Health Evidence Review Commission

November 9, 2023

1:30 PM - 3:30 PM

Clackamas Community College
Wilsonville Training Center, Room 112 (limited seating)
29373 SW Town Center Loop E, Wilsonville, Oregon, 97070

Join online meeting here

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Section 1.0

Call to Order

Agenda
Health Evidence Review Commission (HERC)
November 9, 2023

1:30 pm–3:30pm

Online & Clackamas Community College (Limited seating)

Wilsonville Training Center, Room 112

29373 SW Town Center Loop E

Wilsonville, Oregon 97070

All agenda items are subject to change and times listed are approximate.
Public comment will be taken on each topic per HERC policy at the time
at which that topic is discussed.

	Time	Topic
I.	1:30 PM	Call to Order, Roll Call, Approval of Minutes
II.	1:35 PM	Director's report
III.	1:40 PM	Value-based Benefits Subcommittee report
VII.	3:20 PM	Next Steps • Next meeting January 18, 2023 (Online & Clackamas Community College, Wilsonville)
VIII.	3:25 PM	Public comment on topics not on the agenda
XI.	3:30 PM	Adjournment

Minutes
Health Evidence Review Commission (HERC)
Online meeting & Wilsonville Training Center Room 112
September 28, 2023

Members Present: Devan Kansagara, MD, Vice-Chair; Lynnea Lindsey, PhD; Adriane Irwin, PharmD; Max Kaiser, DO; Mike Collins; Cris Pinzon, MPH, BSN, BS, RN Stacy Geisler, DDS, PhD; Kathryn Schabel, MD; Holly Jo Hodge, MD, MBA; Leslie Sutton.

Members Absent: Kevin Olson, MD, Chair; Ben Hoffman, MD; Deborah Espesete, LAc, MAcOM, MPH.

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

Also Attending: Chris DeMars; (Oregon Health Authority (OHA)); Shauna Durbin, Rachel McCausland, Ronnie Johnston, Val King, MD, MPH & Marcus Bachhuber (Center for Evidence-based Policy); Ashlynn Wilson; Brian Wilhelmsen; Deb Brugman; Dima Flato; DT; Jennifer Olson; Jenny Dresler (Public Affairs Counsel); Joe Gardner; Kacie Frederick; Kate Mutibura; Katie (Performance Home Medical); Kelsie; Laura; Laura Briggs; Laura Lacey; Sarah Like; Linda Nunes; m.m; mariselalopez; Matt Worthy (OHSU); Rhonda McGivney; Melissa; Natalia P; Natalia Puccinelli (CHC of Lane County); observer; Mariham Fahim, MD & Rafat Fields (Abbott Diabetes Care); Rebecca Gale; Roger Citron (DURM director); santons; sayj; Scott Gascon; Sharon McDowell; Shauna Wick; Siobhan Hess; Tammi Young (PacificSource); Thomas Grace, MD (Dexcom); Todd Dodds.

Call to Order

Devan Kansagara, MD, Vice-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 8/17/2023 meeting as presented. CARRIES 10-0.

Director's Report

Jason Gingerich gave a meeting orientation presentation.

Staff changes
He announced Daphne Peck, who has served the Commission in various roles since 2005, was promoted to outreach coordinator. Recruitment is open for a new administrative staff person.

Membership
Gingerich said recruitment is open for new Commissioners and subcommittee members. The vacancy on HERC is for an insurance representative. Additionally, new Commissioner Dr. Larry Lyon has been appointed and is awaiting Senate confirmation this week.

Lyon introduced himself. He is a family doctor from the Eugene area.

Other transitions, if senate confirmations go as planned:

- Hodges' last HERC meeting may be September
- Olson's last meeting is January 2024;
- Collins will be reappointed to the Commission but is resigning from VbBS at the end of the year
- Kaiser will be reappointed

Rulemaking
Liz Walker said the Rules Advisory Committee (RAC) gave great feedback on the advanced meeting materials draft rule. The draft rule will be posted on the Secretary of State bulletin for a 21-day comment period beginning October 1. Meeting details for a public hearing planned for October 19 are also included in the bulletin posting.

Value-based Benefits Subcommittee (VbBS) Report on Prioritized List Changes

Meeting materials pages 92-241

Ariel Smits reported the VbBS met earlier in the day, 9/28/2023. She summarized the subcommittee's recommendations.

Recommended Code Movement (Changes to the 1/1/2024 Prioritized List unless otherwise noted):

- Add new HCPCS codes to various funded and unfunded lines
- Add the procedure codes for insertion of endobronchial valves to a funded line
- Add the procedure codes for topical oxygen therapy to guideline note 173 and Line 662
- Add the procedure codes for screening and diagnostic CT colonography to funded lines or files
- Add the diagnosis codes for various types of ichthyosis to a funded line
- Add the diagnosis code for FoundationOne CDx tumor testing to the diagnostic procedure file
- Add the procedure codes for percutaneous electrical nerve stimulation and neuromodulation for IBS to an unfunded line
- Add procedure codes for continuous glucose monitors to two funded lines
- Make various straightforward coding changes

Item Considered but No Recommendations for Changes Made:

- MILD procedure for low back pain

Recommended Guideline Changes (Changes to the 1/1/24 Prioritized List unless otherwise noted):

- Add a new guideline for endobronchial valves
- Edit The PANDAS/PANS guideline to add additional examples of provider types
- Add a new guideline for diagnostic CT colonography
- Edit the preventive services guideline to correct the reference to the OHA vaccine program and to outline limited coverage for screening CT colonography
- Add a new guideline for next generation sequencing testing of cancer tissue
- Delete the GnRH analog guideline
- Edit the deep brain stimulation for refractory epilepsy guideline to reduce the number of required medication trials
- Edit the continuous glucose monitoring guideline to include coverage criteria for type 2 diabetes and gestational diabetes

There was discussion about various surgery guidelines and tobacco restrictions. Smits will bring updated wording for review to the November meeting.

MOTION: To accept the VbBS recommendations on *Prioritized List changes* as modified. See the VbBS minutes of 9/28/2023 for a full description. Carries: 10-0.

Coverage Guidance - Continuous Glucose Monitoring (CGM) for Diabetes Mellitus (A device that measures blood sugar throughout the day)

Meeting materials pages 242-356

Gingerich introduced the appointed experts for this topic who were in attendance and available to answer questions, Kimberly Cleveland and Dr. Laura Lacey. Dr. Barbara Hettinger was also an appointed expert but could not attend the meeting.

Val King, MD, MPH and Amy Cantor, MD, MPH, gave the presentation.

Testimony

Carissa Kemp is the director of state government affairs with the American Diabetes Association (ADA) from Idaho who listed no conflicts of interest. She said the ADA has concerns with the draft coverage guidance and asked the Commission to align with Medicare criteria of allowing CGM without the criteria limiting coverage to multiple injection of insulin. She said many people with diabetes in the lowest income brackets do not have the same access to these lifesaving technologies as to higher income peers.

The latest advances in diabetes management should be accessible for all who stand to benefit.

Mariham Fahim, MD, is from Abbott Diabetes. She is not an OHP provider or an Oregon resident. She listed her employer manufactures the FreeStyle Libre System as her conflict of interest. She asked the Commission to align with the CMS policy of covering CGM for patients who use any insulin. She referred to some studies she said showed superior evidence for coverage.

Kansagara clarified these were observational studies, not randomized control trials.

Thomas Grace MD, CDCES, is an employee of Dexcom. He is not an OHP provider or an Oregon resident. He listed his employer as a conflict of interest. He urged the Commission to change the wording of the guideline to allow for more liberal coverage. He referenced nocturnal hypoglycemia as a reason to expand coverage as it is not only risky but can be fatal.

Discussion
Holly Jo Hodges said there was a discussion at VbBS with Roger Citron, OHA contractor, who talked about the pharmacy filling CGM prior authorization requests. She said the Coordinated Care Organizations (CCOs) generally fill them through the durable medical equipment benefit. She compared adherence criteria to what is required for CPAP machines and would like to see something similar in the guideline reflect this.

Kathryn Schabel said the recommendation supported by the evidence is to benefit people who have difficult to manage insulin-dependent type 2 diabetes.

Kansagara addressed the equity issue brought up by advocates and said expanding CGM coverage without evidence may take Medicaid dollars from other needed services.

Hodges said people on one basal (long-acting) insulin injection are less likely to have an issue. It is when short and long acting are combined that problems like hypoglycemia might arise.

Stacy Geisler asked if the definition of “multiple injections” could be defined. After some discussion, the group settled on "use short- or intermediate-acting insulin injections" for the language in the coverage guidance and guideline note.

Commissioners discussed how to best to ensure OHP members are using the devices. They discussed an adherence regimen to ensure CGM is used for diabetes treatment planning. They also allowed for two CGM trials a year.

MOTION: To approve the proposed coverage guidance as amended. Carries 10-0.

Approved Coverage Guidance

QUESTION ONE

Should continuous glucose monitoring (CGM) be covered for individuals with type 2 diabetes mellitus (T2DM) who use insulin?

We recommend coverage for therapeutic CGM in individuals with T2DM or gestational diabetes who use short- or intermediate-acting insulin injections when all of the following criteria are met:

A. **Have received or will receive diabetes education specific to the use of CGM, AND**
B. **Have used the device for at least 50% of the time for a 90-day period by their first follow-up visit (within 3-6 months), AND**
C. **Have one of the following at the time of CGM therapy initiation:**
    a. **Baseline HbA1c levels greater than or equal to 8.0%, OR**
    b. **Frequent or severe hypoglycemia, OR**
    c. **Impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM), OR**
    d. **Diabetes-related complications (for instance, peripheral neuropathy, end-organ damage)**

Every 6 months following the initial prescription for CGM, the prescriber must conduct an in-person or telehealth visit with the member to document adherence to their CGM regimen to ensure that CGM is used for diabetes treatment planning.

Two trials per year of CGM are allowed to meet adherence for continuation of coverage.

Retrospective (physician-owned) CGM is not recommended for coverage.

QUESTION TWO

Should continuous glucose monitoring (CGM) be covered for individuals with type 2 diabetes mellitus (T2DM) who do not use insulin?

We do not recommend coverage for CGM in individuals who do not use insulin, including those with gestational diabetes mellitus (GDM).

Prioritized List Changes

1) **Add several CPT codes to Lines 1 and 27**

Add the following CPT codes to Line 1 PREGNANCY and Line 27 TYPE 2 DIABETES MELLITUS:

a) 95249 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording

b) 95250 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording

c) 95251 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report

2) Add several HCPCS codes to the Ancillary Procedures File

a) A4238 Supply allowance for adjunctive, non-implanted continuous glucose monitor (CGM), includes all supplies and accessories necessary for use of the device (i.e., sensors, transmitter); 1 month supply = 1 unit of service

b) A4239 Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (CGM), includes all supplies and accessories necessary for use of the device (i.e., sensors, transmitter); 1 month supply = 1 unit of service

c) E2102 Adjunctive, non-implanted continuous glucose monitor or receiver; May be covered once every 3 years

d) E2103 Non-adjunctive, non-implanted continuous glucose monitor or receiver; May be covered once every 3 years

3) Revise the existing continuous glucose monitoring guideline based on the Coverage Guidance Box Language

Revise Guideline Note 108 CONTINUOUS GLUCOSE MONITORING to align with coverage guidance recommendation, as amended by the Value-based Benefits Subcommittee and Health Evidence Review Commission on September 28, 2023:

GUIDELINE NOTE 108, CONTINUOUS GLUCOSE MONITORING
Lines 1, 8, 27, 60

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

Therapeutic continuous glucose monitors are included on Lines 1 and 27 for individuals with type 2 diabetes or gestational diabetes who use short- or intermediate-acting insulin injections when ALL of the following criteria are met:

A. Have received or will receive diabetes education specific to the use of CGM, AND
B. Have used the device for at least 50% of the time for a 90-day period by their first follow-up visit (within 3-6 months), AND
C. Have one of the following at the time of CGM therapy initiation:
    1. Baseline HbA1c levels greater than or equal to 8.0%, OR
    2. Frequent or severe hypoglycemia, OR
    3. Impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM), OR
    4. Diabetes-related complications (for instance, peripheral neuropathy, end-organ damage)

Every 6 months following the initial prescription for CGM, the prescriber must conduct an in-person or telehealth visit with the member to document adherence to their CGM regimen to ensure that CGM is used for diabetes treatment planning.

Two trials per year of CGM are allowed to meet adherence for continuation of coverage.

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

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.

Public Comment

There was no public comment at this time.

Adjournment

The meeting adjourned at 4:00 pm. Next meeting will be from 1:30-4:30 pm on Thursday, 11/9/2023 Online and Wilsonville Training Center, Room 112 (Limited guest seating).

Value-based Benefits Subcommittee (VbBS) Summary

For Presentation to:
Health Evidence Review Commission on September 28, 2023

For specific coding recommendations and guideline wording, please see the text of the September 28, 2023, VbBS minutes.

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- Add new HCPCS codes to various funded and unfunded lines
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- Add the procedure codes for topical oxygen therapy to guideline note 173 and Line 662
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- Add the diagnosis codes for various types of ichthyosis to a funded line
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- Add procedure codes for continuous glucose monitors to two funded lines
- Make various straightforward coding changes

Item Considered but No Recommendations for Changes Made:

- MILD procedure for low back pain

Recommended Guideline Changes (Changes to the 1/1/24 Prioritized List unless otherwise noted):

- Add a new guideline for endobronchial valves
- Edit the PANDAS/PANS guideline to add additional examples of provider types
- Add a new guideline for diagnostic CT colonography
- Edit the preventive services guideline to correct the reference to the OHA vaccine program and to outline limited coverage for screening CT colonography
- Add a new guideline for next generation sequencing testing of cancer tissue
- Delete the GnRH analog guideline
- Edit the deep brain stimulation for refractory epilepsy guideline to reduce the number of required medication trials
- Edit the continuous glucose monitoring guideline to include coverage criteria for type 2 diabetes and gestational diabetes

Minutes
Value-based Benefits Subcommittee (VbBS)

Online and Clackamas Community College, Wilsonville OR
September 28, 2023

Members Present: Holly Jo Hodges, MD, MBA, Chair; Brian Duty, MD, Vice-Chair; Cris Pinzon, MPH, RN; Kathryn Schabel, MD; Mike Collins; Adriane Irwin, PharmD.

Members Absent: Kevin Olson, MD; David Saenger, MD.

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

Also Attending: Shauna Durbin, Rachel McCausland, Ronnie Johnston, Val King, MD, MPH & Marcus Bachhuber (Center for Evidence-based Policy); Dawn Mautner, MD; Jason Daniels (OHA); Rebecca Gale; Lawrence Lyon, MD; Ashlynn Wilson; Deb Brugman; Rafat Fields (Abbott Diabetes Care); Jennifer Olson; Stephanie A; Taylor Sibley; Mariham Fahim; Laura; Carissa Kemp (American Diabetes Association); Diana; Dr. Matthew Garoufalis; Dr. Dave Griffin; Stacy Reel; Edward Ysunza; Kyle Dickey; Marie Frazzitta; Kacie Frederick; Thomas Grace, MD; Linda Nunes; Sharon McDowell; Laura Lacey; Melissa; Joseph El Youssef; Roger Citron (DURM Director); DT; Renee Taylor; Brian Wilhelmsen; Kelsie; Kyle Dickey; Stephanie A; Katie (Performance Home Medical); Kelsie, Sarah Like.

Call to Order, Minutes Approval, Staff Report

The meeting was called to order at 8:30 am and roll was called. A quorum of members was present at the meeting. Minutes from the August 17, 2023, VbBS meeting were reviewed and approved with no modifications.

Jason Gingerich gave the orientation statement and staff report. Daphne Peck has moved into a new role as the community outreach coordinator for HERC. A new employee will take over communications with members and meeting coordination. Membership updates were given. Dr. Larry Lyon was introduced, who will be joining HERC as a new member beginning at the November meeting. Gingerich announced that there is an open recruitment for an insurance representative for HERC, and other open positions on subcommittees.

Liz Walker gave an update on rulemaking. New HERC rules will be placed on the secretary of state bulletin and public comments are welcome beginning October 1.

Straightforward/Consent Agenda

Discussion: There was no discussion about the consent agenda items, other than the placement of the Moderna RSV vaccine. A member stated that there is no vaccine that is FDA approved that used that CPT code (90683) and therefore the code was best placed on the Excluded file rather than the Ancillary file.

Recommended Actions:

1) Add 11920-11922 (Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation) to line 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
2) Modify GN221 as shown in Appendix A
3) Delete GN93
4) Modify GN106 as shown in Appendix A
5) Add CPT 90480 and 91318-91322 (COVID vaccine administration) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
6) Delete from line 3: CPT 91302, 91303, 91310, 91312, 91313, 91314, 91315, 91316, and 91317
    a. Recommend HSD place these CPT codes on the EXCLUDED FILE
7) Add CPT 90380 and 90381 (Respiratory syncytial virus, monoclonal antibody) and 90679 (Respiratory syncytial virus vaccine, preF, recombinant, subunit, adjuvanted, for intramuscular use) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
8) Advise HSD to place CPT 90683 (Respiratory syncytial virus vaccine, mRNA lipid nanoparticles, for intramuscular use) on the Excluded file

MOTION: To approve the recommendations as modified. CARRIES 6-0.

MILD procedure for low back pain

Discussion: Smits presented the meeting materials. There was no discussion about the staff recommendation to continue non-coverage.

Recommended Actions:

1) Modify GN173 as shown in Appendix A

MOTION: To approve the recommendations as presented. CARRIES 6-0.

October 2023 HCPCS codes

Discussion: Smits noted that one code was a straightforward placement, and 2 codes were referred to BHAP for discussion. The remainder of the codes were recommended for non-coverage. There was minimal discussion.

Recommended Actions:

1) Add HCPCS C9789 (Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed) to 214 CANCER OF KIDNEY AND OTHER URINARY ORGANS
2) Add the HCPCS codes below to line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS and modify GN173 as shown in Appendix A
    a. A9268 Programmer for transient, orally ingested capsule
    b. A9269 Programable, transient, orally ingested capsule, for use with external programmer, per month
    c. A9292: Prescription digital visual therapy, software-only, FDA cleared, per course of treatment
    d. C9788 Opto-acoustic imaging, breast (including axilla when performed), unilateral, with image documentation, analysis and report, obtained with ultrasound examination
    e. C9790 Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance
    f. C9791 Magnetic resonance imaging with inhaled hyperpolarized xenon-129 contrast agent, chest, including preparation and administration of agent
    g. E0490: Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote
    h. E0491: Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply
    i. K1028: Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application
    j. K1029 Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply

MOTION: To approve the recommendations as presented. CARRIES 6-0.

Breast reduction for macromastia

Discussion: The group desired that there be clear coverage for women with symptomatic macromastia, who have neck, back or shoulder pain, or severe intertrigo. There was concern

about adding the codes from the current macromastia line to only the back line as shoulder pain and intertrigo. The group wanted the ICD-10-CM and CPT codes from the macromastia line added to the shoulder pain line as well as the intertrigo line. It was noted that intertrigo was on an unfunded line (line 503). The group requested that severe intertrigo be added to the severe inflammatory skin disease line where it would be funded if it met guideline note criteria. The inflammatory skin disease line would then have the macromastia codes. As part of the 2026 Biennial Review (which starts in January 2024), the macromastia line would be changed to "symptomatic macromastia" and reprioritized and the duplicative coding deleted. Asymptomatic macromastia would then be included on the line for musculoskeletal conditions with no treatment required line.

