physicians or NPPs, to bill the RTM codes." CMS considers all five codes to be "incident to" services.

In November 2021, according to the final rule published by CMS, primary billers for these codes have been finalized as "therapists and other qualified healthcare professionals to bill the RTM codes as described. However, where the practitioner's Medicare benefit does not include services furnished incident to their professional services, the items and services described by these codes must be furnished directly by the billing practitioner or, in the case of a PT or OT, by a therapy assistant under the PT's or OT's supervision."

CMS finalized RVUs for these five codes, designating CPT 98980 and 98981 to have similar RVUs to CPT 99457 and 99458 to maintain parity between RTM and RPM. However, CMS notes "The treatment management RTM codes (CPT codes 98980 and 98981), because they are not E/M codes, cannot be designated as care management services." Code 98975 was cross-walked to the PE RVU of CPT 99453 and codes 98976-77 were cross-walked to the PE RVU of 99454.

However, CMS is unclear on what types of devices or equipment are meant to be represented by these codes. Their proposed rule stated they are "seeking comment on the typical type of device(s) and associated costs of the device(s) that might be used to collect the various kinds of data included in the code descriptors (for example, respiratory system status, musculoskeletal status, medication adherence, pain) for the RTM services." CMS notes that for these codes a "device used must meet the FDA definition of a medical device." There was no clarification provided in the final rule released on 11/3/2021.

HERC staff recommendations:

1) Advise HSD to place the following codes on the EXLCUDED filed until CMS clarifies utilization and definition of included devices
    a. **98975**: Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment
    b. **98976**: Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days
    c. **98977**: Remote therapeutic monitoring (eg, respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled

(eg, daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days

d. **98980**: Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes
e. **98981**: Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes

2022 CPT Code Review
New Vaccine Codes

Codes

1) **90626**: Tick-borne encephalitis virus vaccine, inactivated; 0.25 mL dosage
2) **90627**: Tick-borne encephalitis virus vaccine, inactivated; 0.5 mL dosage
3) **90671:** Pneumococcal conjugate vaccine, 15 valent (PCV15)
4) **90677**: Pneumococcal conjugate vaccine, 20 valent (PCV20)
5) **90758**: Zaire ebolavirus vaccine, live,
6) **90759**: Hepatitis B vaccine (HepB), 3-antigen (S, Pre-S1, Pre-S2), 10 mcg dosage, 3 dose schedule

Information

1) Tick borne encephalitis virus vaccine
    a. Information from the CDC website (accessed October 11, 2021):
        i. Tick-borne encephalitis, or TBE, is a human viral infectious disease involving the central nervous system. TBE is caused by the tick-borne encephalitis virus (TBEV), a member of the family *Flaviviridae*. Three virus sub-types are described: European or Western tick-borne encephalitis virus, Siberian tick-borne encephalitis virus, and Far eastern Tick-borne encephalitis virus (formerly known as Russian Spring Summer encephalitis virus, RSSEV).
        ii. On August 13, 2021, the Food and Drug Administration approved a tick-borne encephalitis (TBE) vaccine, TICOVAC™, manufactured by Pfizer. The vaccine is an inactivated vaccine that has been licensed and used in Europe for about 20 years. The vaccine has both pediatric and adult formulations and is the only one currently licensed in the United States. An Advisory Committee on Immunization Practices (ACIP) Work Group was formed in 2020 to discuss the use of TBE vaccine in children and adults traveling to or residing in areas at risk and in laboratory workers. The Work Group is currently reviewing the epidemiology of TBE among travelers and laboratory workers, and data on the safety and effectiveness of the TBE vaccine. The Work Group is developing evidence-based recommendations for consideration by ACIP which will likely be approved in 2022
    b. 15 and 20 valent pneumococcal conjugate vaccines
        i. Two new pneumococcal vaccines received FDA approval in July 2021.
            1. PCV20 is a Pfizer product
            2. PCV15 is a Merck product
        ii. According to the ACIP website, these vaccines were initially scheduled to be reviewed at the February, June and October 2021 ACIP meetings. However, no discussion has actually occurred to date at ACIP.
        iii. The official ACIP vaccine recommendations remain only for the 13 and 23 valent vaccines.
    c. Ebola vaccine
        i. This is considered a travel vaccine due to the fact that Ebola is only currently found in certain areas of Africa
        ii. According to the CDC (webpage accessed October 10, 2021), the Ebola vaccine is only for health care providers caring for Ebola patients at federally designated Ebola Treatment centers and biosafety level 4 workers
    d. Hepatitis B vaccine (HepB), 3-antigen (S, Pre-S1, Pre-S2)
        i. VBI product

ii. Currently ACIP only recommends Engerix, Hepisav-B, Recombivax HB (all appear to be single antigen vaccines) as well as Pediarix and Twinrix (combination vaccines)

<u>HERC staff recommendation:</u>

1) Place all of the following codes on the EXCLUDED FILE
    a. **90626**: Tick-borne encephalitis virus vaccine, inactivated; 0.25 mL dosage
    b. **90627**: Tick-borne encephalitis virus vaccine, inactivated; 0.5 mL dosage
    c. **90671:** Pneumococcal conjugate vaccine, 15 valent (PCV15)
    d. **90677**: Pneumococcal conjugate vaccine, 20 valent (PCV20)
    e. **90758**: Zaire ebolavirus vaccine, live
    f. **90759**: Hepatitis B vaccine (HepB), 3-antigen (S, Pre-S1, Pre-S2), 10 mcg dosage, 3 dose schedule
2) HSD can move to covered status if/when ACIP approval is received. HERC can then act to add the vaccine to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
    a. Note: the Ebola vaccine is considered a travel vaccine and will remain on the EXCLUDED FILE

1) HCPCS **C1832** Autograft suspension, including cell processing and application, and all system components
    a. Description: this HCPCS code describes the creation and application of epidermal autographs. This procedure is done with the RECELL® Autologous Cell Harvesting Device. Autologous skin cell suspension has been studied for the treatment of burns, diabetic foot ulcers, and venous ulcers. The purported advantage to autologous skin cell suspension is the reduction in donor site morbidity.
        i. From the FDA (2021):
            1. RECELL® is a single-use, stand-alone, battery-operated, autologous cell harvesting device containing enzymatic and delivery solutions, sterile surgical instruments, and actuators. The RECELL Device enables a thin split-thickness skin sample to be processed to produce a RES® Regenerative Epidermal Suspension for immediate delivery onto a prepared wound bed. The cell suspension contains a mixed population of cells, including keratinocytes, fibroblasts, and melanocytes, obtained from the disaggregation of the skin sample. The preservation of melanocytes is important for restoring natural pigmentation to the recipient area. Additionally, sub-populations of keratinocytes critical for re-epithelialization have been identified in RES including basal keratinocytes, suprabasal keratinocytes, and activated keratinocytes.
            2. The RECELL Autologous Cell Harvesting Device is indicated for the treatment of acute thermal burn wounds. The RECELL Device is used by an appropriately-licensed healthcare professional at the patient's point of care to prepare autologous RES® Regenerative Epidermal Suspension for direct application to acute partial-thickness thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients.
    b. Evidence
        i. NOTE: due to the limited FDA approval of this technology (autologous skin cell suspension is only FDA approved for treatment of burns and then only when used with split thickness skin grafts), only this limited indication was researched
        ii. **Barnett 2021,** a pilot study of autologous skin cell suspension for hand burns
            1. Retrospective cohort study, N=59 patients
                a. N=37 treated with autologous skin cell suspension ASCS) with split-thickness skin grafting (STSG)
                b. N=22 treated with split thickness skin grafting alone
            2. There was no difference in time to wound re-epithelialization between both groups (ASCS, 11 ± 4 days vs STSG, 11 ± 5 days). Mean length-of-stay was 23 ± 13 days compared to 10 ± 13 days ($P < .05$) between the ASCS and STSG groups, respectively. No patients in the ASCS group required reoperation, whereas 2 patients in the STSG group required such for an infection-related graft loss and a web space contracture release.
        iii. **Kowal 2019**, cost effectiveness of use of autologous cell harvesting devices compared to standard wound care in the US
            1. Modeling study

2. ASCS treatment is cost-saving or cost neutral (<2% difference) and results in lower LOS compared to SOC across expected patient profiles and scenarios. In aggregate, ASCS treatment saves a burn center 14–17.3% annually. Results are sensitive to, but remain robust across, changing assumptions for relative impact of ASCS use on LOS, procedure time, and number of procedures

c. HERC staff summary: autologous skin cell suspension is experimental for the FDA approved indication of treatment of burns

d. HERC staff recommendation

i. Place HCPCS C1832 on line 662/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 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
C1832	Autograft suspension, including cell processing and application, and all system components	Insufficient evidence of effectiveness	November, 2021

2) HCPCS **C1833** Monitor, cardiac, including intracardiac lead and all system components (implantable)

a. Description: Implantable cardiac monitors utilize electrogram devices to record cardiac data and detect ischemic events in patients who have had prior acute coronary syndrome (ACS) events and who remain at high risk for recurrent ACS events. The devices are intended to provide an early warning of ischemic events and to minimize the time between ischemic event onset and medical care.

b. Evidence:

i. **Gibson 2019**, ALERTS trial

1. Industry sponsored randomized trail of implantable cardiac monitors
2. N=907 patients at high risk for acute cardiac events
    a. N=437 had the alarms activated immediately, N=446 had alarms activated after 6 months
3. Primary study safety endpoint was absence of system-related complications. Primary efficacy endpoint was a composite of cardiac/unexplained death, new Q-wave myocardial infarction, or detection to presentation time >2 hours
4. Safety: 31 system related complications were reported in 30 patients (3.3%). Complications included infections, pain, device malfunction, and device erosion
5. The efficacy endpoint for a confirmed occlusive event within 7 days was not significantly reduced in the treatment compared with control group (16 of 423 [3.8%] vs. 21 of 428 [4.9%], posterior probability ¼ 0.786).