Staff will work on operationalizing the requested changes and bring back the final guideline wording to the November VBBS meeting. Staff will also present the VBBS intent to HERC at their meeting on September 28th and include any HERC input in this finalization process.

Endobronchial valves

Discussion: Smits reviewed the summary document. There was some discussion about adding a criterion in the new guideline that patients should not be lung volume reduction surgery candidates; however, the group decided against that as this procedure is less invasive and should be an option available to patients who might not wish an open surgery. The group unanimously elected to approve option 2.

Recommended Actions:

1) Add CPT 31647-31649 and 31651 (bronchoscopy with insertion or removal of bronchial valve(s)) to line 283 CHRONIC OBSTRUCTIVE PULMONARY DISEASE; CHRONIC RESPIRATORY FAILURE and remove these codes from line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
    a. 31647 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe
    b. 31648 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe
    c. 31649 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), each additional lobe
    d. 31651 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), each additional lobe
2) Delete the entry for endobronchial valves from GN173 as shown in Appendix A
3) Add a new guideline to line 283 as shown in Appendix B

MOTION: To approve the recommendations as presented. CARRIES 6-0.

Topical oxygen therapy

Discussion: Smits reviewed the summary document. It was noted that the included studies were limited to intermediate outcomes such as wound healing, rather than critical outcomes such as amputation rates. Pinzon was interested this technology as another tool in the diabetic foot ulcer treatment tool kit.

Public Testimony:

Matthew Garoufalis, an Illinois podiatrist who is the CMO of AOTI (a manufacturer of a topical oxygen device) and past president of the American Podiatry Association testified about his use of this technology on hundreds of patients. He referred to the Yellin 2021 real world study that showed reduced hospitalizations and decreased amputation rate with TOT.

Dave Griffin, a non-Oregon community podiatrist, testified that TOT can address access issues, particularly transportation issues. He testified that black and brown patients frequently lack transportation and access to care and experience a higher rate of diabetes and diabetic foot ulcers. He noted the high mortality from diabetic foot ulcers, and the high cost of care for this condition. TOT is done in the home and is high quality care. Schabel asked him how TOT could impact equity. Griffin responded that TOT is used at home and addressed transportation needs. Pinzon asked if this technology could be used with the houseless population. Griffin answered no, as it requires electricity.

Edward Ysunza, the chief podiatrist at the Portland VA testified about the VA experience with TOT for the past 2 years. He noted that the VA has found very good results in patients who fail usual care. He noted that studies have shown fewer hospitalizations, amputations, and ulcer recurrence. It helps patients be more involved in their own care. Pinzon asked about how generalizable the VA population is to the Medicaid population. Ysunza responded that Oregon VA patients are similar to the general Oregon population.

The subcommittee discussed that TOT was more accessible and would benefit patients with transportation issues. There was a discussion that if a subpopulation that could benefit most from TOT could be identified, then coverage might be considered for that group. Schabel noted that the studies that should be done would compare TOT to no therapy (reflecting the population with little access to care). Irwin and Collins felt that the data does not support that TOT will actually meet the needs of any population, marginalized or not. The decision was to approve the staff recommendation. HERC staff were directed to monitor the CMS review of TOT and bring this topic back for reconsideration if CMS decides to add coverage for TOT.

Recommended Actions:

1) Add topical oxygen therapy to line 662/GN173 as shown in Appendix A
    a. A4575 Topical hyperbaric oxygen chamber, disposable
    b. E0446 Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories

MOTION: To approve the recommendations as presented. CARRIES 5-1 (Schabel nay).

Edits to the PANDAS/PANS guideline

Discussion: Love requested that the term "naturopath" be changed to "naturopathic physician" in the guideline. There was no other discussion and staff recommendations with the modification to the reference to naturopathic physicians was approved.

Recommended Actions:

1) Modify guideline note 228 as shown in Appendix A

MOTION: To approve the recommendations as modified. CARRIES 6-0.

CT colonography

Discussion: Smits presented the staff summary. There was discussion regarding including patients on anti-coagulation that could not be bridged for colonoscopy as an eligible group for CT colonography. There was concern from some members that such patients might not be able to have a polyp removed or a cancer treated if found. The decision was made to not include this population and accept the staff recommendation as presented.

Recommended Actions:

2) Advise HSD to add CPT 74261-74262 (Computed tomographic (CT) colonography, diagnostic, including image postprocessing; with/without contrast material) to the Diagnostic Procedures File
3) Remove CPT 74261-74262 from line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS and delete the entry in GN173
4) Add a new Diagnostic guideline as shown in Appendix B
5) Delete CPT 74263 (Computed tomographic (CT) colonography, screening, including image postprocessing) from line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS and from the GN172 entry as shown below and add to line 3 PREVENTIVE SERVICES WITH EVIDENCE OF EFFECTIVENESS
6) Modify GN106 as shown in Appendix A

MOTION: To approve the recommendations as presented. CARRIES 6-0.

PSMA PET for prostate cancer

Discussion: Tabled to November 2023

Cardiac resynchronization therapy

Discussion: Tabled to November 2023

Ichthyosis

Discussion: There was minimal discussion on this topic.

Recommended Actions:

1) Add the following ICD-10-CM codes to line 426 SEVERE INFLAMMATORY SKIN DISEASE effective 1/1/2024
    a. Q80.0 Ichthyosis vulgaris
    b. Q80.1 X-linked ichthyosis
    c. Q80.2 Lamellar ichthyosis
    d. Q80.3 Congenital bullous ichthyosiform erythroderma
    e. Q80.4 Harlequin fetus
    f. Q80.8 Other congenital ichthyosis
    g. Q80.9 Congenital ichthyosis, unspecified
2) Strike through line 539 ICHTHYOSIS effective 1/1/2024

~~**Line: 539**~~
~~Condition:ICHTHYOSIS~~
~~Treatment:MEDICAL THERAPY~~
~~ICD-10:Q80.0-Q80.9~~
~~CPT:98966-98972,99051,99060,99070,99078,99202-99215,99281-99285,99341-99359,99366,99374,99375,99381-99404,99411-99417,99421-99449,99451,99452,99487-99491,99495-99498,99605-99607~~
~~HCPCS:G0068,G0071,G0088,G0090,G0248-G0250,G0318,G0323,G0425-G0427,G0463,G0466,G0467,G0490,G0511,G2012,G2211,G2212,G2214,G2251-G3003~~

3) Delete line 539 ICHTHYOSIS effective 1/1/2026
4) Modify guideline note 21 as shown in Appendix A

MOTION: To approve the recommendations as presented. CARRIES 5-0 (Duty absent).

FoundationOne CDx

Discussion: Smits reviewed the summary document. There was minimal discussion, other than defining "adequate functional status" as having an ECOG (Eastern Cooperative Oncology Group Performance Status) score of 0-2.

Public testimony
Deb Brugman from FoundationOne and a genetic counselor by training, noted that 16 Medicaid programs cover the FoundationOne CDx test. She noted that the proposed guideline criteria were in line with Medicare guidelines and expert guidelines.

Recommended Actions:

1) Advise HSD to move PLA 0037U (FoundationOne CDx) from the Excluded file to the Diagnostic Procedure File
2) Adopt a new diagnostic guideline as shown in Appendix B

MOTION: To approve the recommendations as presented. CARRIES 6-0.

Nasal fracture repair

Discussion: Tabled to November 2023

Treatment of liver metastases

Discussion: Tabled to November 2023

Percutaneous electrical nerve stimulation and neuromodulation for IBS

Discussion: There was minimal discussion on this topic.

Recommended Actions:

1) Modify guideline note 173 as shown in Appendix A

MOTION: To approve the recommendations as presented. CARRIES 5-0 (Duty absent).

Coverage guidance: continue glucose monitoring

Discussion: King presented the evidence summary for the draft coverage guidance report. Cantor reviewed the summary document, including the proposed changes to the current guideline note for continuous glucose monitoring.

Hodges stated support for coverage of CGMs that are therapeutic, since non-therapeutic devices do not replace finger sticks and do not allow for clinical decision-making. She asked for clarification of criteria for CGM re-initiation. Roger Citron (OHA P&T) described the prior authorization (PA) process and considerations for how often people will need sensors, a transmitter and receiver. He said when PA comes up for renewal, documentation would be needed from the provider attesting to use. He said PA can be initially lax and become more restrictive if non-use was evident. Hodges and Citron discussed initial PA periods, given an expectation of a follow-up visit within 3-6 months with the patient and prescriber. This clause was added to criterion (B) of the guideline note. Pinzon asked about replacement of lost CGM items and how that would affect the PA process. Citron said that PA pharmacy requests are responded to within 24 hours so there should not be a delay in filling prescriptions but that the DME process may be different. Pinzon asked King about the MOBILE trial and how the recommendation came to require multiple daily insulin doses. King said that MOBILE study participants were a mix of intermediate-acting and basal insulin regimens, and it was EbGS's recommendation to require multiple doses given the low confidence of the evidence. Pinzon expressed surprise that the longest follow-up available of the studies was 24 weeks, given that this is a chronic condition which is very common. King said EbGS members expressed similar sentiments.

Public testimony

Thomas Grace, Illinois-based provider employed by Dexcom (CGM manufacturer): Grace testified about the MOBILE study and the heterogeneity of insulin regimens given the basal dose. He stated that people with diabetes who use insulin often fear becoming hypoglycemic and that CGM use can prevent hypoglycemia. He said there is a lot of real-world evidence and that other metrics besides HbA1c exist to measure blood sugar. He advocated for coverage of CGM even for patients with HbA1c levels lower than 8.0, who didn't meet the other criteria for coverage.

Carissa Kemp, Idaho-based Director of State Government Affairs of the American Diabetes Association: Kemp said that the ADA is excited to see the draft recommendation expanding the eligible CGM population but has concerns about the multiple daily dose requirement. Kemp said that Medicare recently changed its requirement to any insulin use and asked that the subcommittee align with this recommendation. She asked for the subcommittee to remove the HbA1c criterion from being one of the possible pathways for obtaining CGM. She also stated that CGM can achieve cost savings. She said that many people with diabetes do not have access to technologies such as CGM compared to higher income peers and that this is a health equity issue.

Mariham Fahim, non-Oregon provider employed by Abbott Diabetes Care (CGM manufacturer): Fahim thanked the subcommittee for considering this expansion but asked the subcommittee to further expand the population by removing the multiple daily dose requirement. She said that real-world evidence shows that CGM adoption is cost-neutral among Medicaid programs. She said that another study shows a 0.6% HbA1c reduction after 12 months use of CGM. She said that Abbott has more data to showcase the benefits of CGM.

Hodges asked the appointed experts to weigh in. Gingerich real aloud the biographical statements of the three ad-hoc experts:

Barbara Hettinger, MD, PhD, is an endocrinologist at the Portland Veterans Affairs Medical Center, specializing in diabetes. She is in active practice and prescribes continuous glucose monitors, which are under review today. Dr. Hettinger is also the Associate Program Director OHSU's Endocrinology, Diabetes and Clinical Nutrition Fellowship program, and she serves on local committees to develop criteria for use of continuous glucose monitors. She has no conflicts of interest to declare.

Laura Lacey, PharmD, is a clinical pharmacist and diabetes specialist. In 2019 she joined the St. Charles Medical Group in Bend. Dr. Lacey utilizes continuous glucose monitors in her regular practice and works under a collaborative practice agreement to provide specialized diabetes management, including insulin pump and continuous glucose monitor management. She has no conflicts of interest to declare.

Kimberly Cleveland, RN, is a diabetes educator at Samaritan Lebanon Community Hospital. Her specialties include diabetes management and diabetes foot care. Ms. Cleveland conducts group classes and individual sessions on diabetes self-management education and provides training on the use of personal continuous glucose monitors. She serves as the Advocacy Co-Chair for the Oregon chapter of Association of Diabetes Specialists. She has submitted legislative testimony in favor of CGM coverage in Oregon's current legislative session.

Lacey said that there needs to be more clarity in the pharmacy PA request process and if provider documentation attesting to use will be sufficient. Hodges said that the utilization documentation would require a download of the monitor's utilization, as is the case with other DME devices that require adherence compliance, such as CPAP. There was a discussion of whether providers would actually have the ability to look at such a download, and whether it was practical during a short visit.

The subcommittee continued to discuss the draft recommendation, including the EbGS's decision to narrow the eligible population to those who require multiple daily doses of insulin. EbGS initially considered noncoverage as their recommendation given the low strength of the evidence, and decided to recommend coverage for a narrower subset given the large expected utilization for this device and the high cost associated with CGM. After discussing several

alternatives, the subcommittee clarified that CGM would be covered for patients requiring either short-acting or intermediate-acting doses of insulin.

Collins disclosed his personal interest given that he is a CGM user and said that when he was doing finger sticks, he would not be checking as often as he should. Now that he wears a CGM, he gets an alarm when he gets a low level.

Walker said there was a CGM coverage mandate bill this past legislative session which had recommended more than two daily insulin doses per day in order to be eligible for CGM. Irwin said she is struggling between the available evidence and the pragmatic decisions taken today. Pinzon said that CGM is a powerful tool and getting feedback is useful. Schabel said that given that EbGS went from a no-coverage recommendation to a recommendation of coverage among those who are on multiple insulin doses is compelling for her. She moved to approve the draft coverage guidance as modified for referral for HERC consideration.

Recommended Actions:

1) Add the following CPT codes to Line 1 PREGNANCY and Line 27 TYPE 2 DIABETES MELLITUS effective 1/1/2024
    a. 95249 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording
    b. 95250 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
    c. 95251 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report
2) Add the following HCPCS codes to the ANCILLARY PROCEDURES file effective 1/1/24
    a. A4238 Supply allowance for adjunctive, non-implanted continuous glucose monitor (CGM), includes all supplies and accessories necessary for use of the device (i.e., sensors, transmitter); 1 month supply = 1 unit of service
    b. A4239 Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (CGM), includes all supplies and accessories necessary for use of the device (i.e., sensors, transmitter); 1 month supply = 1 unit of service
    c. E2102 Adjunctive, non-implanted continuous glucose monitor or receiver; May be covered once every 3 years
    d. E2103 Non-adjunctive, non-implanted continuous glucose monitor or receiver; May be covered once every 3 years
3) Modify guideline note 108 as shown in Appendix A

MOTION: To approve the recommendations as modified. CARRIES 6-0.

Public Comment

No additional public comment was received.

Issues for next meeting

- Breast reduction for macromastia
- PSMA PET scans for prostate cancer
- Cardiac resynchronization therapy
- Nasal fracture repair
- Treatment of liver metastases

Next meeting

November 9, 2023, online and Clackamas Community College, Wilsonville, OR.

Adjournment

The meeting adjourned at 1:00 PM.

Appendix A
Revised Guideline Notes

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

Lines 426,482,504,533,542,555,656

Inflammatory skin conditions included in this guideline are:

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

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, 533, 542, 555 and 656.

For severe psoriasis, treatments included on this line are topical agents, phototherapy, targeted immune modulator medications and other systemic medications.

For severe atopic dermatitis/eczema, treatments included on this line are topical moderate- to high-potency corticosteroids, topical calcineurin inhibitors (for example, pimecrolimus, tacrolimus), narrowband UVB, topical phosphodiesterase (PDE)-4 inhibitors, and oral immunomodulatory therapy (e.g., cyclosporine, methotrexate, or oral corticosteroids). Targeted immune modulators (for example, dupilumab) are included on this line when:

A) Prescribed in consultation with a dermatologist or allergist or immunologist, AND
B) The patient has failed (defined as inadequate efficacy, intolerable side effects, or side effects that pose a health risk) either
    1) a 4 week trial of a combination of topical moderate to high potency topical steroids and a topical non-steroidal agent OR
        an oral immunomodulator, OR
    2) 12 weeks of phototherapy.

JAK inhibitor (upadacitinib) therapy is included on this line when other immunomodulatory therapy has failed to adequately control disease (defined as inadequate efficacy, intolerable side effects, or side effects that pose a health risk).

ICD-10-CM Q82.8 (Other specified congenital malformations of skin) is included on Line 426 only for Darier disease.

Appendix A
Revised Guideline Notes

~~**GUIDELINE NOTE 93, IMPLANTABLE GNRH ANALOG THERAPY**~~

~~*Line 187*~~

~~Use of drug delivery implant therapy for GnRH analogue therapy (such as histrelin) (CPT 11981-11983) is covered only when injectable depot medications (such as Lupron) are contraindicated or after such medications have been tried and complications preclude further use.~~

[changes in red made at the September 28, 2023 HERC meeting]

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, 2022.
   1) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/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 https://downloads.aap.org/AAP/PDF/periodicity_schedule.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 (revised** January 2022). Available at https://www.hrsa.gov/womens-guidelines as of July 28, 2022.

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~~
https://www.oregon.gov/oha/ph/preventionwellness/vaccinesimmunization/immunizationproviderresources/pages/payor.aspx
   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.

2) Other ACIP recommended vaccines not on the routine vaccine schedule are covered as specified in the MMWR as required by federal law: https://www.cdc.gov/vaccines/hcp/acip-recs/index.html

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

Screening CT colonography (CPT 74263) is only covered for patients who are unable to complete a screening colonoscopy due to colon structural problems (for example, colonic obstruction, stricture, or compression or tortuous or redundant colon) ~~on the same day at the CT colonography is done.~~

~~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 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 aged 65 or 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 96110 (Developmental screening (e.g., 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

Lines 1, 8, 27, 60

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

Therapeutic continuous glucose monitors are included on Lines 1 and 27 for individuals with type 2 diabetes or gestational diabetes who use short- or intermediate-acting insulin injections when ALL of the following criteria are met:

A. Have received or will receive diabetes education specific to the use of CGM, AND
B. Have used the device for at least 50% of the time for a 90-day period by their first follow-up visit (within 3-6 months), AND
C. Have one of the following at the time of CGM therapy initiation:
   1. Baseline HbA1c levels greater than or equal to 8.0%, OR
   2. Frequent or severe hypoglycemia, OR
   3. Impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM), OR
   4. Diabetes-related complications (for instance, peripheral neuropathy, end-organ damage)

Every 6 months following the initial prescription for CGM, the prescriber must conduct an in-person or telehealth visit with the member to document adherence to their CGM regimen to ensure that CGM is used for diabetes treatment planning.

Two trials per year of CGM are allowed to meet adherence for continuation of coverage.

CPT 95250 and 95251 (Ambulatory continuous glucose monitoring) are included on ~~this line~~ these lines 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.

Appendix A
Revised Guideline Notes

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
A0475, E0446	Topical oxygen therapy	Insufficient evidence of effectiveness	September2023
A9268, A9269	Ingestible vibrating devices for the treatment of constipation	Insufficient evidence of effectiveness	September 2023
A9292	Prescription digital visual therapy for amblyopia	Insufficient evidence of effectiveness	September 2023
C9788	Optoacoustic breast imaging	Insufficient evidence of effectiveness	September 2023
C9790	Histotripsy for malignant renal tissue	Insufficient evidence of effectiveness	September 2023
C9791	Magnetic resonance imaging with inhaled hyperpolarized xenon-129 contrast agent, chest, including preparation and administration of agent	Insufficient evidence of effectiveness	September 2023
E0490, E0491, K1028, K1029	Daytime intraoral neuromuscular electrical tongue stimulation for snoring and obstructive sleep apnea	Insufficient evidence of effectiveness	September 2023
S8930 0720T	Electrical stimulation of auricular acupuncture points by proprietary electrical stimulation devices, such as P-Stim and E-pulse [note: auricular electroacupuncture provided by a licensed provider in a clinical setting is covered under CPT 97813-97814] Percutaneous electrical nerve field stimulator (PENFS), percutaneous electrical nerve stimulation (PENS) and percutaneous neuromodulation therapy (PNT) for irritable bowel syndrome (for example, IB-Stim)	No evidence of effectiveness	March, 2018 September 2023 for IBS indications

Appendix A
Revised Guideline Notes

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~~ November 2023
~~31647-31649, 31651~~	~~Bronchial valve insertion/removal/replacement~~	~~Insufficient evidence of effectiveness~~	~~December, 2012~~
~~74261-74262~~	~~Computed tomographic (CT) colonography~~		~~December, 2009~~
~~74263,~~ 81528, 81327, G0327	~~Screening CT colonography,~~ FIT-DNA (Cologuard), mSEPT9, Chromoscopy	Insufficient evidence for use in population screening	~~August 2021~~ August 2923

GUIDELINE NOTE 221, DEEP BRAIN STIMULATION FOR TREATMENT OF REFRACTORY EPILEPSY

Line 174

Deep brain stimulation for treatment of refractory epilepsy is included on this line only when

A) The surgery is performed at a Level 4 epilepsy center, AND

B) The patient has failed ~~multiple (three~~ two or more~~)~~ anti-seizure medications, AND

C) The patient is ineligible for resective surgery OR has failed vagus nerve stimulation or resective surgery.

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 228, PANDAS, PANS AND AUTOIMMUNE ENCEPHALITIS

Line 313

ICD-10-CM G04.82 (Other encephalitis and encephalomyelitis) is only included on this line for autoimmune encephalitis and related non-PANDAS/PANS conditions and is not included in this

guideline. Autoimmune encephalitis must meet established diagnostic criteria (for example, the International Encephalitis Consortium 2013 diagnostic criteria).

Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) is included on this line when coded with ICD-10-CM D89.89 (Other specified disorders involving the immune mechanism, not elsewhere classified). Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS) is included on this line when coded with ICD-10-CM D89.9 (Disorder involving the immune mechanism, unspecified).

Up to 3 monthly immunomodulatory courses of intravenous immunoglobulin (IVIG) therapy is included on this line to treat PANDAS and PANS when both of the following are met:

A) A clinically appropriate trial of two or more less-intensive treatments (for example, appropriate limited course of nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, selective serotonin reuptake inhibitors (SSRIs), behavioral therapy, short-course antibiotic therapy) was either not effective, not tolerated, or did not result in sustained improvement in symptoms (as measured by a lack of clinically meaningful improvement on a validated instrument directed at the patient's primary symptom complex). These trials may be done concurrently, AND
B) A consultation with and recommendation from a pediatric subspecialist (for example, pediatric neurologist, pediatric psychiatrist, pediatric mental health nurse practitioner, neurodevelopmental pediatrician, pediatric rheumatologist, pediatric allergist/immunologist, as well as the recommendation of the patient's primary care provider (for example, family physician, pediatrician, pediatric or family nurse practitioner, family or pediatric physician assistant, naturopathic physician). The subspecialist consultation may be a teleconsultation. For adolescents, an adult subspecialist consult may replace a pediatric subspecialist consult.

A reevaluation at 3 months by both the primary care provider and pediatric expert is required for continued therapy of IVIG. This evaluation must include clinical testing with a validated instrument, which must be performed pretreatment and posttreatment to demonstrate clinically meaningful improvement.

Long term antibiotic therapy is not included on this line for treatment of PANDAS/PANS.

Therapeutic plasma exchange (CPT 36514) does not pair with PANDAS or PANS (ICD-10-CM D89.89 or D89.9).

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

Appendix B
NEW GUIDELINE NOTES

[changes in red made at the September 28, 2023 HERC meeting]

DIAGNOSTIC GUIDELINE DX, DIAGNOSTIC CT COLONOGRAPHY

Diagnostic CT colonography (CPT 74261-74262) is covered for evaluation of symptomatic individuals who

1) Are unable to undergo colonoscopy due to known structural problems (for example, colonic obstruction, stricture, or compression or tortuous or redundant colon); OR
2) Who were unable to complete a diagnostic colonoscopy due to colon structural problems ~~on the same day that the CT colonography is done.~~

[changes in red and blue made at the September 28, 2023 HERC meeting]

GUIDELINE NOTE XXX ENDOBRONCHIAL VALVES

Line 283

Endobronchial valves (CPT 31647-31649 and 31651) are only included on this line when ALL of the following criteria are met:

1) The patient has severe heterogeneous or homogeneous emphysema
    a) Severe emphysema is demonstrated by pulmonary function testing showing
        i) Forced expiratory volume in one second (FEV 1) ≤ 45% predicted and, if age 70 or older, FEV 1≥ 15% predicted value
        ii) Total lung capacity (TLC) ≥ 100% predicted post-bronchodilator
        iii) Residual volume (RV) ≥ 150% predicted post-bronchodilator
2) The patient has significant hyperinflation in regions of the lung that have little to no collateral ventilation
3) The patient is receiving optimized medical care
4) The patient is stable with ≤20 mg prednisone (or equivalent) dose a day
5) The patient has participated in pulmonary rehabilitation and has a post-rehabilitation 6-min walk of ≥ 140 m
6) ~~The patient is a non-smoker or abstinent from all nicotine products for 6 months prior to surgery, as shown by negative cotinine levels at least 6 months apart, with the second test within 1 month of the procedure date~~
7) The patient is a non-smoker as determined by the performing provider

DIAGNOSTIC GUIDELINE DX, NEXT GENERATION SEQUENCING OF MALIGNANCIES

Next Generation Sequencing (NGS, for example CPT 81479, 81455, 0037U) is covered when all of the following requirements are met:

1) The patient has
    a. Either recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer; AND
    b. Has not been previously tested using the same NGS test for the same primary diagnosis of cancer, unless the criteria in 4) below are met; AND

   c. Decided to seek further cancer treatment (for example, therapeutic chemotherapy) and has adequate performance status (ECOG 0-2) to undergo such treatment; AND

2) The diagnostic laboratory test using NGS must have:
   a. Clinical Laboratory Improvement Amendments (CLIA)-certification; AND
   b. The test is being used as a companion diagnostic test in accordance with Food & Drug Administration (FDA)-approved therapeutic labeling; AND
   c. Results provided to the treating physician for management of the patient using a report template to specify treatment options; AND
3) A single CPT or HCPCS code is covered for each multigene panel performed on tumor tissue. Additional codes for individual genes and for molecular pathology procedures CPT 81400-81408 are excluded from coverage when the multigene panel is covered under the appropriate CPT or HCPCS code.
4) Repeat NGS testing may be required in the setting of patients who have clinically progressed per standardized professional guidelines after therapy. Coverage in this situation is limited to 3 times per primary malignancy unless there is indication for additional testing after individualized review of medical necessity.

Highlights
Genetic Advisory Panel (GAP)
Virtual Meeting
October 18, 2023
2:00 PM-4:00 PM

Members Present: Karen Kovak; Sue Richards, PhD; Carl Stevens, MD; Nicoleta Voian, Becky Clark.

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

Also Attending: Ashley Lewton, Belinda Denny, Helen Rust, Joan Chappell (Washington HCA), Lindsay Fredrikson, Melissa Limburner, Ashley Svenson (Myriad Genetics).

The meeting was called to order at 2:00 PM. Roll was called. This is an advisory panel to staff of 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 9/29/21 meeting. Given the advisory nature of this meeting, a quorum was not necessary as no votes were taken. The highlights from the 2022 GAP meeting were reviewed and no changes were suggested.

1) Routine NCCN reference update for genetics-related guidelines: no discussion regarding the updates to the breast cancer risk reduction guideline. However, members of GAP raised concerns about the guideline as currently written.
    a. The current guideline refers to only genetic testing for breast, ovarian, pancreatic and colon cancer syndromes. GAP members pointed out that NCCN now has guidelines for 37 different types of cancer or tumor syndromes (see the NCCN table in the packet for details). GAP recommended either adding references to all of these NCCN guidelines or removing the current section that references just the two specific NCCN guidelines.
    b. There is a section in the guideline that limits testing to known BRCA variants in patients with a known family mutation. This is not current standard of care. If a patient has a known variant in one family member, there may still be other variants in the family, or other variants coming from the other parent side of the family. There is also a mention in this section about specific testing for people of Ashkenazi Jewish heritage, which has been removed from all other HERC genetic guidelines. GAP recommended striking this entire section.
    c. There is a section in the guideline not allowing additional charges for rush testing. Members pointed out that there are no longer any charges for rush testing and recommended striking this section.
    d. The section on genetic testing should allow providers other than the specifically mentioned types to provide counseling and order testing. Breast surgeons, gynecologists, oncologic surgeons, and many others are now doing these services. GAP recommended just restricting to a health care professional with expertise in genetics to provide counseling and order testing. When asked whether there was concern about inappropriate orders from community providers, GAP responded that this concern was much lower than concern for not allowing timely testing.

2) 2024 genetic-related CPT codes: there was no discussion regarding the code placement recommendations.
    a. Carl Stevens raised concerns about section 1A of the new next generation sequencing guidelines. Currently, section 1A limited NGS testing to "Either recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer." This was written to be consistent with current CMS guideline wording. However, Dr. Stevens notes that there are many cases in which testing early in the course of a cancer diagnosis is preferable. Some types of cancer have targeted therapies if they contain specific gene mutations. Some types of cancer with specific mutations can be cured with targeted therapy in early stages. Dr. Stevens felt that any cancer that has a molecular profile that is amenable to any of the targeted therapy should be allowed to have targeted therapy rather than general chemotherapy. He suggested changing 1A to "tissue diagnosis confirming cancer and have been evaluated by an oncologist or oncologic surgeon."

3) Genetic testing for developmental disabilities, intellectual disability, and autism spectrum disorder:
    b. HERC staff suggesting adding a section to the non-prenatal genetic testing guideline to include PTEN testing for macrocephalic boys with ASD. The other genetic tests in the AAP guideline currently have no guideline limitations and would be indicated for children with syndromic exam findings. GAP however, did not agree with the suggested guideline note changes.
    c. GAP members felt that there are many syndromes that have exam findings that can indicate various genetic tests. The members felt that the staff suggested edits to Diagnostic Guideline D1 that outlined the various tests that might be indicated for persons with autism spectrum disorder or intellectual disability were not needed and might be confusing.
    d. GAP members felt that PTEN, testing for Rhett syndrome, etc. were all appropriate in certain clinical scenarios and it should be the intent of the HERC that such testing be allowed for patients with autism, intellectual disability or developmental delay.

4) Other business: GAP members requested that the 2024 GAP meeting include an evidence review and discussion regarding whole genome sequencing. Currently, whole genome sequencing is limited to newborns. It was noted that the Washington HTA is currently reviewing coverage for whole genome sequencing for children over the age of one. HERC staff will wait for the Washington HTA report and then bring this topic to GAP for discussion.

Highlights

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

Virtual Meeting
October 11, 2023
1:00 PM – 3:00 PM

Members Present: Gary Allen, DMD; Karen Nolon; Laura McKeane; Dayna Steringer; Deborah Loy; Stacy Geisler, DMD, MD; Manu Chaudhry, DMD; Alison Noble.

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

Also Attending: Jessica Dusek**,** Janet Herb, and Amy Umphlett (OHA); Samantha Shepherd, Stephanie Asher, Mathew Sinnott, Pixie Needham, Jonathan Kim, sayj, Heather Simmons, Alyssa Franzen (CareOregon), Gita Yitta (AllCare CCO), Cathleen Olesitse, Jennie, Kimberley, Kathy, Laura Blanke, Vesna Hopkins, Yuberca Ward.

Roll Call/Minutes Approval/Staff Report

The meeting was called to order at 1:00 PM and roll was called. Highlights from 11/4/2022 meeting were reviewed and no changes were suggested.

- **Topic: 2024 CDT code placements**

• D0396: The staff suggestion was to place on line 469 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH) Treatment ADVANCED RESTORATIVE (I.E., BASIC CROWNS). OHAP discussed that the 3D dental scan was similar to D0470 (diagnostic casts) which is currently on the Excluded file. Both D0396 and D0470 are used for crowns, dentures and orthodontic care. Current OHA dental rule states that these codes are not to be billed separately. OHAP members discussed that the code for the 3D scan which is used to make the 3D print (D0801-D0802 3d dental surface scan) are on line 256. Both D0396 and D0470 can be used for determination of the orthodontic benefit, which would make these types of procedures diagnostic. OHAP recommended after discussion that D0396 be placed on the Diagnostic Procedures File, and that D0470 and D0801-D0802 also be placed on the Diagnostic Procedure File. D0801-D0802 would be removed from line 256. OHA rulemaking will take place in the first quarter of 2024 and discussion could occur then about whether the rule should continue to require that these codes be bundled and not paid separately. HERC staff were directed to look at the ADA rulebook for all CDT codes that are considered diagnostic for consideration for placement on the Diagnostic Procedures File. HERC staff and OHA staff were directed to look at the dental rule (OAR 410-123-1200) for all codes that are listed as not separately billable and

see if this is still appropriate. The codes representing the services not separately billable in this rule will be brought to the next OHAP meeting for review. OHAP requested a meeting in the first quarter of 2024 to review the diagnostic CDT codes, the non-separately billable codes, and any CDT codes on the Excluded file.

• D1301: There was discussion about whether a dental office could bill separately for immunization counseling, or whether this was bundled into the actual vaccine administration fee. Smits noted that medical offices can bill separately for vaccine counseling, and be paid for this even if the patient elects to not receive the vaccine. The final decision was to place this code on the preventive services line.

• D0276: no discussion

• D2989: minimal discussion

• D2991: HERC staff literature review found several evidence-based reviews on hydroxyapatite which found that it can be beneficial in dental care products (toothpaste, mouthwash, etc.) but that its use in dentistry needs clinical trials. There was discussion that there are commercially available medicaments with hydroxyapatite which could be used in a dental office. There was discussion about making this code Excluded, but OHAP felt that it would be better placed on line 646 to make it clear that it was non-covered.

• D6089: This code is part of implant care. OHAP felt that this was outside the scope of general dentists, and should only be done by an implant trained oral health provider. The recommended placement was on the implant line

• D7284: There was discussion about whether this code was diagnostic or a surgical procedure. There is another CDT code for the pathology associated with the biopsy. Salivary glands can be excised for both diagnostic purposes, for example, to diagnose Sjogren's syndrome or evaluate an abnormal appearing gland. It can also be done as a therapeutic procedure, to remove a large or painful gland. OHAP determined that even when done as a therapeutic procedure, this procedure still had an element of being a diagnostic test and should be on the Diagnostic Procedures file.

•D7939: minimal discussion

•D9938 and D9939: no discussion

•D9954 and D9955: The Oregon Dental Board site was accessed, and it clearly states that the fabrication of an oral appliance is within the scope of a dentist, but only after a diagnosis of obstructive sleep apnea has been made by a physician. There was minimal discussion regarding the fabrication of an oral appliance. From the dental board site: "dentists legally are not in a position to diagnose sleep disordered breathing and sleep apnea; a physician must make the diagnosis and then prescribe oral appliance therapy before the dentist can treat it."

HERC staff noted that there were two HCPCS codes for oral appliances (K1027 and E0486) that are currently listed as "never reviewed." All of these codes should be added to the sleep apnea line. Use of oral appliances is governed by the sleep apnea treatment guideline. CDT D9947-D9951 which code for fabrication and adjustment of oral devices are on line 202.

•D9956: There was considerable debate about whether dentists could legally order a sleep study. The dental board site was accessed as noted above, and it was confirmed that diagnosing obstructive sleep apnea is outside the scope of practice for dentists in Oregon. This code was recommended for the Excluded file.

•D9957: This code had been suggested by staff to be placed on the sleep apnea line. However, due to the concern that diagnosis of OSA was outside of Oregon dental licensure, it was unclear if screening for OSA would be in scope. HERC staff was directed to ask the dental board about whether screening for OSA is in scope; if so, this code should be Diagnostic Procedures file. If not, D9957 should be Excluded.

- **Discussion on denture and implant coverage**

HERC staff have heard OHA member concern regarding lack of coverage for dentures and dental implants. Staff asked the OHAP what they would recommend for coverage expansion if funding for additional dental services was procured.

Members are aware of frustration around coverage of dentures. Allen noted that adult dentures are not a mandatory benefit under Medicaid by federal rule, and are only covered to the extent allowed by the Oregon Legislature. There are budgetary constraints to expanding benefits in these areas. Denture benefits are very expensive.

Suggestions for the most beneficial expansions of denture benefit would be to allow partial dentures for fewer numbers of missing teeth, when the front teeth are involved, or for missing premolars. There was discussion about allowing denture replacement sooner than currently allowed (10 years for full dentures) when the dentures are lost or stolen. Other members noted that current rule does allow denture replacement when stolen, lost in natural disaster, or other circumstances outside of the member's control. It was noted that earlier replacement may not be part of the rates for dental organizations. One member suggested focusing any additional funding on treatments to retain natural teeth, such as crowns after root canals. Currently, this benefit is very limited by age and type of teeth. Coverage of crowns was also cut years ago by rule/Legislative intent due to budget issues.

- **Additional topics discussed**

Allen requested that frenulectomy (lip tie) be limited to members under age 21 in the Prioritized List guideline. These services were limited to children in rule, but have been dropped from the current OHA dental rule for unclear reasons. OHAP requested that the

guideline regarding frenulectomy be modified to indicate that coverage is limited to patients under the age of 21.