Within a 90-day window, alarms significantly decreased detection to arrival time at a medical facility (51 min vs. 30.6 h; Pr [pt < pc] >0.999).

6. Conclusion: Overall, the implantable cardiac system was safe, and the rate of complications was low. However, the ALERTS trial failed to meet the pre-specified primary efficacy endpoint of the randomized trial.

c. Other payer policies: no private payer surveyed is covering this technology
d. HERC staff summary: intracardiac ischemia monitoring is experimental
e. HERC staff recommendation
    i. Place HCPCS C1833 on line 662/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 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
C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)	Insufficient evidence of effectiveness	November, 2021

3) HCPCS **G0465** Autologous platelet rich plasma (prp) for diabetic chronic wounds/ulcers, using an fda-cleared device (includes administration, dressings, phlebotomy, centrifugation, and all other preparatory procedures, per treatment)
    a. Similar code: G0460 (Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment)
    b. G0460 was reviewed in May, 2021. Based on that review, G0460 was placed on line 662/GN173.
        i. Staff summary: Platelet rich plasma has moderate evidence of effectiveness for increasing the healing rate and reducing the healing time for chronic lower extremity diabetic ulcers. Evidence is insufficient to estimate the effect of PRP on important outcomes such as pain, hospitalization, amputations and wound recurrence for diabetic ulcers. There is also insufficient evidence for the use of platelet rich plasma for non-diabetic chronic wounds. One highly regarded evidence-based source (AHRQ) found moderate SOE for use of PRP for diabetic lower extremity ulcers; however, another highly regarded evidence based source (NICE) does not recommend PRP for this indication. Currently, no private insurer surveyed is covering PRP for any indication, although this may change in the future based on the 2021 CMS decision.
    c. HERC staff summary: there is insufficient evidence regarding the efficacy of platelet rich plasma as a treatment for diabetic wounds/ulcers
    d. HERC staff recommendation:
        i. Place HCPCS G0465 on line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR

HAVE HARMS THAT OUTWEIGH BENEFITS and modify the GN173 entry for this technology as shown below

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

Line 662

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

Procedure Code	Intervention Description	Rationale	Last Review
G0460 G0465	Autologous platelet rich plasma for diabetic or non-diabetic chronic wounds/ulcers including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment	Insufficient evidence of effectiveness	May, 2021

Biennial Review 2024
Angioedema Line Removal

Question: Should the redundant angioedema line be struck through until the next biennial review?

Question source: Dr. Ben Hoffman, HERC staff

Issue: Dr. Ben Hoffman brought concerns to HERC staff that angioedema and biotinidase deficiency were both below the funding line. Biotinidase deficiency is an inborn error of metabolism that leads to severe developmental issues unless treated with a supplement. Angioedema is a condition in which medications, foods, or other triggers can cause swelling of the mucous membranes, airway, and GI tract. Angioedema can be life threatening when it causes airway obstruction.

On researching this question, HERC staff discovered that the lower line was completely redundant to another, covered line. Line 192 HEREDITARY ANGIOEDEMA contains all the diagnosis codes and all of the treatment codes included on line 487 ANGIOEDEMA. There is no guideline or other indication of when one of these diagnoses would be on a covered vs an uncovered line.

Lines 192 and 487 were created out of a split line (then line 343) during the 2012 ICD-10 review. The allergists who reviewed that line felt that hereditary angioedema was much more serious than angioneurotic edema and should be prioritized on separate lines. However, there is a single ICD-10 code for all forms of angioedema (ICD-10-CM T78.3XXA-T78.3XXD Angioneurotic edema). ICD-10 D84.1 (Defects in the complement system) also lists hereditary angioneurotic edema as a subdiagnosis. During the ICD-10 Allergy review, the allergists did note that angioneurotic edema has a variety of manifestations, including death.

Current Prioritized List status

ICD-10 Code	**Code Description**	**Current Placement**
D81.810	Biotinidase deficiency	60 METABOLIC DISORDERS 192 HEREDITARY ANGIOEDEMA 241 ACUTE AND SUBACUTE NECROSIS OF LIVER; SPECIFIED INBORN ERRORS OF METABOLISM (E.G., MAPLE SYRUP URINE DISEASE, TYROSINEMIA) 487 ANGIOEDEMA
D84.1	Defects in the complement system [hereditary angioneurotic edema listed as a subdiagnosis]	60,192,241 313 DISORDERS INVOLVING THE IMMUNE SYSTEM
T78.3	Angioneurotic edema	192, 487 Dysfunction lines (71, 292, 345, 377)

Biennial Review 2024
Angioedema Line Removal

Line: 192
Condition: HEREDITARY ANGIOEDEMA
Treatment: MEDICAL THERAPY
ICD-10: D81.810,D84.1,T78.3XXA-T78.3XXD
CPT: 98966-98972,99051,99060,99070,99078,99184,99202-99239,99281-99285,99291-99366, 99374-99404,99411-99416,99421-99429,99441-99449,99451,99452,99468-99472,99475-99480,99487-99491,99495-99498,99605-99607
HCPCS: G0068,G0071,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427,G0463-G0467, G0490,G0508-G0511,G2011,G2012,G2064,G2065

Line: 487
Condition: ANGIOEDEMA
Treatment: MEDICAL THERAPY
ICD-10: D81.810,T78.3XXA-T78.3XXD
CPT: 98966-98972,99051,99060,99070,99078,99184,99202-99239,99281-99285,99291-99404, 99411-99449,99451,99452,99468-99472,99475-99480,99487-99491,99495-99498,99605-99607
HCPCS: G0068,G0071,G0088-G0090,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427, G0463-G0467,G0490,G0508-G0511,G2011,G2012,G2064,G2065,G2211,G2212,G2214, G2251,G2252

HERC staff summary
Based on the ICD-10 Allergy review, two angioedema lines were created. However, these lines are completely redundant in terms of coding. In order to continue to have two lines, a guideline with extensive descriptions of the types of angioedema that are not covered would need to be created. HERC staff feels that as angioedema in some forms has the ability to cause death, it should be prioritized above the funding line. As a result, staff is recommending striking the lower line. This should have no effect on coverage, as the diagnosis and procedure code pairings on line 487 are all reproduced on line 192. Additionally, it can cause confusion to have a potentially life threatening condition appear to be non-funded.

Additionally, biotinidase deficiency has nothing to do with angioedema and should be removed from these lines and left only on the lines for inborn errors of metabolism.

HERC staff recommendations:
1) For the January 1, 2022 Prioritized List:
    a. Strike through line 487 ANGIOEDEMA
    b. Rename line 192 ~~HEREDITARY~~ ANGIOEDEMA
    c. Delete ICD-10-CM D81.810 (Biotinidase deficiency) from line 192 HEREDITARY ANGIOEDEMA
        i. Keep on the metabolic disorders lines
2) For the January 1, 2024 Prioritized List:
    a. Delete line 487

Platelet Rich Plasma

Question: Is platelet rich plasma covered for any indication on the Prioritized List?

Question source: Holly Jo Hodges, CCO medical director

Issue: Platelet-rich plasma (PRP) therapy uses injections of a concentration of a patient's own platelets to accelerate the healing of injured tendons, ligaments, muscles and joints. The mechanism of action of PRP is unclear.

Platelet rich plasma for treatment of knee osteoarthritis was reviewed as part of a coverage guidance and wording excluding it from use for this indication was put into a guideline. PRP for treatment of spinal conditions was added to Guideline Note 37 at the October, 2021 meeting. PRP for treatment of ulcers and wounds was discussed in May, 2021 but left on line 662/GN 173.

CCOs would like further direction on coverage, as they get frequent requests for coverage of PRP for a wide variety of indications. Currently, the only code for general PRP is a level III CPT code, 0232T INJECTION(S), PLATELET RICH PLASMA, ANY SITE, INCL. These types of codes are generally considered experimental by Medicaid and not placed on the Prioritized List.

PRP can be used to treat a wide variety of tendinopathies, tendon tears, joint inflammation, plantar fasciitis, osteoarthritis, low back pain, and other musculoskeletal conditions.

Current Prioritized List status

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

Lines 346,529

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

A) Decompressive surgery is included on Line 346 to treat debilitating symptoms due to central or foraminal spinal stenosis, and only when the patient meets the following criteria:
   1) Has MRI evidence of moderate or severe central or foraminal spinal stenosis AND
   2) Has neurogenic claudication OR
   3) Has objective neurologic impairment consistent with the MRI findings. Neurologic impairment is defined as objective evidence of one or more of the following:
      a) Markedly abnormal reflexes
      b) Segmental muscle weakness
      c) Segmental sensory loss
      d) EMG or NCV evidence of nerve root impingement
      e) Cauda equina syndrome
      f) Neurogenic bowel or bladder
      g) Long tract abnormalities

   Foraminal or central spinal stenosis causing only radiating pain (e.g. radiculopathic pain) is included only on Line 529.