- **Public Comment:** no additional public comment was received

- **Issues for next meeting:**

• Review of diagnostic CDT code placement
• Review of current excluded CDT codes in OHA rule

- **Next meeting:**
    - TBD

Highlights
10-13-2023
Behavioral Health Advisory Panel (BHAP)
Online

Members Present: Lynnea Lindsey, PhD; Kathy Savicki, LCSW; Gary Cobb; Eric Davis, MSW, CADC III, PSS; MSCP; Sheldon Levy, PhD; John Bischof, MD; Ryan Bair, DSW, LCSW; Ida Moadab, PhD; Mikilah Johnson, LMFT; Tara Candela, JD, PMHNP-BC; Frances Robbins, PMHNP

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

Also Attending: Luke Todd, Stanlee Menniti, Amy Chandler and Dalila Morales (OHA); Nicole Canedo; olive; George Fox nursing students; Tami Stump (Polk County); Selena DeLeon; Kera Hood; junbro; cy Jackson; Tracy; joliw; Stephanie Asher (Providence); Danielle D; Holly Jo Hodges; Sandi Koch; bireland@trilliumfamily.org; sarsmi5; Jenna Halstead; Kristina Nelson; Carol Lurix; Kim Lee and Erika Armsbury (CareOregon); Mary Richmond; Christie Taylor; Jennifer M; DeAnn Carr, Becky Johnson; Maritzza Y Herrara; Schuyler Ellis; Maritza; Matt Stayner; Bettina Schempf; Sara Hatch; Molly McGrew; devid.melear@uhsinc.com; Kate York; Amanda Stephens; Linda Finch; Rachel-Hearthstone; Taylor Dombek

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1. Call to order/purpose of meeting/staff updates

The meeting was called to order at 10:05 AM. Smits gave a short presentation on the purpose or BHAP and an overview of the HERC process. Introductions were done.

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2. PRIORITIZED LIST ISSUES

A. 2023 HCPCS codes related to behavioral health
   a. BHAP recommended coverage for HCPCS H2040 and H2041, which are designed for case rate care for programs that do early intervention for psychosis (EASA programs). These codes should be added to any line with a psychotic condition. Lynnea Lindsey volunteered to provide HERC staff with the ICD-10-CM codes used by the early psychosis intervention program in her organization. These codes should appear on any line with one of the ICD-10-CM codes on this list.

B. Problems related to unspecified psychosocial circumstance
   a. BHAP agreed that ICD-10-CM Z65.9 (Problem related to unspecified psychosocial circumstances) and Z65.8 (Other specified problems related to psychosocial circumstances) should be added to a covered line to allow Oregon Pediatric Improvement Partnership (OPIP) and other early intervention programs to assist

kids. Its important to provide support for children in challenging psychosicial circumstances as early as possible in a child's life to avoid development of mental health issues. BHAP recommended placement of these codes on line 445 ADJUSTMENT DISORDERS. HERC staff was directed to reach out to child psychiatrists and the OPIP program to determine if an age limit should be placed on this diagnosis. The two proposed age limits were 5 and younger and 12 and younger. HERC staff was also directed to reach out to other Medicaid programs for information on other state coverage policies.

C. Transcranial magnetic stimulation (TMS)
    a. Number of covered sessions: there was general agreement that adding 6 taper sessions was a desirable change. Testimony was heard from Schuler Ellis, a psychiatric nurse practitioner who providers TMS therapy, that up to 56 sessions should be considered for late responder patients. BHAP however, felt that the addition of the 6 taper sessions was sufficient.
    b. Adding coverage for TMS for obsessive compulsive disorder (OCD): Mr. Ellis testified that his personal experience is that TMS provides a good response for OCD, with about a 30% reduction in patients who do respond. OCD is difficult to treat, medications are not as helpful. BHAP members were not in favor of adding coverage for OCD based on the lack of consistent data showing a benefit.
    c. Adding coverage for adolescents: no BHAP member recommended this, and Mr. Ellis testified that he agreed that the adolescent data is emerging, and agrees with not covering at this time.
    d. Requirements before TMS approval: BHAP members were split on whether there was sufficient access to psychotherapy currently in Oregon to continue to require a trial of psychotherapy prior to TMS. There was also question about whether the current requirement of 6 sessions even constitutes a realistic trial of psychotherapy. Robbins stated that in her opinion, TMS should be first line treatment with no requirements. The group noted that TMS was only FDA approved for "treatment resistant depression." There was vigorous discussion about what constitutes "treatment resistant depression." Mr. Ellis testified that most private payer policies have removed the requirement for a trial of psychotherapy. The final recommendation of the BHAP was to modify the guideline to require at least one medication trial and a second treatment trial, which could either be medication or psychotherapy. This reflects that psychotherapy is equally effective to medications and addresses some member concerns about medication side effects.
    e. Additional public comment: an audience member noted that there are multiple versions of TMS now being used, and recommended that "repetitive" be removed from the guideline title to reflect this.

D. Behavioral Health related denied claims review
    a. BHAP members felt that residential care was not appropriate for autism spectrum disorder per se. People on the autism spectrum who have another serious mental health issue can assess residential programs for the other serious mental health disorder.

b. BHAP members when that group psychotherapy was appropriate for some people on the autism spectrum and recommended adding the code for this service to the autism spectrum line.

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3. Other issues

Tami Stump requested that the HERC consider adding peer related services to the diagnostic list to allow services before a diagnosis is made. Peer services are on the fee schedule for pre-treatment planning. There was discussion about scope of service, and the fact that peers cannot make a diagnosis to generate an ICD-10-CM diagnosis code for claims. Luke Todd, an OHA staff member who works with mobile crisis intervention services, noted that HCPCS H2011 is open for peer services to bill. He suggested possibly using the ICD-10-CM Z65.9 code discussed earlier as a diagnostic code to pair with peer services. HERC staff will reach out to the peer services program at OHA to discuss this further.

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4. ADJOURNMENT

The meeting was adjourned at 11:40 AM

Section 2.0

Staff Report

Section 3.0

Plain Language Summaries

Value-based Benefits Subcommittee (VbBS)
Plain Language Summary of Topics
November 9, 2023

This plain language summary provides a short and non-technical explanation of the topics that will be discussed at the meeting, along with the staff recommendations. Decisions are not final unless approved by the Health Evidence Review Commission (which usually meets later on the same day). The Commission may approve, modify, or not approve staff recommendations.

OHAP Straightforward Guideline Note Changes

Plain Language Summary:

Coverage question: Should OHP cover a medical procedure to clip a small piece of tissue under the lip (frenulectomy/frenulotomy) for patients ages 12-21?

Should OHP cover this treatment? Yes, staff propose covering if the patient has receding gums, a condition when gum tissue starts to pull back and wear away from teeth.

BHAP Straightforward Code Change

Plain Language Summary:

Coverage question: Should OHP cover therapy given in a group setting for autism treatment?

Should OHP cover this treatment? Yes, staff recommend that this should be covered.

Problem Related to Unspecified Psychosocial Circumstances

Plain Language Summary:

Coverage question: Should OHP cover a non-specific mental health and social condition?

Should OHP cover this treatment? Yes, staff suggest covering this as multiple groups in Oregon recommend covering this condition.

Value-based Benefits Subcommittee (VbBS)
Plain Language Summary of Topics
November 9, 2023

Transcranial Magnetic Stimulation (TMS) 2023 Review

Plain Language Summary:

Coverage question: TMS uses magnets to create a strong, targeted electric current in certain parts of the brain. which may help improve mental health conditions including depression. Should OHP:
1) Increase the number of treatments allowed?
2) Cover TMS for obsessive compulsive disorder (OCD)?
3) Cover TMS for people under 21 with severe depression?
4) Change the requirements for getting TMS?

Should OHP cover these treatments? Staff recommends:
1) Yes, the number of sessions should be increased by 6.
2) No, there is not any data showing that TMS works for OCD.
3) No, the data is still emerging for this age group.
4) Yes, change the requirements a trial of one medication and a second treatment trial, which could be a medication or therapy.

Hereditary Cancer Genetic Testing Guideline Update

Plain Language Summary:

Coverage question: Should OHP make major changes to the guideline on medical testing that helps determine a higher risk of developing certain types of cancer due to their family's genetic history.

Should OHP cover these tests? Yes, staff suggests adding tests recommended by a national expert group for 37 conditions, letting them simplify the guideline. In addition, strike the section about rush testing and strike the wording that requires "suitably trained" health professionals.

Value-based Benefits Subcommittee (VbBS)
Plain Language Summary of Topics
November 9, 2023

Genetic Testing for Developmental Disabilities, Intellectual Disability, and Autism Spectrum Disorder

Plain Language Summary:

Coverage question: Should OHP update the guideline on medical testing that helps decide a higher risk of developing certain types of disabilities or disorders?

Should OHP cover these tests? Staff recommends no changes to the guideline. There are still problems with the large genetic tests for X linked disorders.

OncoExTra

Plain Language Summary:

Coverage question: Should OHP cover a medical testing that helps figure out the risk for advanced cancer (OncoExTra)?

Should OHP cover this treatment? Yes, staff recommend covering as similar tests using more generic codes are already covered.

Computer Assisted Bronchoscopy 2023 Review

Plain Language Summary:

Coverage question: Should OHP cover a procedure that uses computer pictures to help guide where a doctor looks in the lungs to get sample tissue?

Should OHP cover this treatment? Yes, newly published medical studies show this procedure is both safe and accurate.

Value-based Benefits Subcommittee (VbBS)
Plain Language Summary of Topics
November 9, 2023

Anterior Thoracic Vertebral Body Tethering

Plain Language Summary:

Coverage question: Should OHP cover a medical process to attach a device to the bones of the spine to treat abnormal curves of the spine?

Should OHP cover this treatment? No, the risks for this process are too high and it is considered not yet proven (experimental) by private insurance.

Posterior Nasal Nerve Ablation

Plain Language Summary:

Coverage question: Should OHP cover a medical process to destroy a nerve that can cause a constant runny nose?

Should OHP cover this treatment? No. The process is not well-studied, and it is considered not yet proven (experimental) by private insurance.

Phrenic Nerve Stimulator

Plain Language Summary:

Coverage question: Should OHP cover a device that uses electrical pulse to make the nerve a in the neck work better to help a person who is using a breathing machine?

Should OHP cover this treatment? Yes. This is a standard option for treatment of certain patients who are very ill.

Value-based Benefits Subcommittee (VbBS)
Plain Language Summary of Topics
November 9, 2023

Urethral Stricture Dilation with Drug-Coated Balloon Catheter

Plain Language Summary:

Coverage question: Should a procedure that uses a tube coated with medicine to open the urethra be covered?

Should OHP cover this treatment? No, this procedure is not well studied.

Transcervical Ablation of Uterine Fibroids

Plain Language Summary:

Coverage question: Should OHP cover a medical procedure to destroy noncancer growths in the uterus?

Should OHP cover this treatment? No, evidence does not support this specific medical procedure.

Suprachoroidal Injections

Plain Language Summary:

Coverage question: Should OHP cover a certain way to deliver medication to the back of the eye?

Should OHP cover this treatment? Yes, for treatment of a condition where there's swelling in the center part of the eye (the macula) caused by inflammation (uveitic macular edema).

Value-based Benefits Subcommittee (VbBS)
Plain Language Summary of Topics
November 9, 2023

Coronary Lithotripsy

Plain Language Summary:

Coverage question: Should OHP cover a medical procedure to help open blocked blood vessels to the heart?

Should OHP cover this treatment? No. It has not been compared to more common treatments and no studies found evidence of it working well.

Enhanced Liver Fibrosis (ELF) Test

Plain Language Summary:

Coverage question: Should OHP cover a certain test to check on the health of the liver?

Should OHP cover this treatment? Maybe, this is one good way to test for advanced liver disease but costs more than other tests.

HIPEC

Plain Language Summary:

Coverage question: Should OHP cover a treatment for certain types of advanced cancer? Doctors heat up a special chemotherapy medicine and put it directly into the abdomen (peritoneum) to treat cancer that might be there. The heat and the medicine together can help fight the cancer.

Should OHP cover this treatment? Yes, the advantages of treatment are greater than the potential harms for certain advanced cancers.

Value-based Benefits Subcommittee (VbBS)
Plain Language Summary of Topics
November 9, 2023

Breast Reduction for Macromastia

Plain Language Summary:

Coverage question: Should OHP cover surgery to reduce the size of breasts when they cause back and/or neck pain?

Should OHP cover this treatment? Yes, when there are no other reasons for the neck and back pain, and in situations where the surgery seems likely to help with the neck and back pain this surgery should be covered.

Gender Affirming Treatment Standard of Care

Plain Language Summary:

Coverage question: Should OHP pick a "standard of care" for gender affirming treatments?

Should OHP cover this treatment? Yes, OHP should use the World Professional Association for Transgender Health (WPATH) Standards of Care 8.0.

Tobacco Cessation Requirements in Prioritized List Guidelines

Plain Language Summary:

Coverage question: Should OHP members have to stop smoking or using nicotine before they can have certain types of surgery?

Should OHP cover this treatment? Yes, with some changes for spinal fusion and lung surgery for COPD. No, for surgery for erectile dysfunction.

Value-based Benefits Subcommittee (VbBS)
Plain Language Summary of Topics
November 9, 2023

PET Scan for Prostate Cancer

Plain Language Summary:

Coverage question: Should OHP cover a specific type of imaging test to see whether prostate cancer has spread to other parts of the body?

Should OHP cover this treatment? Yes, for people diagnosed with more severe forms of prostate cancer.

Cardiac Resynchronization Therapy

Plain Language Summary:

Coverage question: Should OHP clarify the requirements for treatments that helps the heart beat with the right rhythm (pacemaker and heart defibrillator).

Should OHP make this change? Yes.

Nasal Fracture Coverage Clarification

Plain Language Summary:

Coverage question: Should OHP cover treatments for a broken nose?

Should OHP cover this treatment? Yes, fixing a broken nose may need adjusting by hand, with or without using splints. This should be done within 14 days after the break happened. Rhinoplasty (a nose surgery) is needed when the nose is blocked and causing breathing problems.

Value-based Benefits Subcommittee (VbBS)
Plain Language Summary of Topics
November 9, 2023

Treatment of Liver Metastases

Plain Language Summary:

Coverage question: Liver metastases are tumors that started out in some other part of the body and have spread to the liver. Should OHP cover treatments for this condition?

Should OHP cover these treatments? Yes, certain types of treatments should be covered in limited cases.

Foot and Toenail Care for Patients in Facilities

Plain Language Summary:

Coverage question: Should OHP cover nail and foot care for people who live in nursing homes?

Should OHP cover this treatment? Certain conditions should be covered because active fungal infections in a nursing home can be passed from patient to patient and is a public health issue.

Central Auditory Function Testing

Plain Language Summary:

Coverage question: Should OHP cover testing for a condition that makes it difficult for a person to understand speech and follow instructions, especially when there is a lot of noise around.

Should OHP cover this treatment? No. The problem is a bit unclear, and even the experts can't decide on a consistent way to identify it. There are no widely accepted tests, and there are no medications for this condition. Other health plans are not covering this condition.

Value-based Benefits Subcommittee (VbBS)
Plain Language Summary of Topics
November 9, 2023

Photoscreening 2023

Plain Language Summary:

Coverage question: Should OHP cover a test (photoscreening) that checks a child's vision using a special camera instead of an eye chart? It helps find out how well a child can see.

Should OHP cover this test?
Option 1: No. This test is not as cost-effective as using an eye chart for screening.
Option 2: Yes, cover this test because experts recommend it.

Severe Exfoliating Skin Conditions

Plain Language Summary:

Coverage question: Should OHP cover severe shedding of the skin that can affect overall health?

Should OHP cover this treatment? Yes, based on expert input.

Refugee Screening

Plain Language Summary:

Coverage question: Should OHP cover medical screenings for people arriving from other countries who are seeking safety and protection from war or other dangers?

Should OHP cover this treatment? Yes, this screening is a federal requirement.

CDT code	Nomenclature	Descriptor	Comments	Recommended Placement
D0396	3D printing of a 3D dental surface scan	3D printing of a 3D dental surface scan to obtain a physical model.	Similar to D0470 (Diagnostic casts) which is Excluded. OHAP recommended coverage of D0470 as this is required as part of the orthodontic benefit Codes for the 3D scan itself is on line 256 (D0801-D0802 3d dental surface scan). OHAP felt these codes were best placed on the Diagnostic Procedures FIle	Diagnostic Procedures File **Add D0470 (Diagnostic casts) to Diagnostic Procedures File **Delete D0801-D0802 (3d dental surface scan) from line 256 DEFORMITIES OF HEAD AND HANDICAPPING MALOCCLUSION and place on the Diagnostic Procedures File
D1301	immunization counseling	A review of a patient's vaccine and medical history, and discussion of the vaccine benefits, risks, and consequences of not obtaining the vaccine. Counseling also includes a discussion of questions and concerns the patient, family, or caregiver may have and suggestions on where the patient can obtain the vaccine.	Dental office administration of vaccine CDT codes are included on line 3.	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
D2976	band stabilization – per tooth	A band, typically cemented around a molar tooth after a multi-surface restoration is placed, to add support and resistance to fracture until a patient is ready for the full cuspal coverage restoration.	Similar codes are on line 343	343 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH) Treatment BASIC RESTORATIVE
D2989	excavation of a tooth resulting in the determination of non-restorability		Done as part of other treatment, should be bundled with other restorative codes.	343 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH) Treatment BASIC RESTORATIVE

CDT code	Nomenclature	Descriptor	Comments	Recommended Placement
D2991	application of hydroxyapatite regeneration medicament – per tooth	Preparation of tooth surfaces and topical application of a scaffold to guide hydroxyapatite regeneration.	Dental group felt that this needs further research. HERC staff literature review found several evidence based reviews on hydroxyapatite which found that it can be beneficial in dental care products (toothpaste, mouthwash, etc.) but that its use in dentistry needs clinical trials.	646 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT Treatment ELECTIVE DENTAL SERVICES
D6089	accessing and retorquing loose implant screw - per screw		Part of implant care. DCO group had concerns that this is out of the allowed scope of care of general dentists	619 DENTAL CONDITIONS (E.G., MISSING TEETH) Treatment IMPLANTS
D7284	excisional biopsy of minor salivary glands		Used for diagnosis of a variety of conditions. May also have therapeutic purposes.	Diagnostic Procedures File
D7939	indexing for osteotomy using dynamic robotic assisted or dynamic navigation	A guide is stabilized to the teeth and/or the bone to allow for virtual guidance of osteotomy.	Osteotomy not covered; used for implant services.	619 DENTAL CONDITIONS (E.G., MISSING TEETH) Treatment IMPLANTS
D9938	fabrication of a custom removable clear plastic temporary aesthetic appliance		Cosmetic	645 DENTAL CONDITIONS WHERE TREATMENT IS CHOSEN PRIMARILY FOR AESTHETIC CONSIDERATIONS Treatment COSMETIC DENTAL SERVICES
D9939	placement of a custom removable clear plastic temporary aesthetic appliance		Cosmetic	645 DENTAL CONDITIONS WHERE TREATMENT IS CHOSEN PRIMARILY FOR AESTHETIC CONSIDERATIONS Treatment COSMETIC DENTAL SERVICES

CDT code	Nomenclature	Descriptor	Comments	Recommended Placement
D9954	fabrication and delivery of oral appliance therapy (OAT) morning repositioning device	Device for use immediately after removing a mandibular advancement device to aid in relieving muscle/jaw pain and occlusal changes.	OSA guideline: "Mandibular advancement devices (oral appliances) are covered for those for whom CPAP fails or is contraindicated" These devices are on line 202.	202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER Also add to line 202: **HCPCS K1027 (Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment) **HCPCS E0486 (Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment)
D9955	oral appliance therapy (OAT) titration visit	Post-delivery visit for titration of a mandibular advancement device and to subsequently evaluate the patient's response to treatment, integrity of the device, and management of side effects.	See D9954	202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER
D9956	administration of home sleep apnea test	Sleep apnea test, for patients who are at risk for sleep related breathing disorders and appropriate candidates, as allowed by applicable laws. Also, to help the dentist in defining the optimal position of the mandible.	Per the Board of Dentistry, this is outside the scope of practice for dentists in Oregon	Excluded File
D9957	screening for sleep related breathing disorders	Screening activities, performed alone or in conjunction with another evaluation, to identify signs and symptoms of sleep-related breathing disorders.	Per the Board of Dentistry, this is outside the scope of practice for dentists in Oregon	Excluded File

Denture, Crowns and Dental Implants

Coverage Question: Should any changes be made in current denture, crown or dental implant coverage?

Question source: OHP ombuds office, HERC staff listening session

Background: The OHP ombuds office has been collecting member complaints regarding dentures. These include difficulty in finding an OHP provider for dentures, barriers to replacing lost or stolen dentures, and barriers to obtaining partial dentures when molars but not front teeth are pulled. The ombuds office is requesting consideration of 1) allowing partial denture coverage for back teeth and 2) allowing more frequent replacement of dentures when dentures are lost or stolen.

Current coverage of dentures is limited to one set of full dentures every 10 years or partial dentures every 5 years) by rule, and by determination of the Oregon Legislature.

Dentures are governed by OAR 410-123-1260 (see Appendix A for the portion of the rule regarding dentures).

OHP members also brought up lack of coverage for dental implants at the HERC staff listening session.

Previous HSC/HERC reviews:

OHAP has periodically reviewed denture services as codes arise as new CDT codes. Implants have been discussed at various OHAP meetings in the past few years, mainly in the setting of a new CDT code related to implant services.

Current Prioritized List/Coverage status:

Complete dentures (CDT D5110, D5120) and resin-based partial dentures (CDT D5211, D5212) are on line 454 DENTAL CONDITIONS (E.G., MISSING TEETH, PROSTHESIS FAILURE) Treatment REMOVABLE PROSTHODONTICS (E.G., FULL AND PARTIAL DENTURES, RELINES)

Partial dentures with cast metal framework (CDT D5214, D5223, D5224) are on line 592 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH) treatment ADVANCED RESTORATIVE-ELECTIVE (INLAYS, ONLAYS, GOLD FOIL AND HIGH NOBLE METAL RESTORATIONS)

Flexible base dentures (CDT D5225-D5228) are on line 646 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT Treatment ELECTIVE DENTAL SERVICES

Various dental implant CDT codes are on line 619 DENTAL CONDITIONS (E.G., MISSING TEETH) Treatment IMPLANTS (I.E., IMPLANT PLACEMENT AND ASSOCIATED CROWN OR PROSTHESIS)

Other payer policies:

Denture, Crowns and Dental Implants

Dentures (full or partial) are only covered for adults by only a few state Medicaid programs (Alaska, Idaho, Michigan, Louisiana, Montana, Nevada, New York, North Carolina, and South Dakota). Some of these state Medicaid programs have a dollar amount treatment cap of between $1,000 and $1,125.

Medicare does not pay for dentures, although some coverage may be obtained through a Medicare Advantage program.

Most commercial payers will require significant cost-sharing for dental implant coverage. Most Medicaid programs do not cover dental implants, considering them cosmetic. Some coverage may be obtained for children under the age of 21 through the EPSDT benefit.

OHAP input:

OHAP members are aware of frustration around coverage of dentures. Adult dentures are not a mandatory benefit under Medicaid by federal rule, and are only covered to the extent allowed by the Oregon Legislature. There are budgetary constraints to expanding benefits in these areas. Denture benefits are very expensive.

Suggestions for the most beneficial expansions of denture benefit would be to allow partial dentures for fewer numbers of missing teeth, when the front teeth are involved, or for missing premolars. There was discussion about allowing denture replacement sooner than currently allowed (10 years for full dentures) when the dentures are lost or stolen. However, it is already in rule that members may have more frequent denture replacement when stolen, lost in natural disaster, or in other circumstances outside of the member's control. However, the cost of earlier replacement may not be part of the rates for dental organizations. One area to focus future funding is on any additional funding on treatments to retain natural teeth, such as crowns after root canals. Currently, this benefit is very limited by age and type of teeth. Coverage of crowns other than stainless steel crowns, was cut years ago by rule/Legislative intent due to budget issues.

HERC staff recommendation:

1) This report is for situational awareness only. No changes are recommended currently to the denture, crown or dental implant benefit
2) Staff is working with other parts of OHA on whether it would be appropriate for HERC to address the budgetary dental limitations including crowns and dentures.

Denture, Crowns and Dental Implants

Appendix A
Except of OAR 410-123-1260 regarding dentures

(9) PROSTHODONTICS, REMOVABLE (D5000-D5899):

(a) Clients age 16 years and older are eligible for removable resin base partial dentures and full dentures;

(b) See OAR 410-123-1000 for detail regarding billing fabricated prosthetics;

(c) The fee for the partial and full dentures includes payment for adjustments during the six-month period following delivery to clients;

(d) Resin partial dentures:

(A) The Division may not approve resin partial dentures if stainless steel crowns are used as abutments;

(B) For clients through age 20, the client shall have one or more anterior teeth missing or four or more missing posterior teeth per arch with resulting space equivalent to that loss demonstrating inability to masticate. Third molars are not a consideration when counting missing teeth;

(C) For clients age 21 and older, the client shall have one or more missing anterior teeth or six or more missing posterior teeth per arch with Documentation by the provider of resulting space causing serious impairment to mastication. Third molars are not a consideration when counting missing teeth;

(D) The Dental Practitioner shall note the teeth to be replaced and teeth to be clasped when requesting Prior Authorization (PA).

(e) Replacement of removable partial or full dentures, when it cannot be made clinically serviceable by a less costly procedure (e.g., reline, rebase, repair, tooth replacement), is limited to the following:

(A) For clients at least 16 years of age, the Division shall replace:

(i) Full dentures once every ten years, only if Dentally Appropriate;

(ii) Partial dentures once every five years, only if Dentally Appropriate.

(B) The five- and ten-year limitations apply to the client regardless of the client's OHP or MCE enrollment status at the time the client's last denture or partial was received. For example: A client receives a partial on February 1, 2020 and becomes a FFS OHP client in 2023. The client is not eligible for a replacement partial until February 1, 2025. The client gets a replacement partial on February 3, 2025 while FFS and a year later enrolls in an MCE. The client would not be eligible for another partial until February 3, 2030, regardless of MCE or FFS enrollment;

(C) Replacement of partial dentures with full dentures is payable five years after the partial denture placement. Exceptions to this limitation may be made in cases of Acute trauma, natural disaster, or catastrophic illness that directly or indirectly affects the dental condition and results in additional tooth

loss. This pertains to, but is not limited to, cancer and periodontal disease resulting from pharmacological, surgical, and medical treatment for aforementioned conditions. Severe periodontal disease due to neglect of daily dental hygiene may not warrant replacement.

(f) The Division limits reimbursement of adjustments and repairs of dentures that are needed beyond six months after delivery of the denture as follows for clients 21 years of age and older:

(A) A maximum of four times per year for:

(i) Adjustments to dentures, per arch. Full and partial (D5410 - D5422);

(ii) Replace missing or broken teeth – complete denture, each tooth (D5520);

(iii) Replace broken tooth on a partial denture - each tooth (D5640);

(iv) Add tooth to existing partial denture (D5650).

(B) A maximum of two times per year for:

(i) Repair broken complete denture base (D5511, D5512);

(ii) Repair resin partial denture base (D5611, D5612);

(iii) Repair cast partial framework (D5621, D5622);

(iv) Repair or replace broken retentive/clasping materials – per tooth (D5630);

(v) Add clasp to existing partial denture – per tooth (D5660).

(g) Replace all teeth and acrylic on cast metal framework (D5670, D5671):

(A) Is covered for clients age 16 and older a maximum of once every ten (10) years, per arch;

(B) Ten years or more shall have passed since the original partial denture was delivered;

(C) Is considered replacement of the partial so a new partial denture may not be reimbursed for another ten years; and

(D) Requires Prior Authorization as it is considered a replacement partial denture.

(h) Denture rebase procedures:

(A) The Division shall cover rebases only if a reline may not adequately solve the problem;

(B) For clients through age 20, the Division limits payment for rebase to once every three years;

(C) For clients age 21 and older:

Denture, Crowns and Dental Implants

(i) There shall be Documentation of a current reline that has been done and failed; and

(ii) The Division limits payment for rebase to once every five years.

(D) The Division may make exceptions to this limitation in cases of Acute trauma or catastrophic illness that directly or indirectly affects the dental condition and results in additional tooth loss. This pertains to, but is not limited to, cancer and periodontal disease resulting from pharmacological, surgical, and medical treatment for aforementioned conditions. Severe periodontal disease due to neglect of daily dental hygiene may not warrant rebasing;

(i) Denture reline procedures:

(A) For clients through age 20, the Division limits payment for reline of complete or partial dentures to once every three years;

(B) For clients age 21 and older, the Division limits payment for reline of complete or partial dentures to once every five years;

(C) The Division may make exceptions to this limitation under the same conditions warranting replacement;

(D) Laboratory relines:

(i) Are not payable prior to six months after placement of an immediate denture;

(ii) For clients through age 20, are limited to once every three years;

(iii) For clients age 21 and older, are limited to once every five years.

(j) Interim partial dentures (also referred to as “flippers”):

(A) Are allowed if the client has one or more anterior teeth missing; and

(B) The Division shall reimburse for replacement of interim partial dentures once every five years but only when Dentally Appropriate.

(k) Tissue conditioning:

(A) Is allowed once per denture unit in conjunction with immediate dentures; and

(B) Is allowed once prior to new prosthetic placement.

(10) MAXILLOFACIAL PROSTHETIC SERVICES (D5900-D5999):

(a) Fluoride gel carrier is limited to those patients whose severity of dental disease causes the increased cleaning and fluoride treatments allowed in rule to be insufficient. The Dental Practitioner shall document failure of those options prior to use of the fluoride gel carrier;

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(b) All other maxillofacial prosthetics (D5900-D5999) are medical services. Refer to OAR 410-123-1220:

(A) Bill for medical maxillofacial prosthetics using the professional (CMS1500, DMAP 505 or 837P) claim format;

(B) For clients receiving services through a CCO, PHP, or MCE bill medical maxillofacial prosthetics to the CCO, PHP, or MCE;

(C) For clients receiving medical services through FFS, bill the Division.

(11) ORAL & MAXILLOFACIAL SURGERY (D7000-D7999): Billing Procedures:

(a) Bill on a dental claim form using CDT codes for procedures that are directly related to the teeth and the structures directly supporting teeth;

(b) The Medical/Surgical Program is responsible for all dental health procedures performed due to an underlying medical condition (i.e., procedures on or in preparation for treatment of the jaw, tongue, roof of mouth). Such procedures shall be billed using ICD-10, HCPCS and CPT billing codes using the professional (CMS1500, DMAP 505 or 837P) claim format;

(c) D7285, D7286, D7287, D7288 diagnosis codes are reimbursable for all members;

(d) D7990 ancillary code is reimbursable for all members;

(e) All ancillary and diagnosis codes must be dentally necessary.

(f) Alveoloplasty not in conjunction with extractions are reimbursable for members under age 21, and for pregnant individuals (D7320, D7321).

OHAP Straightforward Guideline Note Changes

Plain Language Summary:

Coverage question: Should OHP cover a medical procedure to clip a small piece of tissue under the lip (frenulectomy/frenulotomy) for patients ages 12-21?

Should OHP cover this treatment? Yes, staff propose covering if the patient has receding gums, a condition when gum tissue starts to pull back and wear away from teeth.

Issue: Until 2021, the dental administrative rules contained a limitation of buccal/labial frenulectomy/frenulotomy to children. That portion of the rule has been dropped for unclear reasons. Frenotomy (clipping of the ligament under the tongue) is only covered for newborns with breast feeding difficulties per Guideline Note 139.

The frenulum is a band of tissue in the central portion of the upper lip which serves to provide stability for the upper lip. When this band is short or tight, some practitioners will cut the tissue (frenulectomy) particularly if there is breastfeeding pain, poor latch or other difficulties.

Frenulectomy was last reviewed in November 2022. At that time, the evidence reviewed was regarding frenulectomy as a treatment for breast feeding difficulties or childhood articulation problems. There has not been a review of frenulectomy for adults. A brief literature search by HERC staff found mention of lip tie in adults causing receding gums (gingival recession). The only evidence on frenulectomy found was on breastfeeding, which found that it was not beneficial.

HERC staff recommendation:

1) Modify GN48 as shown below

GUIDELINE NOTE 48, FRENULECTOMY/FRENULOTOMY

Lines 344,661

Labial frenulectomy/frenulotomy (D7961) is included on this line for patients under age 21 in the following situations:

A) When deemed to cause gingival recession
B) When deemed to cause movement of the gingival margin when frenum is placed under tension.
C) Maxillary labial frenulectomy not covered until age 12 and above.

Otherwise, D7961 is included on Line 661.

BHAP Straightforward Code Change

Plain Language Summary:

Coverage question: Should OHP cover therapy given in a group setting for autism treatment?

Should OHP cover this treatment? Yes, staff recommend that this should be covered.

Issue: Multiple denied claims have been received regarding group psychotherapy for autism spectrum disorder. BHAP recommends that the CPT code for group psychotherapy be added to the autism spectrum disorder line as it could be useful for some people on the autism spectrum.

Multiple denied claims were also seen for residential treatment for autism spectrum disorder. BHAP members felt that residential care was not appropriate for autism spectrum disorder per se. People on the autism spectrum who have another serious mental health issue can assess residential programs for the other serious mental health disorder.

90853 Group psychotherapy (other than of a multiple-family group) [appears on most other behavioral health lines]

HERC staff/BHAP recommendation:

1) Add CPT 90853 Group psychotherapy (other than of a multiple-family group) to line 193 AUTISM SPECTRUM DISORDERS

2023 Behavioral Health Related HCPCS Codes

Coverage Question: Should coverage be added for new HCPCS codes regarding coordinated specialty care for early psychosis management?

Question source: HERC staff

Background: CMS issued 2 new HCPCS codes for coordinated specialty care for patient with early psychosis.

1) H2040 Coordinated specialty care, team-based, for first episode psychosis, per month
2) H2041 Coordinated specialty care, team-based, for first episode psychosis, per encounter

From the CMS meeting minutes:
Coordinated Specialty Care - HCP2212301T8X3

Topic/Issue

Request to establish a new HCPCS Level II code to identify Coordinated Specialty Care. Applicant's suggested language: XXXXX, "Coordinated specialty care is an evidence based service delivered by a multidisciplinary team to individuals experiencing a first episode of psychosis"

Summary of Applicant's Submission The National Association of State Mental Health Programs submitted a request to establish a new HCPCS Level II code to identify Coordinated Specialty Care for early or first episode of psychosis (hereafter referred to as CSC). CSC is delivered by a multi-disciplinary team to individuals in the earliest phase of a psychotic illness with the goal of avoiding long-term disability and other costs associated with severe mental health conditions. CSC has been available internationally for several years and in the US for more than 14 years. Following completion of the National Institute of Mental Health-sponsored multi-site Recovery After an Initial Schizophrenia Episode trial, Congress earmarked new funding in the mental health block grant (MHBG) to be provided to the states to stimulate the development of this evidence-based model of care nationally. According to the applicant, while Medicaid funds and some commercial insurers have been billed for individual components of CSC, key components of CSC, such as outreach and engagement, are not captured by existing codes. According to the applicant, providers of CSC have utilized braided funding approaches that involve some combination of the MHBG funds, Medicaid funds, some commercial insurance funds, other state and local funding, as well as philanthropic and other grant dollars to support CSC treatment. This approach is variable by state and region. In addition, much of this braided funding is from discretionary sources and therefore subject to yearly appropriations. According to the applicant, lack of a recognized code specifically developed for CSC has impeded CSC programs' ability to bill insurers for the full service and to expand the coverage of this treatment to other individuals in need. According to the applicant, use of discretionary funds threatens the sustainability of the programs as well as limits the accessibility of CSC treatment since these funds are inadequate to meet the population need. According to the applicant, it has been estimated that 52 percent of costs associated with adequate implementation of CSC is not covered by existing codes/billing mechanisms According to the applicant, without adequate, stable reimbursement, the sustainability – and the associated personal, societal, and financial costs – will continue to be at significant risk. According to the applicant, given the importance of CSC for staving off the

lifelong disability that often accompanies psychotic illnesses, appropriate codes and sustainable insurance payments are critically needed.

CMS Preliminary HCPCS Coding Recommendation We are open to establishing a new code but would like feedback on whether there is overlap with existing HCPCS Level I, Current Procedural Terminology (CPT®) codes and HCPCS Level II codes. We welcome information from the applicant and other insurers, especially individual state Medicaid agencies, to describe how they would approach a unique HCPCS Level II code to identify CSC. 8 For instance, we are currently aware of many HCPCS Level I CPT® codes and HCPCS Level II codes that describe collaborative psychological and behavioral health care services for medical and administrative activity matching such as evaluation, peer specialty services, individual/family/group therapy, and principal care management. Some example codes include, but are not limited to, CPT® codes 90832, 90834, 90837, 90853, 90846, 99212- 99215, 99424-99427, 99484, 99492-99494, and HCPCS Level II codes G0323, G2214, H0036, H0038, H2023, H2024, T1016, T1024, T2022, and T2023. We believe these and other existing codes can be utilized to describe certain coordinated specialty care in different ways. While the applicant suggests that establishing one unique code to recognize coordinated specialty care may be easier for industry tracking purposes, we have observed that when multiple parties are involved in providing aspects of care - particularly when the care includes clinical professionals who customarily bill for services using CPT® codes like 90832 or evaluation and management service codes - that bundled codes can be complex to administer for the multiple parties involved. More specifically, would payers continue to use some or all of these codes and also a code to identify CSC? If so, should a code for CSC be less universal or "bundled" in its description? If the applicant's suggested description is adopted, would the expectation be that payers describe when to use the code for CSC and when other CPT® codes may be used concurrently for the same patient during a first episode of psychosis? We welcome comments from all interested parties, including state Medicaid agencies and other payers, regarding the request for one bundled code to identify CSC or suggested code language descriptor(s) that would be most useful.