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

2) spinal stenosis in the thoracic or lumbar spine caused by spondylolisthesis resulting in signs and symptoms of neurogenic claudication and which correlate with xray flexion/extension films showing at least a 5 mm translation OR
3) pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of facet joints per level expected to be resected)

For all other indications, spine surgery is included on Line 529.

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

- local injections (including ozone therapy injections)
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- percutaneous laser disc decompression
- radiofrequency denervation
- corticosteroid injections for cervical pain
- intradiscal injections, including platelet rich plasma, stem cells, methylene blue, or ozone

Corticosteroid injections for low back pain with or without radiculopathy are only included on Line 529. Diagnostic anesthetic injections for selective nerve root blocks are included on Line 529 for lumbar or sacral symptoms.

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

GUIDELINE NOTE 104, NEWER INTERVENTIONS FOR OSTEOARTHRITIS OF THE KNEE

Lines 431,463

The following treatments are not included on this line for osteoarthritis of the knee:

- Whole body vibration
- Glucosamine/chondrioitin (alone, or in combination)
- Platelet rich plasma
- Viscosupplementation
- Transcutaneous electrical stimulation (TENS)

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

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

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

Line 662

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

Procedure Code	Intervention Description	Rationale	Last Review
G0460	Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment	Insufficient evidence of effectiveness	May 2021

Platelet Rich Plasma

Evidence

1) **Nazaroff 2021,** systematic review of level I and II studies of platelet rich plasma therapy
    a. N=132 articles
        i. 28 different conditions across eight medical fields. Studies investigating PRP treatment for musculoskeletal (MSK) conditions comprised 74% of all studies. Tendinopathy (n = 29) and osteoarthritis (n = 28) were the two most commonly studied conditions. MSK studies were 76% level 1 evidence while 57% of all other studies were level 1 evidence (p<0.05). Cosmetic studies comprised 14% (n = 19) of all studies, and 53% of these were level I evidence.
        ii. Majority of studies were assessed using the Cochranes Risk of Bias Tool, 80% (n = 106). Among these studies, 30% (n = 32) were assessed to be "Low" risk of bias, 25% (n = 26) were found to have "Some Concerns", and 45% (n = 48) were assessed to be "High" risk of bias
    b. Overall, 61% of the studies found PRP to be favorable over control treatment, with no difference in favorable reporting between MSK and other medical specialties.
    c. Conclusions: In summary, the vast majority of level I and II clinical studies investigating PRP have been conducted for MSK injuries, with only a handful of studies conducted for conditions in other medical specialties. Studies that reported details on PRP processing and composition were in the minority, and PROMs were not often used as an outcome measure in non-MSK studies. Rigorous reporting in human clinical studies across all medical specialties is crucial for evaluating the effects of PRP and moving towards disease-specific and individualized treatment.
2) **Gato-Calvo 2019**, evidence review of platelet rich plasma for treatment of osteoarthritis
    a. N=5 systematic reviews and meta-analyses
        i. A total of 19 individual trials were identified in the five reviews but only 9 were level of evidence I RCTs, and many had moderate or high risks of bias.
    b. At present, results from these RCTs seem to favor PRP use over other intraarticular treatments to improve pain scales in the short and medium term (6–12months), but the overall level of evidence is low. As a result, clinical effectiveness of PRP for knee osteoarthritis treatment is still under debate. This is, prominently, the result of a lack of standardization of PRP products, scarceness of high quality RCTs not showing high risks of bias, and poor patient stratification for inclusion in the RCTs.
3) **Chen 2018**, systematic review and meta-analysis of platelet rich plasma on tendon and ligament healing
    a. N=21 studies (1031 patients)
        i. The majority of studies published investigated rotator cuff (38.1%) or lateral epicondylitis (38.1%).
        ii. Other included conditions: patellar tendinopathy (PT), achilles tendinopathy (AT), anterior cruciate ligament injury (ACL), and hamstring tendinopathy (HT).
    b. 17 studies (844 participants) reported short-term VAS data and 14 studies (771 participants) reported long-term VAS data. Overall, long-term follow-up results showed significantly less pain in the PRP group compared to control (WMD: −0.84; 95% CI: −1.23, −0.44; p<0.01). Patients treated for rotator cuff injury (WMD: −0.53; 95% CI: −0.98, −0.09; p=0.02) and lateral epicondylitis (WMD: −1.39; 95% CI: −2.49, −0.29; p=0.01) both reported significantly less pain in the long-term. Substantial heterogeneity was reported at baseline (I2: 72.0%, p<0.01), short term follow-up (I2: 72.5%, p<0.01), long term follow-up (I2: 76.1%, p<0.01), and overall (I2: 75.8%, p<0.01). The funnel plot

appeared to be asymmetric, with some missingness at the lower right portion of the plot suggesting possible publication bias.

c. No study reported severe adverse events (SAEs).
d. **Conclusion:** This review shows that PRP may reduce the pain associated with lateral epicondylitis and rotator cuff pathology.

4) **Hussain 2017**, evidence based evaluation of platelet rich plasma in orthopedics
    a. Reviewed conditions:
        i. Knee osteoarthritis, rotator cuff repair, epicondylitis, patellar tendinopathy, Achilles tendinopathy, hamstring injuries and anterior cruciate ligament repair
    b. the evidence appears to suggest that PRP may provide some benefit in patients who present with knee osteoarthritis or lateral epicondylitis. On the other hand, evidence appears to be inconsistent or shows a minimal benefit for PRP usage in rotator cuff repair, patellar and Achilles tendinopathies, hamstring injuries, anterior cruciate ligament (ACL) repair, and medial epicondylitis. There is limited confidence in the conclusions from the published meta-analyses due to issues with statistical pooling, and limited subgroup analyses exploring the substantial heterogeneity across studies. Evidence-based clinicians considering the use of PRP in their patients with musculoskeletal injuries should be wary that the literature appears to be inconsistent and thus far, inconclusive.

<u>Other payer policies</u>

1) CMS LCD 2021: This is a NON-coverage policy for all platelet-rich plasma (PRP) injections and/or applications as a means of managing musculoskeletal injuries and/or joint conditions
    a. While promising, we believe that there is insufficient high-quality evidence to justify the use of PRP for the treatment of any condition except for within the confines of a well-designed clinical trial.
2) All private payers surveyed considered PRP to be experimental

HERC staff summary

General reviews of the effectiveness of platelet rich plasma for a wide variety of conditions finds that the literature is highly biased and inconclusive. CMS and all private payers consider PRP experimental, and Medicaid considers CPT level III codes, such as 0232T, to be experimental. HERC staff recommend placing CPT 0232T on line 662/GN173, with individual indications reviewed in the future as evidence matures.

HERC staff recommendation

1) Add CPT 0232T to line 662/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 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
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed	Insufficient evidence of effectiveness	November 2021

Radiofrequency Ablation of Renal Tumors

Question: Should radiofrequency ablation of renal tumors be moved to a covered line?

Question source: Alison Little, CCO medical director

Issue: Conventional treatment of renal cancer is total or partial nephrectomy (open or laparoscopic). For some smaller tumors, cryoablation or radiofrequency ablation may be selected. Radiofrequency ablation (RFA) is one of several less invasive approaches that have been investigated for the treatment of kidney cancer. In RFA, an electric current from a radiofrequency (RF) generator delivers energy into the tumor, via an electrode. Tissue impedance leads to heat generation, production of lethal temperatures, and ablation of tissue. RFA has been used most often for adults with small kidney tumors. Indications include comorbidities that preclude surgery, a single kidney, and multifocal renal cell carcinoma.

Radiofrequency ablation of renal tumors (CPT 50592) is on line 662/GN173 and has not been reviewed in 15+ years.

Current Prioritized List status

CPT Code	**Code Description**	**Current Placement**
50240	Nephrectomy, partial	21 VESICOURETERAL REFLUX 49 CONGENITAL HYDRONEPHROSIS 86 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM 214 CANCER OF KIDNEY AND OTHER URINARY ORGANS 271 CANCER OF BLADDER AND URETER
50250	Ablation, open, 1 or more renal mass lesion(s), cryosurgical, including intraoperative ultrasound guidance and monitoring, if performed	86,214,271
50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed	47 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS 86,214,271 511 BENIGN NEOPLASM OF KIDNEY AND OTHER URINARY ORGANS
50543	Laparoscopy, surgical; partial nephrectomy	47,86,214,271,511
50592	Ablation, 1 or more renal tumor(s), percutaneous, unilateral, radiofrequency	662
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy	ANCILLARY PROCEDURES

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
50592	Radiofrequency ablation, 1 or more renal tumor(s)	Insufficient evidence of effectiveness	December 2005

Evidence

1) **NICE 2010**, percutaneous radiofrequency ablation for renal cell cancer
    a. Current evidence on the safety and efficacy of percutaneous radiofrequency ablation (RFA) for renal cancer in the short and medium term appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit, and provided that patients are followed up in the long term
    b. A meta-analysis of 47 studies (non-randomized comparative studies and case series) including a total of 1375 tumors treated by RFA (n = 775) or cryoablation (n = 600) reported local tumor progression (defined as radiographic or pathological evidence of residual disease after initial treatment, regardless of time to recurrence) in 13% (100/775) and 5% (31/600) of tumors respectively at a mean 19-month follow-up ($p < 0.001$). The meta-analysis reported progression to metastatic disease in 2% (19/775) of tumors treated by RFA and 1% (6/600) of tumors treated by cryoablation (p = not significant)
    c. In a non-randomized comparative study of 233 patients (260 tumors), residual or recurrent tumor on follow-up magnetic resonance imaging (MRI) was reported in 11% (9/81) of tumors treated by percutaneous RFA and 2% (3/ 179) of tumors treated by laparoscopic cryotherapy (1-year and 3-year median follow-up respectively).
    d. Adverse events:
        i. Hemorrhage was reported in 6% (5/85) of patients in a case series of 85 patients.
        ii. Hematoma requiring blood transfusion was reported in 1% (1/104) of patients in a case series and 1% (1/82) of RFA procedures in the non-randomized comparative study of 233 patients. Hematoma not requiring blood transfusion was reported in 5% (4/82) (3 perirenal requiring no treatment; 1 retroperitoneal) of RFA procedures in the non-randomized comparative study of 233 patients. Asymptomatic perirenal hematoma development was reported in 12% (4/34) (managed conservatively with no sequelae) of RFA procedures in the case series of 31 patients.
    e. The Specialist Advisers indicated that there was uncertainty about the procedure's efficacy in tumors 4 cm or greater in diameter.

Expert guidelines

1) NCCN Guideline Kidney Cancer Version 2.2022
    a. Thermal ablation (e.g. cryosurgery, radiofrequency ablation) is an option for the management of patients with clinical stage T1 renal lesions
        i. Thermal ablation is an option for masses <3 cm, but may also be an option for larger masses in select patients. Ablation in masses >3cm is associated with higher rates of local recurrence/persistence and complications
        ii. Biopsy of small lesions confirms a diagnosis of malignancy for surveillance, cryosurgery, and radiofrequency ablation strategies

2) American Urological Association 2017
    a. Physicians should consider thermal ablation **(TA)** as an alternate approach for the management of cT1a renal masses <3 cm in size. For patients who elect TA, a

percutaneous technique is preferred over a surgical approach whenever feasible to minimize morbidity. **(Conditional Recommendation; Evidence Level: Grade C)**

b. Both radiofrequency ablation and cryoablation are options for patients who elect thermal ablation. **(Conditional Recommendation; Evidence Level: Grade C)**
c. A renal mass biopsy should be performed prior to ablation to provide pathologic diagnosis and guide subsequent surveillance. **(Expert Opinion)**
d. Counseling about thermal ablation should include information regarding an increased likelihood of tumor persistence or local recurrence after primary thermal ablation relative to surgical extirpation, which may be addressed with repeat ablation if further intervention is elected. **(Strong Recommendation; Evidence Level: Grade B)**

<u>Other payer policies</u>

1) Aetna 2021

a. Aetna considers radiofrequency ablation (RFA) medically necessary for the following indications
    i. Renal cell carcinoma, up to 4-cm in size, in persons who meet the following criteria:
        1. High-risk surgical candidates; *or*
        2. Persons with renal insufficiency, as defined by a glomerular filtration rate of less than or equal to 60 ml/min/m^2; *or*
        3. Persons with a solitary kidney.

2) ConnecticCare (Connecticut Medicaid) 2020

a. Members with small undefined renal lesions (≤ 4 cm in diameter) that are suspected to be malignant, or with malignant potential, are eligible for coverage of either cryoablation or RFA by any modality (eg laparoscopically or percutaneously) when either of the following criteria is met:
    i. Medically or surgically inoperable tumor(s).
    ii. Poor candidacy for standard treatments (i.e., nephrectomy).

Radiofrequency Ablation of Renal Tumors

HERC staff summary

Treatment of small renal cell carcinomas (<3cm) by radiofrequency ablation or cryotherapy in patients who are poor surgical candidates is recommended by NCCN and the American Urological Association. A highly trusted evidence-based source (NICE) has found sufficient evidence of effectiveness in this population to recommend use. Only two other insurance policies were found, but both recommended coverage in limited circumstances.

HERC staff recommendations:

1) Add CPT 50592 (Ablation, 1 or more renal tumor(s), percutaneous, unilateral, radiofrequency) and 50593 (Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy) to line 214 CANCER OF KIDNEY AND OTHER URINARY ORGANS
    a. Advise HSD to remove CPT 50593 from the Ancillary Procedures File
2) Delete CPT 50592 from line 662/GN173
3) Add a new guideline to line 214 as shown below

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

Line 662

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

Procedure Code	Intervention Description	Rationale	Last Review
~~50592~~	~~Radiofrequency ablation, 1 or more renal tumor(s)~~	~~Insufficient evidence of effectiveness~~	~~December 2005~~

GUIDELINE NOTE XXX THERMAL ABLATION OF RENAL CELL CARCINOMA

Line 214

Thermal ablation (e.g. cryosurgery, radiofrequency ablation; CPT 50592, 50593) is included on this line only when:

1) The patient has biopsy confirmed stage T1 renal cell cancer of <3 cm size; AND
2) The patient either has a surgically inoperable tumor(s) or is a poor candidate for standard treatments (i.e., nephrectomy).

Pelvic Congestion Syndrome

Question: Should the diagnosis and treatment of pelvic congestion syndrome be moved to the covered region of the Prioritized List?

Question source: Carl Stevens, CCO medical director

Issue: Pelvic congestion syndrome is a chronic pelvic pain syndrome of variable location and intensity, which is associated with dyspareunia and postcoital pain and aggravated by standing. The underlying etiology is thought to be related to varices of the ovarian veins, leading to pelvic vascular congestion. Because there are many etiologies of chronic pelvic pain, the pelvic congestion syndrome is often a diagnosis of exclusion, with the identification of varices using a variety of imaging methods, such as magnetic resonance imaging, computed tomography, or contrast venography. However, the syndrome is still not well-defined, and it is unclear whether pelvic congestion syndrome causes chronic pelvic pain. Although venous reflux is common, not all women with this condition experience chronic pelvic pain and, conversely, chronic pelvic pain is reported by women without pelvic congestion syndrome.

Initial treatment of pelvic congestion syndrome includes psychotherapy and medical therapy (e.g., nonsteroidal anti-inflammatory drugs) and hormonal therapy. For patients who fail initial therapy, surgical ligation of the ovarian vein may be considered. Embolization therapy and/or sclerotherapy of the ovarian and internal iliac veins has been proposed as an alternative to surgical ovarian vein ligation.

CareOregon has been receiving requests for pelvic vein embolization for pelvic congestion syndrome and would like HERC guidance on treatments for this condition.

Current Prioritized List status

CPT code	**Code description**	**Current Placement**
37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)	**327** FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION **547** SUBLINGUAL, SCROTAL, AND PELVIC VARICES **627** BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES
ICD-10 Code		
I86.2	Pelvic varices	**547** SUBLINGUAL, SCROTAL, AND PELVIC VARICES
N94.89	Other specified conditions associated with female genital organs and menstrual cycle [includes pelvic congestion syndrome as a subdiagnosis]	**531** CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME, DYSPAREUNIA
R10.2	Pelvic and perineal pain	**531**

Pelvic Congestion Syndrome

Evidence

1) **Champaneria 2014**, Health Technology Assessment, he relationship between pelvic vein incompetence and chronic pelvic pain in women: systematic reviews of diagnosis and treatment effectiveness. https://www.journalslibrary.nihr.ac.uk/hta/hta20050/#/full-report
    a. Accuracy review N=12 studies (10 ultrasound, 2 MRI vs conventional venography
        i. There was no single, clearly defined criterion for a diagnosis that was reported in the all of studies included in the review.
        ii. The proportion of women found to have pelvic vein incompetence (PVI) who reported chronic pelvic pain (CPP) ranged considerably, from 39% to 91%.
    b. Effusiveness review N=22 studies (1 poor quality RCT of 1208 women, 21 case series)
        i. approximately one-third of patients clearly had bilateral embolisation, with metal coil placement being the dominant technique. Early substantial relief from pain symptoms was observed in approximately 75% of women, a figure which generally increased over time and was sustained. Where pain was measured on a visual analogue scale, statistically significant reductions following treatment were observed in all studies. Reintervention rates were generally low. Where measured, embolisation reduced the diameter of dilated veins to a significant degree, with minimal residual reflux. There were few data on the impact on menstruation, ovarian reserve or fertility, but no concerns were noted. Transient pain was a common occurrence following foam embolisation, while there was a < 2% risk of coil migration
    a. Conclusions: The data supporting the diagnosis and treatment of PCS are limited and of variable methodological quality. There is some evidence to tentatively support a causative association, but it cannot be categorically stated that PVI is the cause of CPP in women with no other pathology. Embolisation appears to provide symptomatic relief in the majority of women and is safe. However, the majority of included studies of embolism were relatively small case series and only the randomized controlled trial was considered at risk of potential biases.