Summary of Public Feedback The National Association of State Mental Health Programs, the applicant, responded to CMS' published preliminary HCPCS coding recommendation by providing answers to the questions that CMS presented. The commenters generally stated that a unique HCPCS Level II code to identify team-based CSC would help to ensure increased access for individuals with early psychosis and create a streamlined billing experience for insurers and administrators. Many commenters stated that a team-based code would be better utilized by multidisciplinary clinics to identify the entire coordinated service consistent with each payer's billing guidance. The comments suggested that establishing a new code would also enable public and private insurers to more readily identify CSC in their claims data, facilitate research across the various payers to identify the use of CSC in larger databases, and measure the long-term outcomes and effectiveness of this team-based service. The commenters explained that some public insurers use various combinations of existing codes, such as 90832, H0036, H0038, H0047, T1024, T2022, and T2023, to partially identify services within the CSC model. Many comments stated that while existing codes could be billed for a portion of the provided services such as psychotherapy and medication management, most of these codes are also being used by insurers for other services. According to the comments, the existing codes also do not capture other non-clinical services offered by the CSC team such as education and employment support for the patients. According to the speakers, some public insurers currently use a single code to identify the entire CSC team, while other insurers may also use modifiers or "shadow

claims" to further identify services provided by certain practitioners. 9 Some commenters suggested two HCPCS codes to describe both the monthly and individual encounters. According to the speakers, a monthly case rate is commonly used, but the need for services may vary over time; so, a separate code for an individual encounter rate is helpful when a patient does not meet the minimum requirements to bill a monthly rate. The speakers explained that some insurers may prefer to use only one code for each encounter and may describe each encounter with specific time increments; but the speakers also suggested that existing modifiers would be sufficient for the time increments. The speakers reiterated that two codes for the monthly and individual encounters will allow greater flexibility in the application of various insurance billing policies as well as transparency for the integrity of claims data.

CMS Final HCPCS Coding Decision We appreciate the comments provided in response to CMS' published preliminary recommendation. Based on the information provided in the application and after consideration of the comments received, CMS is finalizing the decision to:
Establish the following two new HCPCS Level II codes:
1. H2040, "Coordinated specialty care, team-based, for first episode psychosis, per month"
2. H2041, "Coordinated specialty care, team-based, for first episode psychosis, per encounter

Current Prioritized List/Coverage status:

CPT 90832, 90834, 90837, 90853, 90846: all behavioral health lines
CPT 99212- 99215, 99424-99427, 99484, 99492-99494: on nearly all lines
HCPCS G0323, G2214: on nearly all lines
HCPCS H0036, H0038, H2023, H2024: all behavioral health lines
HCPCS T1016, T1024, T2022, and T2023: Ancillary

BHAP input:

BHAP recommended coverage for this code, which is designed for case rate care for programs that do early intervention for psychosis (EASA programs). These codes should be added to any line with a psychotic condition. Lynnea Lindsey volunteered to provide HERC staff with the ICD-10-CM codes used by the early psychosis intervention program in her organization. These codes should appear on any line with one of the ICD-10-CM codes on this list.

Per Dr. Lindsey, the most common diagnoses seen in her organization's EASA program

ICD10 Code	Code Description	Current Line(s)
F29	Unspecified psychosis not due to a substance or known physiological condition	275 OTHER PSYCHOTIC DISORDERS
F28	Other psychotic disorder not due to a substance or known physiological condition	275
F41.9	Anxiety disorder, unspecified	411 OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED
F20.9	Schizophrenia, unspecified	22 SCHIZOPHRENIC DISORDERS
F25.0	Schizoaffective disorder, bipolar type	22

2023 Behavioral Health Related HCPCS Codes

F31.9	Bipolar disorder, unspecified	26 BIPOLAR DISORDERS
F20.81	Schizophreniform disorder	22
F25.1	Schizoaffective disorder, depressive type	22
F32.A	Depression, unspecified	202 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE
F31.2	Bipolar disorder, current episode manic severe with psychotic features	26

HERC staff/BHAP recommendation:

1) Add HCPCS H2040 (Coordinated specialty care, team-based, for first episode psychosis, per month) and H2041 (Coordinated specialty care, team-based, for first episode psychosis, per encounter) to the following lines:
    a. 7 MAJOR DEPRESSION, RECURRENT; MAJOR DEPRESSION, SINGLE EPISODE, SEVERE
    b. 22 SCHIZOPHRENIC DISORDERS
    c. 26 BIPOLAR DISORDERS
    d. 277 OTHER PSYCHOTIC DISORDERS
    e. 411 OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED

Problem Related to Unspecified Psychosocial Circumstances

Plain Language Summary:

Coverage question: Should OHP cover a non-specific mental health and social condition?

Should OHP cover this treatment? Yes, staff suggest covering this as multiple groups in Oregon recommend covering this condition.

Coverage Question: Should Z65.9 (Problem related to unspecified psychosocial circumstance) be added for coverage? If so, should there be limitations on coverage?

Question source: Lydia Chiang, MD, Medical Director, Oregon Pediatric Improvement Partnership (OPIP); 988/Crisis Intervention Team

Background: Oregon Pediatric Improvement Partnership (OPIP) is requesting consideration of ICD-10-CM Z65.9 for coverage, specifically for children who are too young to receive a more definitive diagnosis.

From Dr. Chiang:

> In OPIP's current work with the Social Emotional Health Incentive Measure, we are continuing to learn about important social emotional services young children need to support their development, education, and well-being…As you all know, coverage for these services in the health sector, both in the specialty behavioral health setting and in primary care, requires pairing of CPT codes (such as Health Behavior codes, Psychotherapy codes, Preventive Medicine codes) and a diagnosis, which is tricky in young children birth to five. In some recent conversations we have had with experts in this area, a ICD-10 code was raised that is covered in some other states (California for example) for behavioral health services: Z65.9 Problem related to unspecified psychosocial circumstance. Given Oregon's coverage of EPSDT, I wondered if this diagnosis should be considered for inclusion on the Prioritized list, if not for all ages then at least for young children who might otherwise not have another appropriate Diagnosis that would cover Treatment.

The 988 Crisis intervention team is also requesting that Z65.9 be opened to code for crisis services when there is no pre-existing diagnosis or a diagnosis cannot be made during the crisis encounter.

Previous HSC/HERC reviews:

There are no previous reviews of this code

Problem Related to Unspecified Psychosocial Circumstances

Current Prioritized List/Coverage status:

ICD-10-CM Z65.9 (Problem related to unspecified psychosocial circumstances) is Informational

Most similar codes are Informational (for example, Z65.8 Other specified problems related to psychosocial circumstances). A few codes in this section of the coding manual (for example, Z63.4 Disappearance and death of family member and Z63.8 Other specified problems related to primary support group) are on line 445 ADJUSTMENT DISORDERS

Other payer policies:

1) NY Medicaid
    a. New York State (NYS) Medicaid fee-for-service (FFS) accepts International Classification of Diseases, Tenth Revision (ICD-10) code **"Z65.9"** (problem related to unspecified psychosocial circumstances) as an indication of medical necessity on claims for the psychotherapy services listed below when provided by qualified NYS Medicaid-enrolled providers to NYS Medicaid members under 21 years of age. A diagnosis of **"Z65.9"** is intended for prevention-based services when no other behavioral health diagnosis is present.
        i. Covered services are psychotherapy
2) California Medicaid
    a. Allows use of ICD-10-CM Z65.9 when paired with counseling services
3) United Healthcare
    a. Allows ICD-10-CM Z65.9 to be used only as a secondary diagnosis

BHAP input:

BHAP agreed that these diagnoses should be added to allow OPIP and other early intervention programs to assist kids. It is important to address these issues as early as possible in a child's life to avoid development of mental health issues. BHAP recommended placement of these codes on line 445 ADJUSTMENT DISORDERS. HERC staff was directed to reach out to child psychiatrists and the OPIP program to determine if an age limit should be placed on this diagnosis. The two proposed age limits were 5 and younger and 12 and younger. HERC staff was also directed to reach out to other Medicaid programs for information on other state coverage policies.

HERC staff asked other state Medicaid programs about coverage of these codes and found that coverage varies among state. HERC staff reached out to Dr. Meg Cary, a child psychiatrist, who recommended covering these codes with no age restrictions. After the BHAP meeting, the 988/Crisis services team reached out to HERC about use of Z65.9 for crisis services, which would be for any age person. Based on this, HERC staff are recommending opening this code with no restrictions/guideline.

HERC staff/BHAP recommendation:

1) Add ICD-10-CM Z65.9 (Problem related to unspecified psychosocial circumstances) to line 445 ADJUSTMENT DISORDERS

GAP ACMG Guideline Reference Update

Issue: The American College of Medical Genetics (ACMG) recently updated their recommendations for cystic fibrosis (CF) carrier screening. Previously they recommended a 23 gene panel. They have revised their recommendation to include 100 mutations/gene variants, due to advances in genetics and gene identification (see Deignan 2023). On review of this issue, GAP members raised concerns that the current testing criteria for children who are symptomatic is a tiered testing strategy, while carrier screening for CF allows all tests with no tier [from guideline below: Screening for cystic fibrosis carrier status (CPT 81220-81224)]. The Deignan paper supports sequencing including deletions and duplications, which is more consistent with the current carrier screening. GAP recommends simplifying the diagnostic testing criteria to mirror the carrier screening criteria.

On review of this issue, HERC staff noted that there are two ACMG references to two separate guidelines in Diagnostic Guideline D1 that are not clearly identified.

HERC staff recommendation:

1) Update Guideline Note 3 as shown below
    a. Update the CF carrier screening reference to the current ACMG standard
    b. Update the guideline to clearly delineate the two ACMG guidelines referenced
        i. The expanded carrier screening guideline is now #1 and the CF guideline is #2

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, 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.
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:
   a) Screening for genetic carrier status with the minimum testing recommended by the American College of Obstetrics and Gynecology:
      i) Screening for cystic fibrosis carrier status (CPT 81220-81224)
      ii) Screening for fragile X status (CPT 81243, 81244, 81171, 81172)
      iii) Screening for spinal muscular atrophy (CPT 81329)
      iv) 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.
      v) Screening for hemoglobinopathies (CPT 83020, 83021)
   b) 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:
      i) the panel includes only genes with a carrier frequency of ≥ 1 in 200 or greater per ACMG Guideline (2021)[1],
      ii) the included genes have well-defined phenotype, AND
      iii) 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
      iv) the included genes result in conditions have an onset early in life, AND
      v) 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 ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS.

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~~ 81224: 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* [2] ~~(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) CPT 81224, CFTR (cystic fibrosis transmembrane conductance regulator) (e.g. cystic fibrosis) gene analysis; introm 8 poly-T analysis (e.g. male infertility): Covered only after genetic counseling.
   d) CPT 81225-81227, 81230-81231, 81418, 0380U (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).
   e) 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 thromboembolism; 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.
   f) 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 thromboembolism; 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 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.
   h) 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.
   i) 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.

j) 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.

k) 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.

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

m) CPT 81430-81431, Hearing loss (e.g., 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.

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

o) 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.~~

[1] Screening for autosomal recessive and X-linked conditions during pregnancy and preconception: a practice resource of the American College of Medical Genetics and Genomics (ACMG) 2021, found at https://www.gimjournal.org/action/showPdf?pii=S1098-3600%2821%2905152-2

[2] American College of Medical Genetics Statement: updated recommendations for CFTR carrier screening 2023, found at https://www.gimjournal.org/action/showPdf?pii=S1098-3600%2823%2900880-8

Computer Assisted Bronchoscopy 2023 Review

Plain Language Summary:

Coverage question: Should OHP cover a procedure that uses computer pictures to help guide where a doctor looks in the lungs to get sample tissue?

Should OHP cover this treatment? Yes, newly published medical studies show this procedure is both safe and accurate.

Coverage Question: Should computer assisted bronchoscopy be moved from Line 662/GN173 and made diagnostic?

Question source: Dr. Shalini Mehta and Dr. Brian Delmonaco, pulmonologists in Corvallis OR

Background: Computer assisted bronchoscopy, also known as electromagnetic navigation bronchoscopy (ENB) or navigational bronchoscopy, is a procedure for diagnosing peripheral lung lesions. When ENB is used for diagnostic purposes, CT scans are first collected and downloaded into the system's software, which reconstructs the scans into three- dimensional images of the lungs. The individual is sedated and positioned over an electromagnetic location board and bronchoscopy is initiated. A microsensor probe is inserted through the working channel of the bronchoscope into the airways. The sensor automatically registers the points and maps the appropriate route to peripheral lung lesions using the combined CT images and computer software. To navigate, the physician views the computer monitor and advances the guide to reach suspicious peripheral lung lesions. Tools can be inserted through the working channel to the lesion to collect samples.

Electromagnetic navigation (EN) guided bronchoscopy is used to assist in biopsy of small peripheral lung lesions to determine if they are non-small cell lung cancer. Several other modalities exist to assist in diagnosing such lesions, including endobronchial ultrasound (EBUS) bronchoscopy (CPT 31652-31654, Diagnostic) and transthoracic needle biopsy.

From Dr. Mehta:

Our societies (AABIP, ATS, and CHEST) include physicians providing care for patients with peripheral lung lesions (PLLs) who are working to improve the provision of lung cancer care in a timely and cost-effective manner. The established published evidence and recognized clinical practice guidelines support our request and recommendation to archive the associated policy and remove the 'investigation and not medically necessary' status for Navigational Bronchoscopy. Herein, we present the evidence base that supports our position.

The current policy points out that most PLLs are diagnosed using the transthoracic needle aspiration (TTNA) technique because it has a higher diagnostic yield than standard

bronchoscopy or electromagnetic navigation bronchoscopy (ENB) and is safe in most patients with PLLs. Meta-analyses of TTNA biopsies published within the radiology literature show complication rates that are several times higher than those seen with ENB (Eur Radiol. 2017 Jan;27(1):138-148; J Thorac Oncol. 2022 Apr;17(4):519-531). Numerous target lesion factors may reduce the diagnostic yield of TTNA and are contraindications for TTNA: the presence of emphysema or blebs, location near major vessels, uncontrollable cough, and a site requiring a significant amount of lung to be traversed or which is near the diaphragm. TTNA may be inappropriate and higher risk for many patients in these cases. Recent cost-effectiveness studies of diagnosis and staging for lung cancer show that CT-guided biopsy alone, when compared with the most cost-effective bronchoscopic strategy, results in more complications, requires more time to complete the evaluation, has a higher rate of undetected mediastinal lymph node involvement (N2-3 disease), and an increased risk of mortality (Chest. 2021; 160(6):2304-2323). Furthermore, deviation from guidelines and performance of a CT-guided biopsy first results in a 17% higher rate of pneumothorax and increases cost by $1,000 per patient.

Several meta-analyses have evaluated the risk of pleural recurrence after a TTNA compared to alternatives (surgery and bronchoscopic biopsy). A recent study (Thorax. 2021 Jun;76(6):582-590) analyzed 2394 patients (TTNA, 1158 patients versus other [bronchoscopy, surgery], 1236 patients) with a median follow-up after surgery of 60.7 months. Compared with other diagnostic procedures, TTNA was associated with a higher risk for ipsilateral pleural recurrence, which manifested solely and concomitantly with other metastases. Furthermore, reductions in the time to recurrence, lung cancer-specific survival, and overall survival were observed in patients <55 years who underwent TTNA. Recently published data also suggests that even patients with small peripheral lesions suspected of lung cancer (T1 tumors) benefit from staging due to the high rate of mediastinal disease (Chest. 2020;158(5):2192-2199). Therefore, committing these patients to a CT-guided biopsy first not only puts them at higher risk for complications, but it will also lead to repeat interventions such as subsequent bronchoscopy for staging, and thus, delay the time to treatment and risk tumor upstaging.

Non-coverage of navigational bronchoscopy leaves our patients without an option for minimally invasive sampling to achieve a tissue diagnosis and staging, as indicated. Regarding navigational bronchoscopy and the coverage of procedures for the evaluation of pulmonary nodules, over 95% of health plans have chosen to extend coverage to navigational bronchoscopy, either by archiving and inactivating a non-coverage policy or by issuing a favorable coverage policy:

- The evidence for sensitivity and the complication rates of navigational bronchoscopy are adequately described in the literature. Navigational bronchoscopy is a component of the Standard of Care in evaluating patients with PLLs.
- They recognize that the trade-offs of specific risks and benefits in the evaluation of individual patients is best done in the context of informed consent between clinicians and patients, based on current guidelines and published evidence.

The clinical guidelines and recommendations published by the American College of Chest Physicians (CHEST), American Thoracic Society (ATS), National Comprehensive Cancer Network (NCCN), UpToDate, and Blue Cross Blue Shield Association (BCBSA) confirm the widely accepted evidence-based guideline that navigational bronchoscopy is a standard of care procedure for patients with peripheral lung lesions.

NCCN Non-Small Cell Lung Cancer (NSCLC) 2022 guidelines:

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"The preferred biopsy technique depends on the disease site and is described in the NSCLC algorithm. For example, radial endobronchial ultrasound (EBUS), navigational bronchoscopy, or transthoracic needle aspiration (TTNA) are recommended for patients with suspected peripheral nodules."

British Thoracic Society guidelines for the investigation and management of pulmonary nodules recommend augmenting the yield from bronchoscopy using either radial endobronchial ultrasound, fluoroscopy, or electromagnetic navigation (ENB) (Thorax. 2015;70:ii1–ii54)

We trust that the information we have outlined and support from our colleagues and other professional societies show that Navigation Bronchoscopy has the evidence base to support its coverage in appropriately selected patients. It is a Standard of Care approach in evaluating patients with PLLs.

Previous HSC/HERC reviews:

Computer assisted bronchoscopy was first reviewed in December, 2009 as part of the 2010 CPT code review. At that time, very little literature was found on the topic and it was determined to be experimental.

Computer assisted bronchoscopy was last reviewed in 2021. The 2021 review included a 2019 NICE technology review and the NCCN 2021 guideline for non-small cell lung cancer. The summary of the 2021 review stated "Computer assisted bronchoscopy is one option for biopsy of a peripheral lung lesion. NICE found the literature to be questionable, and recommended consideration of the technology only for patients who could not undergo transthoracic biopsy. NCCN lists "navigational bronchoscopy" as just one option for evaluating peripheral lung nodules. Private payers consider this technology to be experimental and are not currently covering it. Multiple other diagnostic tests for peripheral lung lesions, such as endobronchial ultrasound (EBUS) bronchoscopy and transthoracic needle biopsy, are currently covered."