Expert Guideline

1) **ACOG 2020**, Practice Bulletin 218 Chronic Pelvic Pain
    a. Pelvic congestion syndrome is a proposed etiology of chronic pelvic pain related to pelvic venous insufficiency. Although venous congestion appears to be associated with chronic pelvic pain, evidence is insufficient to conclude that there is a cause-and-effect relationship. In addition, there is no consensus on the definition of this condition, and diagnostic criteria are variable. Further research is needed to establish greater consistency in diagnosis and homogeneity in treatment studies.

Other payer policies

1) **Aetna 2021**: Aetna considers embolization (e.g., using metallic coils or foam/gel sclerotherapy) of gonadal veins or ovarian veins, with or without the internal iliac veins, medically necessary for the treatment of pelvic congestion syndrome (PCS) when both of the following criteria are met:
    a. The member has had a definitive diagnostic venography, computed tomography (CT) or magnetic resonance imaging (MRI); *and*
    b. The member has failed a trial of appropriate pharmacotherapy (e.g., analgesics, hormonal therapy).

2) **United Healthcare 2021**: Embolization of the Ovarian Vein or Internal Iliac Vein is unproven and not medically necessary for treating Pelvic Congestion Syndrome due to insufficient evidence of efficacy
3) **Wellmark BCBS 2021**: Endovascular occlusion of the ovarian vein and internal iliac veins is considered investigational as a treatment of pelvic congestion syndrome because the evidence is insufficient to determine the effects of the technology on net health outcomes.

Pelvic Congestion Syndrome

HERC staff summary

Pelvic congestion syndrome is a poorly defined entity with no standardized diagnostic criteria. Pelvic vein embolization for treatment of pelvic congestion syndrome appears promising, but the evidence base to date is very small and at high risk of bias. Most private insurers do not cover treatment for pelvic congestion syndrome. ACOG notes there are no agreed upon diagnostic or treatment criteria.

HERC staff recommendations:

1) Add a new guideline note to line 531 CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME, DYSPAREUNIA as shown below

GUIDELINE NOTE XXX PELVIC CONGESTION SYNDROME

Line 531

Pelvic congestion syndrome is included on this line using ICD-10-CM N94.89. This condition does not pair with any vein embolization procedures due to lack of evidence of effectiveness.

Cyanoacrylate ablation Therapy for Varicose Veins

Question: Should cyanoacrylate ablation therapy be paired as a treatment for varicose veins?

Question source: Max Kaiser, CCO medical director

Issue: Cyanoacrylate glue occlusion (CPT 36482-36483) for varicose veins aims to close the veins by adherence then fibrosis of the lumen, without the need for tumescent anesthesia and with reduced need for postoperative compression therapy. The procedure is done using local anesthesia. An introducer sheath is inserted into the distal great saphenous vein and, using ultrasound guidance, a delivery catheter is advanced into position before the saphenofemoral junction. The proximal vein is compressed, and medical glue is delivered in measured doses through the tip of the catheter to seal the vein.

This procedure was reviewed as a new CPT code in November 2017. At that time, evidence review found three case series of 50, 62, and 180 patients were identified from 2016 and 2017 that indicated that vein ablation with cyanoacrylate was feasible. A NICE review of treatment of varicose veins from 2013 was reviewed and found to only recommend endothermal ablation or ultrasound-guided foam sclerotherapy. Based on the lack of evidence on this technology, it was placed on line 662/GN173.

Dr. Kaiser is requesting a re-review of this technology. He states: "After having performed the procedure for a few years, our local surgeons feel it is a superior procedure to radio frequency ablation (covered per GN 68) in terms of patient comfort, possibly lower cost as it's lower RVUs, and has a similar or improved efficacy/side effect profile."

Current Prioritized List status:
ICD-10-CM I82.xxx (Varicose veins, with pain/with other complications/with ulcer/asymptomatic/etc.) are on lines 379 CHRONIC ULCER OF SKIN; VARICOSE VEINS WITH MAJOR COMPLICATIONS and 639 VARICOSE VEINS OF LOWER EXTREMITIES WITHOUT ULCER OR OTHER MAJOR COMPLICATION

ICD-10-CM I87.xxx (Postthrombotic syndrome) is on line 519 POSTTHROMBOTIC SYNDROME

Currently covered endovenous treatments for varicose veins:

CPT 36465-36466: Injection of non-compounded foam sclerosant
CPT 36470-36471: Injection of sclerosant
CPT 36473-36479: Endovenous ablation therapy of incompetent vein (includes radiofrequency ablation, endovenous laser ablation)

GUIDELINE NOTE 68, 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

A) The patient has had an adequate 3-month trial of conservative therapy and failed; AND
B) Ultrasound findings of severe axial venous reflux (>1 second in the greater or small saphenous vein or accessory saphenous vein; AND

C) The patient has one of the following:
   1) Non-healing skin ulceration in the area of the varicose vein(s), OR
   2) Recurrent episodes of cellulitis associated with chronic venous disease OR
   3) Clinically significant bleeding from varicose vein(s).

Otherwise, these diagnoses are included on Lines 519 and 639.

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
36482-36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate)	Unproven treatment	November, 2017

Evidence

1) **NICE 2020**, Cyanoacrylate glue occlusion for varicose veins
    a. 14 included papers
        i. N=2 systematic reviews (1,645 patients in 15 studies; 918 patients in 7 studies)
        ii. N=3 randomized controlled trials (222, 456 and 339 patients)
            1. Comparisons were other endovenous ablation techniques
        iii. N=3 non-randomized comparative studies (310, 244, and 573 patients 0
            1. Comparisons were other endovenous ablation techniques
        iv. N=4 case series (573, 538, 160, 50 patients)
        v. N=2 case reports
    b. Saphenous vein occlusion rates of at least 95% at 6 months after the cyanoacrylate closure (CAC) procedure were reported in 2 systematic reviews. Also, 9 studies described occlusion rates, which were more than 97% at 1 month post-procedure, more than 96% at 6 months, more than 94% at 12 months, and more than 92% at 24 months and was 95% at 36 months. Although there was a trend of better occlusion rates in CAC than in radiofrequency ablation (RFA), endovenous laser ablation (EVLA), and/or mechanochemical ablation (MOCA), these differences were not statistically significant at 6 months after the procedure
    c. Before and after the CAC procedure, a statistically significant reduction (improvement) in VCSS was reported in 9 studies
        i. VCSS is the Venous Clinical Severity Score, a measure of symptoms caused by varicose veins
    d. A statistically significant or clinically relevant reduction in the AVVQ scores posttreatment was reported in 2 systematic reviews. A statistically significant reduction after the CAC procedure at different follow-up intervals was reported in 7 studies
        i. AVVQ is the Aberdeen Varicose Vein Questionnaire which looks at pain, limitations on daily activity, and other quality of life measures
    e. Adverse events included hives, allergic contact dermatitis
        i. Small proportions (1% to 7%) of patients, who developed phlebitis after the CAC procedure, were reported in 8 studies. Phlebitis happened statistically significantly less in CAC patients (2% [3/150]) compared with EVLA patients (8% [15/189], p=0.015) in the non-randomized comparative study of 339 patients
        ii. In the systematic review and meta-analysis of 15 studies (n=1645), thrombophlebitis was reported in 6 CAC studies ranging from less than 1% to 18%, and deep venous thrombosis was described in 4 CAC studies ranging from 0 to 4%1 . In the non-randomized comparative study of 244 patients, thrombophlebitis happened in 2% (2/116) of patients in the CAC group compared with 3% (4/128) in the RFA group (p=0.685)
    f. Conclusion: Evidence on the safety and efficacy of cyanoacrylate glue occlusion for varicose veins is adequate to support the use of this procedure

Other payer policies:

1) Aetna 2021 does not cover cyanoacrylate vein ablation
2) Cigna 2021 does not cover cyanoacrylate vein ablation
3) Wellmark BCBS 2021 does not cover cyanoacrylate vein ablation

HERC staff summary

Cyanoacrylate vein ablation appears to be at least as effective at occluding varicose veins, reducing pain and increasing quality of life from varicose veins as currently covered endovenous treatments according to one trusted source (NICE). No private payer surveyed is covering cyanoacrylate vein ablation.

HERC staff recommendations:

1) Add CPT 36482-36483 (Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate)) to lines 379 CHRONIC ULCER OF SKIN; VARICOSE VEINS WITH MAJOR COMPLICATIONS and 639 VARICOSE VEINS OF LOWER EXTREMITIES WITHOUT ULCER OR OTHER MAJOR COMPLICATION
2) Delete CPT 36482-36483 from line 662 and the GN173 entry

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
~~36482-36483~~	~~Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate)~~	~~Unproven treatment~~	~~November, 2017~~

Breast Reconstruction After Lumpectomy

Question: Is breast reconstruction after lumpectomy a covered service on the Prioritized List?

Question source: Kristin Garrett, CCO medical director

Issue: The Women's Health and Cancer Rights Act requires insurance to cover breast reconstruction including surgery on the contralateral breast after "mastectomy." Currently, GN79 BREAST RECONSTRUCTION states that "breast reconstruction is only covered after mastectomy". Dr. Garrett is requesting clarification of coverage of reconstruction after lumpectomy for breast cancer. Lumpectomy is a surgery where only a portion of the breast is removed, and it is becoming increasingly common for certain stages of breast cancer. Lumpectomy is generally less morbid than mastectomy, and requires fewer follow up procedures. The CPT codes used for lumpectomy list the procedure as "mastectomy, partial."

In some cases, lumpectomy removes only a small portion of breast tissue and no reconstruction is desired. In other cases, lumpectomy can remove a considerable portion of breast tissue, leaving a significant disproportion between breasts. Most private insurance payers will cover breast reconstruction or contralateral breast reduction or similar surgeries after lumpectomy.

There is concern that coverage for reconstruction only after mastectomy might incentivize patients on OHP to opt for mastectomy when a lumpectomy would be a reasonable treatment approach. Mastectomy is a much more morbid procedure, and generally the reconstruction afterwards involves multiple steps and procedures.

From CMS
https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/whcra_factsheet (accessed October 19, 2021)

> The Women's Health and Cancer Rights Act of 1998 (WHCRA) is a federal law that provides protections to patients who choose to have breast reconstruction in connection with a mastectomy.
>
> If WHCRA applies to you and you are receiving benefits in connection with a mastectomy and you elect breast reconstruction, coverage must be provided for:
>
> - All stages of reconstruction of the breast on which the mastectomy has been performed;
> - Surgery and reconstruction of the other breast to produce a symmetrical appearance; and
> - Prostheses and treatment of physical complications of all stages of the mastectomy, including lymphedema.
>
> This law applies to two different types of coverage:
>
> 1. Group health plans (provided by an employer or union);
> 2. Individual health insurance policies (not based on employment).

Current Prioritized List status

CPT 19301-19302 (Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy) are on line 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER

GUIDELINE NOTE 79, BREAST RECONSTRUCTION

Line 191

Breast reconstruction is only covered after mastectomy as a treatment for breast cancer or as prophylactic treatment for the prevention of breast cancer in a woman who qualifies under Guideline Note 3, and must be completed within 5 years of initial mastectomy.

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

Expert guidelines

1) **NCCN Breast Cancer** treatment guideline, version 8.2021
    a. After lumpectomy, prior to radiation therapy
        i. No reconstruction required if ration of tumor to breast volume is small and minimal cosmetic deformity with result, OR
        ii. Consider oncoplastic reduction or mastopexy and simultaneous or delayed contralateral matching procedure, OR
        iii. Consider bilateral breast reduction if symptoms warrant, or
        iv. Local tissue rearrangement, regional flap
    b. After lumpectomy and radiation therapy
        i. Delayed fat grafting
        ii. Delayed flap for correction of contour defects
        iii. Contralateral reduction/mastopexy for symmetry

Other payer policies

1) Aetna 2021
    - Aetna considers reconstructive breast surgery medically necessary after a medically necessary mastectomy or a medically necessary lumpectomy that results in a significant deformity (i.e., mastectomy or lumpectomy for treatment of or prophylaxis for breast cancer and mastectomy or lumpectomy performed for chronic, severe fibrocystic breast disease, also known as cystic mastitis, unresponsive to medical therapy).
2) Cigna 2021
    - Breast reconstruction following mastectomy or lumpectomy is considered medically necessary for EITHER of the following:
        - breast reconstruction procedures performed on the diseased/affected breast (i.e., breast on which the mastectomy/lumpectomy was performed),
        - breast reconstruction procedures performed on the nondiseased/unaffected/contralateral breast, in order to produce a symmetrical appearance

3) Anthem BCBS 2021
    - The Women's Health and Cancer Rights Act of 1998 (WHCRA) mandated that reconstructive breast surgery for women and men who have undergone mastectomy be covered by their benefits for those who have opted to have breast reconstruction. In individuals who have undergone a medically necessary lumpectomy, surgery to create a more normal anatomy is considered reconstructive.
4) MODA 2020
    - Reconstructive breast surgery is performed following a mastectomy, lumpectomy or prophylactic mastectomy for high-risk patients to re-establish symmetry between the two breasts.

Expert input

Danielle Bertoni and John Vetto, breast surgeons: both felt that reconstruction after lumpectomy was standard of care.

HERC staff summary

Due to concern that WHCRA requires coverage for reconstruction after partial mastectomy (lumpectomy) and a desire to not create an incentive to elect a mastectomy when a lumpectomy is sufficient treatment, HERC staff recommend amending GN79 to clarify that breast reconstruction after lumpectomy is a covered service.

HERC staff recommendation:

1) Modify Guideline Note 79 as shown below

GUIDELINE NOTE 79, BREAST RECONSTRUCTION

Line 191

Breast reconstruction is only covered after mastectomy, or lumpectomy that results in a significant deformity or asymmetry, as a treatment for breast cancer or as prophylactic treatment for the prevention of breast cancer in a woman who qualifies under Guideline Note 3, and must be completed within 5 years of initial mastectomy.

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

Breast MRI

Question: How best can the coverage of breast MRI be clarified on the Prioritized List

Question source: several CCO medical directors

Issue: There are currently 3 guidelines that relate to breast MRI on the Prioritized List, and the CCO medical directors frequently have questions about how they relate to one another. They have previously requested clarification of these guidelines, but even those clarifications are not sufficient for the CCO PA process. There have also been questions about the lack of Prioritized List coverage for MRI after breast cancer diagnosis, which has generally become standard of care.

From Max Kaiser, CCO medical director

> The main impetus are cases where member's meet for breast MRI screening, but haven't had the screening, and are now was diagnosed with a new breast cancer. As the member met for screening, the surgeon uses that as reasoning to request screening of the uninvolved breast so they could treat any identified breast cancer at the same time and image the involved breast for other occult lesions. That scenario may warrant clarification with the NCCN caveat that false-positives are common and should be confirmed with tissue sampling. We had also talked about aligning D6 and D26 to indicated when after the member's original treatment an MRI is covered for future screening. Currently it's covered annually. Does this mean 1 year after treatment or would it also be covered, as with the mammogram, 6 months after radiotherapy if treated with breast conserving therapy? I also get fairly regular requests for a breast MRI in a newly diagnosed member that I approve by exception as they align with NCCN, such as poorly defined disease on mammogram/ultrasound or multifocal/multicentric

Current Prioritized List status:

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

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

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

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

For women with both a personal history and a family history of breast cancer which give a greater than 20% lifetime risk of breast cancer, annual mammography, annual breast MRI and annual breast ultrasound are covered.

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

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

For surveillance for a treated breast cancer, see Guideline Note 26 BREAST CANCER SURVEILLANCE.

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

DIAGNOSTIC GUIDELINE D9, MRI FOR BREAST CANCER DIAGNOSIS
In women with recently diagnosed breast cancer, preoperative or contralateral MRI of the breast is not a covered service.

GUIDELINE NOTE 26, BREAST CANCER SURVEILLANCE
Line 191
History and physical exam is indicated every 3 to 6 months for the first three years after primary therapy, then every 6-12 months for the next 2 years, then annually thereafter.

Mammography is indicated annually, and patients treated with breast-conserving therapy, initial mammogram of the affected breast should be 6 months after completion of radiotherapy.

No other surveillance testing is indicated.

For ongoing screening for a new breast cancer, see Guideline Note 2006 BREAST CANCER SCREENING IN ABOVE-AVERAGE RISK WOMEN.

Expert guidelines

1) **NCCN Breast Cancer** treatment guideline, version 8.2021
    a. Clinical indications and applications for breast MRI
        i. May be used for staging evaluation to define extent of cancer or presence of multifocal or multicentric cancer in the ipsilateral breast, or as screening of the contralateral breast cancer at time of initial diagnosis (category 2B). there are no high-level data to demonstrate that the use of MRI to facilitate local therapy decision-making improves local recurrence or survival
        ii. May be helpful for breast cancer evaluation before and after preoperative systemic therapy to define extent of disease, response to treatment, and potential for breast-conserving therapy
        iii. May be useful in identifying otherwise clinically occult disease in patients presenting with axillary nodal metastases (cT0, CN+), with Paget disease, or with invasive lobular carcinoma poorly (or inadequately) defined on mammography, ultrasound or physical examination
        iv. False-positive findings on breast MRI are common. Surgical decisions should not be based solely on the MRI findings. Additional tissue sampling of areas of concern identified by breast MRI is recommended
        v. The utility of MRI in follow-up screening of patients with prior breast cancer is undefined. It should generally be considered only in those whose lifetime risk of a second primary breast cancer is >20% based on models largely dependent on

family history, such as those with the risk associated with inherited susceptibility to breast cancer.

b. Specific clinical situations:
    i. DCIS: breast MRI has not been shown to increase likelihood of negative margins or decrease conversion to mastectomy. Data to support improved long-term outcomes is lacking
    ii. Non-metastatic (M0) invasive breast cancer and higher stage invasive breast cancer: breast MRI is optional, may be useful for characterizing axillary and/or internal mammary nodal disease. MRI findings tend to overestimate extent of disease resulting increase in frequency of mastectomies. Two prospective randomized studies have examined the utility of pre-operative MRI in determining disease extent, and neither demonstrated improvement in rates of post-lumpectomy re-excision. One systematic review found MRI staging altered surgical treatment in 7.8-33.3% of women; however, no differences in local recurrent or survival has been demonstrated.