Current Prioritized List/Coverage status:

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
31627	Computer assisted bronchoscopy	Insufficient evidence of effectiveness	March 2021

On the Diagnostic Procedures File:

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CPT 31623 Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with brushing or protected brushings
CPT 31624 with bronchial alveolar lavage
CPT 31625 with bronchial or endobronchial biopsy(s), single or multiple sites
CPT 31628 with transbronchial lung biopsy(s), single lobe
CPT 31629 with transbronchial needle aspiration biopsy(s), trachea, main stem and/or lobar bronchus(i)
CPT 31632 with transbronchial lung biopsy(s), each additional lobe
CPT 31633 with transbronchial needle aspiration biopsy(s), each additional lobe
CPT 31652-31654 Endobronchial ultrasound (EBUS)
CPT 32408 Transthoracic needle aspiration (TTNA)

Evidence:

1) **Jiang 2020**, meta analysis of navigation bronchoscopy of peripheral pulmonary lesions (PPL)
    a. N=10 studies (2131 patients)
        i. Studies comparing diagnostic yield of navigation bronchoscopy for peripheral pulmonary lesions (PPL) compared to non-navigation bronchoscopy
            1. Comparison methods: endobronchial ultrasound (EBUS), Xray
        ii. 5 RCTs, 2 non randomized trials, 3 case=control studies
    b. Diagnostic yield of navigation bronchoscopy was statistically higher than non-navigation bronchoscopy for PPLs (odds ratio [OR] 1.69, 95% confidence interval [CI] 1.32, 2.18, P < 0.001), particularly for PPLs in the peripheral third lung (OR 2.26, 95% CI 1.48, 3.44, P < 0.001) and for bronchus sign positive PPLs (OR 2.26, 95% CI 1.21, 4.26, P = 0.011). Navigation bronchoscopy had better performance than non-navigation bronchoscopy when PPLs were ≤ 20 mm (OR 2.09, 95% CI 1.44, 3.03, P < 0.001). It also elevated diagnostic yield of malignant PPLs (OR 1.67, 95% CI 1.26, 2.22, P < 0.001) and PPLs in the bilateral upper lobes (OR 1.50, 95% CI 1.09, 2.08, P = 0.014)
    c. A total of seven studies included in the analysis reported complications. Prevalence of complications reported in navigation bronchoscopy and non-navigation bronchoscopy was 3.22% and 2.67%, respectively. There was no significant difference between onset of complications of the above two groups (OR 1.28, 95% CI 0.73, 2.25, P = 0.397). Pneumothorax and hemorrhage were the most common complications reported
    d. Conclusions: Navigation bronchoscopy enhanced diagnostic yield when compared to non-navigation bronchoscopy, particularly for PPLs in the peripheral third lung, PPLs being bronchus sign positive, PPLs ≤ 20 mm, malignant PPLs and PPLs in the bilateral upper lobes.
2) **McGuire 2020**, systematic review and meta-analysis of the accuracy and sensitivity of radial-endobronchial ultrasound and electromagnetic navigation bronchoscopy for sampling of peripheral pulmonary lesions
    a. N=41 studies (2988 lung nodules) in 3204 patients
        i. N=2101 radial-endobronchial ultrasound (R-EBUS)
        ii. N=886 electromagnetic navigation bronchoscopy (ENB)
        iii. 4 RTCs. 38 prospective or retrospective case series
    b. Overall sensitivity to detect cancer was 70.7% [95% confidence interval (CI): 67.2-74.0]; R-EBUS 70.5% (95% CI: 66.1-74.8), ENB 70.7% (95% CI: 64.7-76.8). The overall NPV for cancer was 44.6% (95% CI: 37.9-51.3), R-EBUS 38.3% (95% CI: 31.3-45.4), ENB 53.5% (95% CI: 41.2-65.8).

c. Meta-analysis demonstrated a successful peripheral lung lesion localization rate overall of 93.5% (95% CI: 90.6-96.4), R-EBUS 90.2% (95% CI: 85.6-94.7), ENB 98.2% (95% CI: 96.9-99.4).
d. Pooled overall diagnostic yield was 71.1% (95% CI: 67.3-74.9), R-EBUS 69.1% (95% CI: 64.4-73.7), ENB 73.9% (95% CI: 67.3-80.5).
e. Pooled overall diagnostic accuracy was 74.2% (95% CI: 71.0-77.3); R-EBUS 72.4% (95% CI: 68.7-76.1), ENB 76.4% (95% CI: 70.8-82.0).
f. Biopsy of peripheral nodules caused 58 pneumothoraces/collapsed lung (28 R-EBUS and 30 ENB) in 3056 (1937 R-EBUS, 1119 ENB) procedures: 2% (95% CI: 1.5-2.5), R-EBUS 1.5% (95% CI: 1.0-2.1), ENB 2.7% (95% CI: 1.9-3.8).
g. Conclusion: Both technologies have a high proportion of successful PPL localization with similar sensitivity for malignancy and accuracy

Submitted literature:

1) **Folch 2022**, NAVIGATE 24 month results: electromagnetic navigation bronchoscopy for pulmonary lesions
    a. Single arm pragmatic cohort study (N=1388 enrolled, N=1374 with 1 month follow-up, N=1121 with 12 month follow-up, N=900 with 24 month follow-up)
    b. The primary end point was the incidence of procedure-related pneumothorax grade 2 or higher (requiring intervention or hospitalization)
    c. Total 24-month mortality was 29% (403 of 1388), accounting for most subjects with incomplete follow-up. Furthermore, 16 subjects who died completed the 24-month follow-up and 387 did not. Two-year mortality in subjects with confirmed lung malignancy (true positives plus FNs) was 35.5% (305 of 858).
    d. On the study primary end point, procedure-related pneumothorax Common Terminology Criteria for Adverse Events grade greater than or equal to 2 occurred in 3.2% (44 of 1388) of subjects (5.1% EU, 2.9% U.S.). Any-grade pneumothorax occurred in 4.7% (7.4% EU, 4.3% U.S.). Bronchopulmonary hemorrhage grade 2 or higher occurred in 1.7% (2.3% EU, 1.6% U.S.) and any-grade bronchopulmonary hemorrhage in 2.7% (4.0% EU, 2.5% U.S.). Respiratory failure (grade ≥ 4) occurred in 0.6% (8 subjects, all U.S.), including one death related to complications of general anesthesia 9 days post-ENB in a subject with multiple comorbidities
    e. Among the 1329 subjects undergoing ENB-guided biopsy, 94.8% (1260 of 1329) had navigation completed and tissue obtained. Malignancy was diagnosed in 42.6% (537 of 1260), and 57.4% (723 of 1260) were negative for malignancy on the basis of the ENB-aided procedure
    f. The global diagnostic yield was 67.8% (822 of 1212).
    g. Repeat biopsy after the index ENB procedure (e.g., repeat ENB, surgical biopsy, TTNA, standard bronchoscopy, or EBUS-guided bronchoscopy) was conducted in 26.5% (334 of 1260).
    h. Although ENB has traditionally had a lower diagnostic success rate than percutaneous biopsy, it has a lower complication risk and also allows for the biopsy of multiple nodules and mediastinal staging in the same procedure
    i. Conclusions: ENB demonstrates low complications and a 67.8% diagnostic yield while allowing biopsy, staging, fiducial placement, and dye marking in a single procedure

Computer Assisted Bronchoscopy 2023 Review

Expert guidelines:

1) **NCCN 3.2023** Non-Small Cell Lung Cancer
    a. Diagnostic tools that provide important additional strategies for biopsy include:
        i. EBUS–guided biopsy
        ii. EUS–guided biopsy
        iii. Navigational bronchoscopy
        iv. Robotic bronchoscopy
    b. The least invasive biopsy with the highest yield is preferred as the first diagnostic study:
        i. Patients with central masses and suspected endobronchial involvement should undergo bronchoscopy.
        ii. Patients with peripheral (outer one-third) nodules may benefit from navigational bronchoscopy, radial EBUS, or transthoracic needle aspiration (TTNA).
        iii. Patients with suspected nodal disease should be biopsied by EBUS, EUS, navigational bronchoscopy, or mediastinoscopy.

Other payer policies:

1) Anthem BCBS 2023
    a. Navigational bronchoscopy is considered **medically necessary** for the following indications (A or B):
        i. In individuals for whom nonsurgical biopsy is indicated when both transthoracic needle biopsy and conventional bronchoscopy are considered inadequate to accomplish the diagnostic or interventional objective; **or**
        ii. For the pre-treatment placement of fiducial markers within lung tumor(s).
2) Aetna 2023
    a. Aetna considers electromagnetic navigation (EN)-guided bronchoscopy medically necessary for individuals with a peripheral pulmonary nodule that requires a pathologic diagnosis and is not accessible by standard bronchoscopy methods or by a transthoracic biopsy approach.
3) PacificSource 2022
    a. PacificSource may consider Electromagnetic Navigation Bronchoscopy (ENB) to be medically necessary when ALL the following criteria is met:
        i. The pulmonary nodule is peripheral or if the pulmonary nodule is central, a failed conventional bronchoscopy with endobronchial ultrasound has been attempted
        ii. Transthoracic needle biopsy cannot be done safely (e.g., nearby lung tissue with significant emphysema, risk of pneumothorax unacceptably high) or transthoracic needle biopsy already attempted without establishing a diagnosis

Expert input:

Dr. Mehta and Dr. Delmonaco had input into drafting the guideline criteria

Computer Assisted Bronchoscopy 2023 Review

HERC staff summary:

Since the last review of computer assisted bronchoscopy/navigational bronchoscopy, two systematic review/meta-analyses have been published that demonstrate a diagnostic accuracy and safety profile similar to bronchoscopy and bronchoscopy with endobronchial ultrasound. Private payers surveyed are covering this test for patients with lesions that are not accessible by transthoracic needle biopsy or conventional bronchoscopy or the patient has undergone one of these procedures without obtaining a diagnosis.

HERC staff recommendation:

1) Add CPT 31627 (Computer assisted bronchoscopy) to the Diagnostic Procedure File
2) Remove CPT 31627 from line 662 and modify GN173 as shown below
3) Add a new diagnostic guideline 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
~~31627~~	~~Computer assisted bronchoscopy~~	~~Insufficient evidence of effectiveness~~	~~March 2021~~

DIAGNOSTIC GUIDELINE DX COMPUTER ASSISTED NAVIGATIONAL BRONCHOSCOPY

Computer assisted navigational bronchoscopy (CPT 31627) is covered for EITHER

1) Patients for whom nonsurgical biopsy is indicated when both transthoracic needle biopsy and conventional bronchoscopy are considered inadequate to accomplish the diagnostic or interventional objective; OR
2) The pre-treatment placement of fiduciary markers within lung tumor(s).

OncoExTra

Plain Language Summary:

Coverage question: Should OHP cover a medical testing that helps figure out the risk for advanced cancer (OncoExTra)?

Should OHP cover this treatment? Yes, staff recommend covering as similar tests using more generic codes are already covered.

Coverage Question: Should the PLA code for OncoExTra be added to the Diagnostic file for testing of cancer tissue?

Question source: Exact Sciences

Background: The OncoExTra (Exact Sciences Inc., Genomic Health Inc.), formerly known as Oncotype Map and GEM ExTra, respectively, is an oncology (neoplasia) test that conducts exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction. This test is designed to report clinically significant mutation(s) with therapy associations. Exact Sciences is requesting review of this test.

Previous HERC reviews on cancer tissue have centered on next generation sequencing (NGS) and a new guideline for NGS was added to the Prioritized List at the September 2023 VBBS/HERC meetings. NGS tests generally include about 500 genes for interest. Whole exome testing would provide results of thousands of genes whether or not they are clinically actionable (that is, they are the target for a specific medication). The OncoExtra PLA code states that only clinically significant mutations are reported.

Current coverage for whole exome sequencing is limited to non-prenatal non cancer related genetic testing. The last review of WES was in 2014, and the GAP comment was "Used when there are multiple anomalies in a child, or when other specific testing has not found a diagnosis. 20-30% chance of finding a genetic cause for a syndrome or developmental delay in a population of children who already had non-revealing testing."

Current Prioritized List/Coverage status:

On the Excluded File:
PLA 0329U Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and

OncoExTra

tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations

Similar codes:
PLA 0036U Exome (i.e., somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses

Whole exome codes:
CPT 81415 Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis is currently Diagnostic and covered by Diagnostic Guideline D1 which does not include cancer tissue testing.

Excerpt from DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE

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

DIAGNOSTIC GUIDELINE DX, NEXT GENERATION SEQUENCING OF MALIGNANCIES [EFFECTIVE 1/1/24]

Next Generation Sequencing (NGS, for example CPT 81479, 81455, 0037U) is covered when all of the following requirements are met:

1) The patient has
    a. Either recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer; AND
    b. Has not been previously tested using the same NGS test for the same primary diagnosis of cancer, unless the criteria in 4) below are met; AND
    c. Decided to seek further cancer treatment (for example, therapeutic chemotherapy) and has adequate performance status (ECOG 0-2) to undergo such treatment; AND
2) The diagnostic laboratory test using NGS must have:
    a. Clinical Laboratory Improvement Amendments (CLIA)-certification; AND
    b. The test is being used as a companion diagnostic test in accordance with Food & Drug Administration (FDA)-approved therapeutic labeling; AND
    c. Results provided to the treating physician for management of the patient using a report template to specify treatment options; AND
3) A single CPT or HCPCS code is covered for each multigene panel performed on tumor tissue. Additional codes for individual genes and for molecular pathology procedures CPT 81400-81408 are excluded from coverage when the multigene panel is covered under the appropriate CPT or HCPCS code.
4) Repeat NGS testing may be required in the setting of patients who have clinically progressed per standardized professional guidelines after therapy. Coverage in this situation is limited to 3 times per primary malignancy unless there is indication for additional testing after individualized review of medical necessity.

Expert guidelines:

1) American Society for Clinical Oncology (ASCO) 2022, Somatic Genomic Testing in Patients With Metastatic or Advanced Cancer

OncoExTra

a. Expert consensus
    i. When tumor mutation burden (TMB) may influence the decision to use immunotherapy, testing should be performed with either large multigene panels with validated TMB testing or whole-exome analysis (strength of recommendation: strong).
        1. TMB refers to the number of somatic mutations per megabase of DNA sequenced and often varies from tumor type to tumor type
        2. In 2020, pembrolizumab was approved in its second tumor agnostic indication for the treatment of adult and pediatric patients with unresectable or metastatic, high TMB (defined as ≥ 10 mutations per Mb) solid tumors on the basis of the single-arm KEYNOTE-158 study of 129 patients across 10 different cancer types that demonstrated a 29% ORR in the high TMB cohort not fully accounted for by MSI status
        3. The benchmark method to measure TMB is whole-exome sequencing that interrogates approximately 22,000 genes or approximately 30 Mb of coding regions of the genome (ie, approximately 1% of the genome), but clinical whole-exome sequencing is not commonly used. Instead, multigene panel–based sequencing with fewer genes (324-595 genes in currently available panels) and coding regions (0.8-2.4 Mb) is more often used to estimate TMB

Other payer policies:

1) Aetna 2021 considers OncoExTra to be experimental
2) Regence BCBS 2023
    a. Whole exome sequencing is considered investigational for the diagnosis of genetic disorders when Criterion I [evaluation of neurodevelopmental disorders in pediatric patients] is not met, including but not limited to…testing for cancer treatment selection.
3) United HealthCare 2023
    a. Any other CGP test for solid tumors not addressed above (e.g., oncomap™ ExTra, NeoTYPE® Discovery Profile for Solid Tumors, MSK-IMPACT® , TheraMap™ Solid Tumor, CANCERPLEX® , Solid Tumor Profile Plus, Tempus xT) is considered unproven and not medically necessary for use as a companion diagnostic due to insufficient evidence of efficacy
4) Anthem BCBS 2022
    a. Covers molecular profiling (whole genome, whole exome, and gene panels) for unresectable or metastatic solid tumors when all of the criteria below are met:
        i. The test is used to assess tumor mutation burden and identify candidates for checkpoint inhibition immunotherapy
        ii. Individual has progressed following prior treatment
        iii. Individual has no satisfactory alternative treatment options
    b. Tests covered: 81445, 0037U [FoundationOne CDx], 0211U [Caris Life Sciences], 0244U, 0250U, 0334U

OncoExTra

HERC staff summary:

Review and discussion to date on testing for cancer tissue has centered around panel testing. Panel tests, such as FoundationOneCDx (PLA 0037U), Caris Life Sciences (CPT 81445) and Knight Cancer Labs GeneTrails (CPT 81479). Panel tests typically include approximately 500 genes known to be actionable, defined as a companion diagnostic test to an FDA approved chemotherapy agent. OncoExTra would test for many more than 500 genes. Most private payers surveyed consider this test to be experimental.

Whole exome sequencing of cancer tissue is strongly recommended by ASCO for patients with advanced or metastatic cancer when the test is used to assess tumor mutation burden and identify candidates for checkpoint inhibition immunotherapy. Anthem BCBS covers this testing for this indication, in patients who have progressed following prior treatment and have no satisfactory alternative treatment options.

HERC staff recommendations:

1) Place PLA 0329U (Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations) on the Diagnostic Procedures File
2) Modify the new guideline on cancer genetic sequencing panels as shown below
    a. Edits recommended in another issue summary are shown in purple

DIAGNOSTIC GUIDELINE DX, NEXT GENERATION SEQUENCING OF MALIGNANCIES

Next Generation Sequencing (NGS, for example CPT 81479, 81455, 0037U) is covered when all of the following requirements are met:

1) The patient has
    a. ~~Either recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer~~ a tissue diagnosis confirming cancer and has been evaluated by an oncologist or oncologic surgeon; AND
    b. Has not been previously tested using the same NGS test for the same primary diagnosis of cancer, unless the criteria in 4) below are met; AND
    c. Decided to seek further cancer treatment (for example, therapeutic chemotherapy) and has adequate performance status (ECOG 0-2) to undergo such treatment; AND
2) The diagnostic laboratory test using NGS must have:
    a. Clinical Laboratory Improvement Amendments (CLIA)-certification; AND
    b. The test is being used as a companion diagnostic test in accordance with Food & Drug Administration (FDA)-approved therapeutic labeling; AND
    c. Results provided to the treating physician for management of the patient using a report template to specify treatment options; AND
3) A single CPT or HCPCS code is covered for each multigene panel performed on tumor tissue. Additional codes for individual genes and for molecular pathology procedures CPT 81400-81408 are excluded from coverage when the multigene panel is covered under the appropriate CPT or HCPCS code.
4) Repeat NGS testing may be required in the setting of patients who have clinically progressed per standardized professional guidelines after therapy. Coverage in this situation is limited to 3 times per primary malignancy unless there is indication for additional testing after individualized review of medical necessity.

OncoExTra

5) Whole exome sequencing of cancer tissue (for example, 0329U or 0211U) is covered ONLY when all of the following criteria are met:
    a. The patient has advanced or metastatic cancer; AND
    b. The test is used to assess tumor mutation burden and identify candidates for checkpoint inhibition immunotherapy; AND
    c. The patient has progressed following prior treatment; AND
    d. There are no satisfactory alternative treatment options.

Commented [JG1]: Testing options? Or options besides checkpoint inhibition immunothersapy?