2) **NCCN Breast Cancer screening and diagnosis**, version 1.2021
    a. Recommend annual MRI screening:
        i. For individuals with a genetic mutation, or a first-degree relative of gene mutation carrier
        ii. For individuals who received thoracic radiation therapy between the ages of 10 and 30 years
            1. Begin 8 years after radiation therapy but not prior to age 25 years
        iii. For individuals with a lifetime risk of ≥ 20% as defined by models that are largely dependent on family history
            1. To begin 10 years prior to when the youngest family member was diagnosed with breast cancer, not prior to age 25 years or age 40 years (whichever comes first)

3) **American Society of Breast Surgeons 2017**: consensus guideline on diagnostic and screening MRI of the breast
    a. The ASBrS does not recommend routine diagnostic MRI in newly diagnosed breast cancer patients except as part of a scientific study.
    b. The ASBrS supports the use of MRI in the following situations:
        i. To search for occult breast cancer in patients with Paget's disease of the nipple or in patients with axillary node metastasis when clinical examination and conventional breast imaging fail to detect a primary breast cancer. MRI identifies an ipsilateral cancer focus in 60-70% of patients who present with axillary nodal metastases and no cancer identified on clinical examination, mammography, or ultrasound.
        ii. For determining the extent of cancer or presence of multi-focal or multi-centric tumor or the presence of contralateral cancer, in patients with a proven breast cancer and associated clinical or conventional indeterminate imaging findings suspicious for malignancy. This may include patients with invasive lobular carcinoma or extremely dense breast tissue (limiting mammographic sensitivity), or when there are significant discrepancies in the estimated tumor size as measured on clinical exam, mammogram, and ultrasound. The American College of Radiology Appropriateness Criteria and a recent meta-analysis by Houssami et al conclude there are no proven criteria for any patient sub-

population that benefits the most from routine MRI based on specific patient, tumor, or mammographic characteristics.

iii. To aid the assessment for eligibility and response to neoadjuvant endocrine therapy or chemotherapy before, during, or after treatment. MRI can help identify those patients who are candidates for breast conservation, and assist in determining the extent of resection40,41. After neoadjuvant chemotherapy (NAC), MRI has a sensitivity of 92% to detect residual disease and a specificity of 60% for pathologic complete response (pCR), based on a meta-analysis of studies including 2050 patients reported by Marinovich et al in 2013. Compared to mammography, MRI was better in assessing response to NAC, but a negative MRI did not always exclude residual microscopic disease. In two updated metaanalyses (2016 and 2017) assessing pCR, Gu et al and Sheikhbahaei et al reported pooled sensitivities and specificities of 64%/88% and 92%/55% respectively. MRI is not mandatory in patients undergoing neoadjuvant systemic therapy.

iv. For the further evaluation of suspicious clinical or imaging findings that remain indeterminate after complete mammographic and sonographic evaluations. If lesions meet the criteria for biopsy by clinical examination or conventional imaging, then it may be preferable to perform minimally invasive needle biopsy, targeted by mammogram or US, rather than obtain an MRI.

v. For evaluation of suspected breast implant rupture, especially in patients with silicone implants, if the MRI findings will aid the decision-making for implant removal or aid the diagnostic evaluation of indeterminate clinical or conventional imaging findings in patients with implants. The MRI protocol for detection of silicone leak is different from the protocol for detection of breast cancer. Thus, it is important to clearly define the purpose of the breast MRI if the concern is a silicone leak.

<u>Expert input</u>:

Steve Kornfeld, breast surgeon:

Dr. Kornfeld recommended against including coverage for first degree relatives of mutation carriers, as confirmation testing is readily available and inexpensive. The relative has a 50% chance of having the mutation. If she does not carry it, then she is normal risk and should be screened with mammograms.

Dr. Kornfeld also felt that preoperative breast MRI is standard of care for women, specifically if breast conservation (lumpectomy) is being considered over mastectomy. The rationale is to look for multifocal tumors. This is listed in NCCN as an option (2B recommendation).

Danielle Bertoni, breast surgeon:

I think there is one major group missing which is patients who have a genetic mutation or are at high risk for genetic mutation and are planning breast conservation. If we have a patient who is newly diagnosed with breast cancer and meets criteria for genetic testing or has extensive family history of breast cancer and is planning breast conservation, then we may need to follow them for screening going forward with breast MRI. If this is the case, then we would want the breast MRI prior to going to surgery for their cancer treatment. We would not want to wait until

they are due for MRI screening in 6 months and then find a new lesion in the same or contralateral breast that we could have and should have addressed at diagnosis. This is more of a concern in patients who also have dense breast tissue and are more likely to have things missed by conventional imaging. IF they know they want breast conservation regardless of genetic testing results, we often go to surgery prior to results coming back. In many cases, even if results are negative, they are still high risk based on family history and we would want to screen them with MRI going forward, again especially with dense breast tissue. Ultimately, if someone meets the high risk criteria and has cancer, they should be approved for an MRI at diagnosis.

The other time we have had difficulty getting them approved is if someone has a breast MRI and it has a birads 3 finding. They are recommended for 6 month follow up and it is getting denied.

Winnie Henderson, breast surgeon

Our practice follows the ASBrS recommendations [see above]

Breast MRI

HERC staff summary

The current three guidelines regarding breast cancer screening modalities continue to be confusing to CCOs and difficult to administer. There are generally few barriers to mammography or breast ultrasound; therefore, staff feel that the guidelines should be simplified and only outline when breast MRI is covered.

NCCN addresses coverage of MRI only for two situations: 1) screening for breast cancer in high-risk women, and 2) peri-operative MRI. In terms of perioperative MRI, the current NCCN guidelines give a "may" recommendation, and note that no differences have been found in the rate of re-excision, conversion to mastectomy from planned lumpectomy, local recurrence or survival with pre-operative MRI. The breast surgeons consulted on this topic argue that preoperative breast MRI is standard of care, particularly in women pursuing breast conserving therapy (lumpectomy).

Expert guidelines address coverage of breast MRI in two additional situations: 1) evaluation of suspicious lesions when other imaging is equivocal and 2) evaluation of possible breast implant rupture.

HERC staff recommendations:

1) Delete Diagnostic Guideline D9 and Guideline Note 26
2) Replace current Diagnostic Guideline D6 with the guideline shown below:
    a. Includes NCCN recommended screening for high-risk women [current coverage]
    b. Includes perioperative coverage only for women who would otherwise qualify for high risk MRI screening, based on expert input [clarification of current coverage]
    c. Includes expert guideline recommendations regarding evaluation of possible breast cancer in equivocal cases and for evaluation of possible implant rupture [new coverage]

DIAGNOSTIC GUIDELINE D6 BREAST MRI

Breast MRI is covered in the following circumstances:

1) Annual breast MRI screening for high-risk patients:
    a. For individuals with a genetic mutation known to confer a greater than 20% lifetime risk of breast cancer (e.g. BRCA1, BRCA2, Bannayan-Riley-Ruvalcaba syndrome, Cowden syndrome, or Li-Fraumeni syndrome), beginning 10 years prior to when the youngest family member was diagnosed with breast cancer (but not prior to age 25 years) or age 40 years (whichever comes first)
    b. For individuals who received high dose chest radiation (≥ 20 Gray) between the ages of 10 and 30 years beginning 8 years after radiation exposure or at age 25, whichever is later
    c. For individuals with a lifetime risk of ≥ 20% as defined by models that are largely dependent on family history, beginning 10 years prior to when the youngest family member was diagnosed with breast cancer (but not prior to age 25 years) or age 40 years (whichever comes first)
2) Evaluation of possible breast cancer:
    a. To search for occult breast cancer in patients with Paget's disease of the nipple or in patients with axillary node metastasis when clinical examination and conventional breast imaging fail to detect a primary breast cancer.

   b. For the further evaluation of suspicious clinical or imaging findings that remain indeterminate after complete mammographic and sonographic evaluations in lesions that do not meet criteria for breast biopsy
3) Preoperative breast MRI
   a. ONLY covered for patients with recently diagnosed breast cancer who qualify for MRI screening based on the high-risk criteria above.
4) Evaluation of suspected breast implant rupture
   a. Breast MRI is covered for evaluation of suspected breast implant rupture, if the MRI findings will aid the decision-making for implant removal or aid the diagnostic evaluation of indeterminate clinical or conventional imaging findings in patients with implants.

Breast MRI is NOT covered for breast cancer screening in women with increased breast density.

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

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

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

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

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

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

~~For women with both a personal history and a family history of breast cancer which give a greater than 20% lifetime risk of breast cancer, annual mammography, annual breast MRI and annual breast ultrasound are covered.~~

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

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

~~For surveillance for a treated breast cancer, see Guideline Note 26 BREAST CANCER SURVEILLANCE.~~

~~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~~

DIAGNOSTIC GUIDELINE D9, MRI FOR BREAST CANCER DIAGNOSIS

In women with recently diagnosed breast cancer, preoperative or contralateral MRI of the breast is not a covered service.

GUIDELINE NOTE 26, BREAST CANCER SURVEILLANCE

Line 191

History and physical exam is indicated every 3 to 6 months for the first three years after primary therapy, then every 6-12 months for the next 2 years, then annually thereafter.

Mammography is indicated annually, and patients treated with breast-conserving therapy, initial mammogram of the affected breast should be 6 months after completion of radiotherapy.

No other surveillance testing is indicated.

For ongoing screening for a new breast cancer, see Guideline Note 2006 BREAST CANCER SCREENING IN ABOVE-AVERAGE RISK WOMEN.

Clarification of Childhood Growth and Development as a Comorbid Condition

Question: Should Statement of Intent 4 be modified to include growth and development in children as a called out "co-morbid" condition?

Question source: HERC staff

Issue: STATEMENT OF INTENT 4 ROLE OF THE PRIORITIZED LIST IN COVERAGE outlines when treatment of an unfunded condition might be considered for coverage because the condition exacerbates a funded condition (OAR 141-410-3820 (10)). For example, treatment of allergic rhinitis (unfunded condition) is covered if it is making asthma (funded) difficult to control.

Similarly, health services which would address challenges related to childhood growth, development, and ability to participate in school based on individual circumstances are often considered in the same fashion, but these do not necessarily have specific diagnoses on the Prioritized List. Clarifying the intent of the Commission regarding such services is important in order to align expectations for CCO decision-making and reporting purposes.

Schools are required to provide services necessary to allow children to participate in school, and a limited portion of these services can be billed to fee-for-service to Medicaid (not CCOs). The proposed changes would not affect these obligations (or the limits to the Medicaid billing) that are required to be provided by schools to eligible children per the federal Individuals with Disabilities Act (IDEA) and outlined in the students Individualized Education Plan (IEP). These changes will create a mechanism for Medicaid to cover additional services not provided as a part of an IEP to be provided in the community if they would improve a child's ability to grow, develop or participate in school (see Appendix A for specific rules on school responsibilities).

Feedback from CCO medical directors indicates a need for clarity regarding this; some medical directors indicated they are already making coverage exceptions for these sorts of situations; others have expressed concerns that this could open a pathway to coverage for services the Commission intends to be below the funding line, resulting in cost increases.

Context: Services in the unfunded region of the List appear there for several reasons and require different kinds of considerations. As a baseline, even services in the funded region of the List should be covered only when medically necessary and appropriate for the individual member[1], and can be denied if it is determined that they are not the least costly alternative.

Examples of services in the unfunded region of the List include:

- Services determined by the Commission to be not as important as other higher-priority items based on their low impact on health, such as ear tubes for children with chronic otitis media, treatments for mild to moderate acne, seasonal allergies, mild psoriasis and routine circumcision or circumcision for phimosis without a funded condition.
    - Some of these services are arguably "medically necessary" according to some providers. Others would typically be denied as not medically necessary by commercial insurance plans.
- Services with insufficient evidence of effectiveness, evidence of harm, or harms which outweigh the benefits

[1] See OHA Definition of Medical Necessity and medical appropriateness - OAR 410-120-0000(145-146)

  - Examples include prolotherapy, cranial electrical stimulation, allogenic islet cell transplant from pancreas, functional MRI, whirlpools for wound healing and sensory integration therapy. Many of these would be denied as not medically necessary by many other health plans.
- Services which are effective and have an important impact on health but which have more cost-effective alternatives. Often these appear on Guideline Note 172. Examples relevant for children include photo-screening and mechanical chest wall oscillation (the latter is currently under review by EbGS).
  - Some of these services are arguably "medically necessary" according to some providers. Others would typically be denied as not medically necessary by commercial insurance plans.
- Experimental services.

In addition, current OHA Health Services Division (HSD) rules (OAR 141-410-3820(13)[2]) require a medical director's determination of medical necessity and appropriateness for unpaired services where the HERC has not considered the pairing within the past five years.

In recent months, based on stakeholder feedback during the 1115(a) waiver renewal process, staff have brought recommendations to reconsider prioritization for several services for children. Based on the number of services reprioritized already, staff will continue to review and work toward identifying additional services which may warrant reprioritization.

<u>HERC staff recommendation</u>:

1) Modify SOI4 as shown below
   a. Adds clarity for coverage of services which affect childhood growth, development, or ability to participate in school
   b. Corrects OAR reference to updated rule number

[2] (13) Ad hoc coverage determinations.

(a) When a member requests a hearing pertaining to a funded condition and a funded or unfunded treatment that does not pair on the HERC Prioritized List of Health Services, and the treatment is not included in guideline note 172 or 173 of the prioritized list, before the hearing the Division shall determine if the requested treatment is appropriate and necessary for the member.

(b) For treatments determined to be appropriate and necessary under (a) in this section, the Division determines whether the HERC has considered the funded condition/treatment pair for inclusion on the Prioritized List within the last five years. If the HERC has not considered the pair for inclusion within the last five years, the Division shall make an ad hoc coverage determination in consultation with the HERC.

(c) For treatments determined to not be appropriate and necessary under (a) in this section the hearing process shall proceed.

STATEMENT OF INTENT 4: ROLE OF THE PRIORITIZED LIST IN COVERAGE

The Commission makes its prioritization decisions based on the best available published evidence about treatments for each condition. The Prioritized List prioritizes health services according to their importance for the population served and the legislature determines where to place the funding line on the Prioritized List.

The Commission recognizes that a condition and treatment pairing above the funding line does not necessarily mean that the service will be covered by the Oregon Health Plan (OHP). There may be other restrictions that apply, such as the service not being medically necessary or appropriate for an individual member. Likewise, the absence of a treatment and condition pairing above the funding line is not meant to be an absolute exclusion from coverage. Coverage may still be authorized under applicable federal and state laws, and Oregon's Medicaid State Plan and Waiver for an individual member. For example, OAR 410-141-~~0480~~ 3820 (Oregon Health Plan Benefit Package of Covered Services) includes services such as, but not limited to, the following:

- Diagnostic services, subject to the List's diagnostic guideline notes when applicable;
- Ancillary services (such as hospitalization, durable medical equipment, certain medications and anesthesia) provided for conditions appearing above the funding line, subject to the List's ancillary guideline notes when applicable; and
- Services paired with (or ancillary to) an unfunded condition -which is causing or exacerbating a funded condition, the treatments for the funded condition are not working or contraindicated, and treatment of the unfunded condition would improve the outcome of treating the funded condition (the "Comorbidity Rule" OAR 410-141-~~0480(8)(a through b))~~3820 (10))
- Services paired with (or ancillary to) an unfunded condition (or otherwise not consistent with the funded region of the List) which, based on the child's individual circumstances, adversely affects the child's ability to grow, develop, or participate in school only when providing the unfunded service would improve the child's ability to grow, develop or participate in school.

In addition, Oregon's 1115(a) Waiver includes coverage for services such as, but not limited to:

- Services on unfunded lines for children from birth through age 1
- Services provided for a condition appearing in the funded region of the List in conjunction with federal requirements for Early and Periodic Screening, Diagnosis and Treatment (EPSDT) and Oregon's waiver

As a result, the Prioritized List must be used in conjunction with applicable OHP provisions found in federal and state laws, the State Plan and Waiver in coverage determination.

Appendix A

410-141-3565
Managed Care Entity Billing

(8) Payment by the MCE to participating providers for capitated or coordinated care services is a matter between the MCE and the participating provider:

(h) MCEs may not delay or deny payments for occupational therapy, physical therapy, speech therapy, nurse services, etc., when a child is receiving such services as school-based health services (SBHS) through either an Individual Educational Plan (IEP) or an Individualized Family Service Plan (IFSP). These services are supplemental to other health plan covered therapy services and are not considered duplicative services. Individuals with Disabilities Education Act (IDEA) mandated school sponsored SBHS will not apply toward the member's therapy allowances. SBHS Medicaid covered IDEA services are provided to eligible children in their education program settings by public education enrolled providers billing MMIS for these services to Medicaid through the Authority for reimbursement under Federal Financial Participation (FFP) as part of cost sharing on a fee-for-service basis;

Comments from Linda Williams, OHA (HSD)

Jason [Gingerich] and I discussed services to allow a child to "participate in school" as the responsibility of the school district for health related services provided to eligible children with disabilities as required by the Individuals with Disabilities Act (IDEA).

School Districts and Education Service Districts can and do provide services provided by or under the supervision of medically qualified staff within the scope of practice of their license for services provided to eligible children for: OT, PT, SLP, Audiologist, LCSW, Psychologists, Psychiatrist, nurse services provided by or under the supervision of NP or RN.

The above services are defined as related services under the IDEA and provided pursuant to a child's Individualized Family Service Plan (IFSP) for:

- Early Intervention infants and toddler birth to 3yrs.
- Early Childhood Special Education (ECSE) 3 & 4 years; and

For children/students Kindergarten through grade 12 for children/students age 5 to 21 yrs. pursuant to the eligible child/student's Individualized Education Program (IEP).

School district are also required to provide services as an accommodation for a child/student with a disability eligible under Section 504 of the Rehabilitation Act of 1973 pursuant to a 504 plan

Clarification of Childhood Growth and Development as a Comorbid Condition

Medicaid is first payer before education for IDEA services as required by section 1903(c) of the Social Security Act to ensure children with disabilities have access to and benefit from their Free and Appropriate Public Education (FAPE) required by federal regulations see 34CFR300.154

The important thing to remember regarding services above described is:

A child/student with a disability eligible under the IDEA or eligible under The Rehabilitation Act of 1973, Section 504, required by schools to provide are provided in support of a child's education.

Schools are not clinics charged with responsibilities of providing "medical services" to address overall healthcare needs that are the responsibility of MCO CCO primary care providers