Commented [SA2R1]: Treatment other than checkpoint inhibition

Code	Description	Information/Similar codes	Code Placement Recommendation
27278	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]), without placement of transfixation device	Similar code 27279 (Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device) is on lines 183,398,530 govered by GN 161 SACROILIAC JOINT INJECTIONS AND SACROILIAC JOINT FUSION	183 FRACTURE OF PELVIS, OPEN AND CLOSED 398 SEVERE SACROILIITIS 530 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
61889	Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)	Similar code 61885 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array) is on lines 174,249,285	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 249 PARKINSON'S DISEASE
61891	Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s)	See 61889	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 249 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT

Code	Description	Information/Similar codes	Code Placement Recommendation
61892	Removal of skull-mounted cranial neurostimulator pulse generator or receiver with cranioplasty, when performed	See 61889	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 249 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
64596	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array	Similar code 64590 (Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling) in on lines 327,457,529. 64590 is modified to specify "requiring pocket creation and connection between electrode array and pulse generator or receiver"	327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION 457 URINARY INCONTINENCE 529 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS
64597	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; each additional electrode array (List separately in addition to code for primary procedure)	See 64596	327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION 457 URINARY INCONTINENCE 529 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS

Code	Description	Information/Similar codes	Code Placement Recommendation
64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator	Similar code 64595 (Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver) is on lines 285 and 424. 64595 is modified to specify "with detachable connection to electrode array"	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 424 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
75580	Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care profes	FFR was reviewed in May 2022 and CPT 0501T-0504T were added to the Diagnostic Procedure File	Diagnostic Procedures File
76984	Ultrasound, intraoperative thoracic aorta (eg, epiaortic), diagnostic	other vascular ultrasound codes are on the Diagnostic Procedures file	Diagnostic Procedures File
76987	Intraoperative epicardial cardiac ultrasound (ie, echocardiography) for congenital heart disease, diagnostic; including placement and manipulation of transducer, image acquisition, interpretation and report	ECHO codes are all Diagnostic, and intraoperative ECHO appears to be standard of care for certain cardiac procedures	Diagnostic Procedures File
76988	Intraoperative epicardial cardiac ultrasound (ie, echocardiography) for congenital heart disease, diagnostic; placement, manipulation of transducer, and image acquisition only	See 76987	Diagnostic Procedures File
76989	Intraoperative epicardial cardiac ultrasound (ie, echocardiography) for congenital heart disease, diagnostic; interpretation and report only	See 76987	Diagnostic Procedures File

Code	Description	Information/Similar codes	Code Placement Recommendation
82166	Anti-mullerian hormone (AMH)	Used in infertility testing; used to test for early menopause; used for monitoring certain types of ovarian cancer; used for work up of atypical genitalia and for work up of undescended testes	Diagnostic Procedures File
86041	Acetylcholine receptor (AChR); binding antibody	Used to diagnose myasthenia gravis	Diagnostic Procedures File
86042	Acetylcholine receptor (AChR); blocking antibody	Used to diagnose myasthenia gravis	Diagnostic Procedures File
86043	Acetylcholine receptor (AChR); modulating antibody	Used to diagnose myasthenia gravis	Diagnostic Procedures File
86366	Muscle-specific kinase (MuSK) antibody	Used to diagnose myasthenia gravis when acetylcholine receptor testing is negative	Diagnostic Procedures File
87523	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis D (delta), quantification, including reverse transcription, when performed	Antibody testing for hepatisis D (CPT 86692) is Diagnostic. Detection of other hepatitis viruses by DNA or RNA testing is Diagnostic	Diagnostic Procedures File
87593	Infectious agent detection by nucleic acid (DNA or RNA); Orthopoxvirus (eg, monkeypox virus, cowpox virus, vaccinia virus), amplified probe technique, each	Detection of other viruses by DNA or RNA testing is Diagnostic	Diagnostic Procedures File
90380	Respiratory syncytial virus, monoclonal antibody, seasonal dose; 0.5 mL dosage, for intramuscular use		Added to line 3 at the September 2023 HERC meeting
90381	Respiratory syncytial virus, monoclonal antibody, seasonal dose; 1 mL dosage, for intramuscular use		Added to line 3 at the September 2023 HERC meeting

Code	Description	Information/Similar codes	Code Placement Recommendation
90589	Chikungunya virus vaccine, live attenuated, for intramuscular use	There is currently no FDA approved vaccine for Chikungunya virus	Excluded File (This virus is set to be reviewed by ACIP in 2024)
90611	Smallpox and monkeypox vaccine, attenuated vaccinia virus, live, non-replicating, preservative free, 0.5 mL dosage, suspension, for subcutaneous use		Added to line 3 in August 2022
90622	Vaccinia (smallpox) virus vaccine, live, lyophilized, 0.3 mL dosage, for percutaneous use		Added to line 3 in August 2022
90623	Meningococcal pentavalent vaccine, conjugated Men A, C, W, Y- tetanus toxoid carrier, and Men B-FHbp, for intramuscular use	FDA and ACIP have approved Pfizer's MenABCWY vaccine as of October 2023	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
90679	Respiratory syncytial virus vaccine, preF, recombinant, subunit, adjuvanted, for intramuscular use		Added to line 3 at the September 2023 HERC meeting
90683	Respiratory syncytial virus vaccine, mRNA lipid nanoparticles, for intramuscular use		Added to line 3 at the September 2023 HERC meeting
92622	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; first 60 minutes	Implantation of osseointegrated implants (CPT 69716) is on lines 311 and 446	311 HEARING LOSS - AGE 5 OR UNDER 446 HEARING LOSS - OVER AGE OF FIVE
92623	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; each additional 15 minutes (List separately in addition to code for primary procedure)	Implantation of osseointegrated implants (CPT 69716) is on lines 311 and 446	311 HEARING LOSS - AGE 5 OR UNDER 446 HEARING LOSS - OVER AGE OF FIVE

Code	Description	Information/Similar codes	Code Placement Recommendation
93584	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; anomalous or persistent superior vena cava when it exists as a second contralateral superior vena cava, with native drainage to heart	Per AMA, these codes are to be used as an add on code with congenital heart catheterization codes (93593, 93594, 93595, 93596, 93597) which are on 21 lines containing congenital heart disease diagnoses	45 CORONARY ARTERY ANOMALY 67 VENTRICULAR SEPTAL DEFECT 70 CONGENITAL PULMONARY VALVE ANOMALIES 76 PATENT DUCTUS ARTERIOSUS; AORTIC PULMONARY 84 ENDOCARDIAL CUSHION DEFECTS 85 CONGENITAL PULMONARY VALVE ATRESIA 88 DISCORDANT CARDIOVASCULAR CONNECTIONS 89 CONGENITAL MITRAL VALVE STENOSIS/INSUFFICIENCY 104 ETRALOGY 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
93585	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; azygos/hemiazygos venous system (List separately in addition to code for primary procedure)	See 93584	45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653

Code	Description	Information/Similar codes	Code Placement Recommendation
93586	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; coronary sinus (List separately in addition to code for primary procedure)	See 93584	45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653
93587	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating at or above the heart (eg, from innominate vein) (List separately in addition to code for primary	See 93584	45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653
93588	Venography for congenital heart defect(s), including catheter placement, and radiological supervision and interpretation; venovenous collaterals originating below the heart (eg, from the inferior vena cava) (List separately in addition to code for primary	See 93584	45, 67, 70, 76, 84, 85, 88, 89, 104, 105, 110, 118, 128, 130, 134, 138, 176, 188, 232, 264, 653

Plain Language Summary:

Coverage question: Should OHP cover a medical process to attach a device to the bones of the spine to treat abnormal curves of the spine?

Should OHP cover this treatment? No, the risks for this process are too high and it is considered not yet proven (experimental) by private insurance.

Codes:

1) **22836** Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments
2) **22837** 8 or more vertebral segments
3) **22838** Revision (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed

Information: Anterior vertebral body tethering is a surgical treatment for scoliosis. Scoliosis is an abnormal lateral and rotational curvature of the spin. Standard treatments for scoliosis includes bracing and spinal fusion. The tethering procedure is being evaluated as a procedure that can reduce the rate of spine growth unilaterally, allowing the other side of the spine to "catch up." Anterolateral tethering uses polyethylene ligaments that are attached to the convex side of the vertebral bodies by pedicle screws or staples. The ligament can be tightened to provide greater tension than the staple. The vertebral Body Tethering System™ is indicated for skeletally immature patients that require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis. This technology was approved in 2019 by the FDA under a Humanitarian Device Exception.

Evidence

NICE 2022, evidence review for vertebral body tethering for idiopathic scoliosis in children and young people

1. In a meta-analysis of 24 studies (n=1,280: 1,278 patients with idiopathic scoliosis and 2 patients with syndromic scoliosis), the pooled mean Cobb angle of the main thoracic curve was 46.0° (95% CI 42.3° to 50.0°; 10 studies) in patients who had anterior vertebral body tethering (VBT) and 53.3° (95% CI 52.8° to 53.9°; 14 studies) in patients who had posterior spinal fusion (PSF) preoperatively. Of the studies with a follow up of 36 months or more after operation (number of studies not reported), the mean main thoracic curve was corrected to 22.5° (95% CI 14.1° to 30.9°) for anterior VBT and 22.7° (95% CI 19.6° to 25.8°) for PSF. In the same meta-analysis, the pooled mean Cobb angle of the lumbar curve was 28.7° (95% CI 25.6° to 32.0°; 9 studies) for anterior VBT and 30.9° (95% CI 29.2° to 32.5°; 5 studies) for PSF preoperatively. This was corrected to 18.0° (95% 3.5° to 32.5°) and 15.2° (13.3° to 17.1°) at a follow up of 36 months or more (number of studies not reported; Shin 2021)

2. In the meta-analysis of 24 studies (n=1,280), the mean thoracic rotation was 13.7° (95% CI 12.1° to 15.2°; 6 studies) in patients who had anterior VBT and 15.4° (95% CI 12.4° to 18.4°; 3 studies) in patients who had PSF preoperatively. After operation, thoracic rotation changed to 8.4° (95% CI 1.0° to 15.7°) with anterior VBT and 13.0° (95% CI 3.3° to 22.6°) with PSF at a follow up of 36 months or more (number of studies not reported; Shin 2021).
3. In the meta-analysis of 24 studies (n=1,280), there was no statistically significant difference found in the postoperative SRS-22 self-image or total scores between patients who had anterior VBT and patients who had PSF (self-image, 4.27 [95% CI 4.0 to 4.56; 2 studies] compared with 4.23 [95% CI 4.07 to 4.40; 7 studies]; total score, 4.36 [95% CI 4.06 to 4.65; 2 studies] compared with 4.30 [95% CI4.17 to 4.43; 7 studies]; Shin 2021)
4. The pooled complication rate was 26% (95% CI 12% to 40%, I2=86.14%; 10 studies) in patients who had anterior VBT and 2% (95% CI 0% to 4%, I2=19.21%; 9 studies) in patients who had PSF in the meta-analysis of 24 studies (n=1,280).

Raitio 2022, systematic review of vertebral body tethering

1. N=23 studies (843 patients), minimum follow up 2 years
a. All registry or cohort studies
2. In the included studies, the mean preoperative main thoracic curve was 49 degrees, which corrected to 24 degrees in first postoperative imaging. VBT provided sustainable median-term results as the reported curves after a minimum of two-year follow-up averaged at 23 degrees
3. In the included studies, the complication rate was 18% with pulmonary (pneumothorax, pleural effusion) and instrumentation-related (tether breakage, overcorrection) being the most common. Reoperations related to tethering were required in 10% of cases. These included tether release(s) for overcorrection, replacing and extending tethers for breakage or curve progression, and chest tube insertions for pulmonary complications. The vast majority avoided spinal fusion, as only 4.7% of VBT patients required conversion to PSF after unsuccessful tethering.
4. There was only one study comparing traditional fusion and AVBT. Newton et al. compared the outcomes of AVBT and PSF using pedicle screw instrumentation at a mean of 3.5 years follow-up. The correction of major thoracic curves was significantly better in the PSF group (70%) as compared with AVBT (38%). There were nine revisions in the AVBT group including three conversions into PSF with three more pending. Twelve patients had a broken tether, but the majority (74%) of the patients in the AVBT cohort had avoided spinal fusion at the end of follow-up.
5. Conclusion: While the reported median-term results of VBT appear promising, long-term results of this technique are currently lacking

<u>Expert guidelines</u>

1) **Pediatric Orthopaedic Society of North America/Scoliosis Research Society** joint position statement on anterior fusionless scoliosis technologies for immature patients with idiopathic scoliosis

a. In summary, a wide variety of centers and surgeons across the US, Canada, and outside North America have reproduced clinical results demonstrating acceptable safety and efficacy of anterior vertebral body tethering (AVBT) in skeletally immature patients. The FDA has judged this treatment as 'safe' and with 'probable benefit', and given this FDA approval the SRS and POSNA support insurance payor coverage for FDA approved usage of such devices

Other payer policies

1) NICE 2022: Evidence on the safety of vertebral body tethering for idiopathic scoliosis in children and young people is limited but raises concerns of serious complications. Evidence on its efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research.
2) United Health Care 2023: Vertebral body tethering for the treatment of scoliosis is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy
3) Aetna 2023 considers vertebral body tethering to be experimental
4) Cigna 2023 considers vertebral body tethering for adolescent idiopathic scoliosis to be experimental

HERC staff summary

The literature to date for vertebral body tethering for scoliosis consists of cohorts studies, registry studies, and case series. There appears to be only one study directly comparing this technology to other surgical interventions, and no studies comparing it to bracing. There appears to be a high rate of complications from this procedure. One highly regarded evidence-based guideline (NICE 2022) recommends against coverage. Private payers surveyed are currently not covering this procedure as experimental.

HERC staff recommendations:

1) Place vertebral body tethering CPT codes on line 662 and
   a. **22836** Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments
   b. **22837** 8 or more vertebral segments
   c. **22838** Revision (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed
2) 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
22836-22838	Anterior thoracic vertebral body tethering	Insufficient evidence of effectiveness	November 2023

2023 CPT Code Review
Posterior Nasal Nerve Ablation

Plain Language Summary:

Coverage question: Should OHP cover a medical process to destroy a nerve that can cause a constant runny nose?

Should OHP cover this treatment? No. The process is not well-studied, and it is considered not yet proven (experimental) by private insurance.

Codes:

1) **31242** Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve
2) **31243** Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve

Information: Information: Posterior nasal nerve ablation is a treatment for chronic rhinitis, which causes a runny nose or post-nasal drip. Other treatments for chronic rhinitis include intranasal saline, intranasal corticosteroids, intranasal anticholinergics, oral/topical antihistamines, and/or oral/topical decongestants. Posterior nasal nerve ablation is a minimally invasive procedure to disrupt this nerve and reduce parasympathetic innervation to the nasal cavity. Chronic rhinitis (ICD-10-CM J31.0) is on line 562.

Evidence

Balai 2023, systematic review and meta-analysis of posterior nasal nerve neurectomy for rhinitis

1. 6 single arm studies and 2 sham controlled RCTs (463 total patients)
    a. 6 of the 8 studies were industry sponsored
    b. 6 studies on cryotherapy, 1 study on radiofrequency ablation and 1 study on laser ablation
    c. 4 single arm studies considered to be at moderate risk of bias and 2 at serious risk of bias. The two randomized sham-controlled trials were both deemed to be at an overall low risk of bias
2. In the pre-post single-arm studies the primary outcome was a change in TNSS from pre-operative baseline, to varying intervals of post-operative follow-up. Whereas in the two randomized sham-controlled trials the primary outcome was responder rate at follow-up, where a response was defined as a ≥ 30% improvement (decrease) in TNSS from baseline. Timing of outcome measures ranged from 7 days to 2 years post-procedure.
3. In the pooled analysis of data from these two randomized controlled trials [Del Signore 2021--cryoablation, Stolovitzky 2021—radiofrequency ablation], active treatment was associated with significantly greater responder rate (OR 3.85, 95%CI 2.23-6.64, $p < 0.00001$).

4. Conclusion: This systematic review identified there is some limited evidence to suggest cryotherapy or radiofrequency ablation of the posterior nasal nerve can improve TNSS in adult patients. However, this is from a limited number of trials with short follow-up. Future research should focus on prospective randomized controlled trials with larger numbers of participants and medium to long term follow up in order to help draw more valid conclusions regarding the true effectiveness of PNNN in this patient cohort

Expert guidelines

American Academy of Otolaryngology-Head and Neck Surgery 2023, position statement: PNN ablation for the treatment of chronic rhinitis

1) Available at: https://www.entnet.org/resource/position-statement-posterior-nasal-nerve/
    a. Accessed October 5, 2023
2) Based on these safety and efficacy data, the AAO endorses the use of PNN ablation for the treatment of medically-refractory chronic rhinitis. We do not consider these treatments to be experimental

Other payer policies

1) Premara BCBS 2023
    a. Cryoablation for chronic rhinitis (allergic or nonallergic) is considered investigational. (e.g., Clarifix™device)
    b. Radiofrequency ablation for chronic rhinitis (allergic or nonallergic) is considered investigational. (e.g., RhinAer™ stylus)
2) Aenta 2023: considers nerve ablation for the treatment of rhinitis to be experimental

HERC staff summary

Ablation of the posterior nasal nerve (cryotherapy or radiofrequency ablation) has not been well studied. The existing studies are mostly cohort studies, the majority are industry sponsored, and all are short term. Private payers consider these procedures to be experimental.

HERC staff recommendations:

1) Place posterior nasal nerve ablation CPT codes on line 662
    1. **31242** Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve
    2. **31243** Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve
2) 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
31242, 31243	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation or cryoablation, posterior nasal nerve	Insufficient evidence of effectiveness	November 2023

2023 CPT Code Review
Phrenic Nerve Stimulator

Plain Language Summary:

Coverage question: Should OHP cover a device that uses electrical pulse to make the nerve a in the neck work better to help a person who is using a breathing machine?

Should OHP cover this treatment? Yes. This is a standard option for treatment of certain patients who are very ill.

Codes:

1) **33276** Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed
2) **33277** Insertion of phrenic nerve stimulator transvenous sensing lead
3) **33278** Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; system, including pulse generator and lead(s)
4) **33279** Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only
5) **33280** Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only
6) **33281** Repositioning of phrenic nerve stimulator transvenous lead(s)
7) **33287** Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator
8) **33288** Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s)
9) **93150** Therapy activation of implanted phrenic nerve stimulator system, including all interrogation and programming
10) **93151** Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system
11) **93152** Interrogation and programming of implanted phrenic nerve stimulator system during polysomnography
12) **93153** Interrogation without programming of implanted phrenic nerve stimulator system

Information: The phrenic nerve stimulator provides electrical stimulation of the patient's phrenic nerve. The phrenic nerve causes the diaphragm to contract and relax. A phrenic nerve stimulator causes the diaphragm to contract rhythmically and produce breathing in patients who have hypoventilation (a state

in which an abnormally low amount of air enters the lungs). The device is used to treat hypoventilation caused by a variety of conditions, including respiratory paralysis resulting from lesions of the brain stem and cervical spinal cord and chronic pulmonary disease with ventilatory insufficiency. The phrenic nerve stimulator is intended to be an alternative to management of patients with respiratory insufficiency who are dependent upon the usual therapy of intermittent or permanent use of a mechanical ventilato..

Similar codes:

1) Previously was coded with 64575 (Incision for implantation of neurostimulator electrode array; peripheral nerve) and similar codes. These codes are Ancillary

Current Prioritized List status

1) Quadriplegia is on the 4 dysfunction lines
2) Central hypoventilation syndrome is on line 202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER
3) Respiratory failure is on line 233 ADULT RESPIRATORY DISTRESS SYNDROME; ACUTE RESPIRATORY FAILURE; RESPIRATORY CONDITIONS DUE TO PHYSICAL AND CHEMICAL AGENTS

Expert guidelines

American Thoracic Society 2016

1. Diaphragm pacing is a way to help support people who cannot breathe on their own. It can be used in place of a mechanical ventilator at times. It is a treatment option for some people diagnosed with congenital central hypoventilation syndrome (CCHS) as well as those who have suffered a high cervical spinal cord injury.
2. To be a candidate, a patient must have normal diaphragm muscle function, intact phrenic nerves, mild or no lung disease
3. The main risks of diaphragm pacing include risk of injury to the phrenic nerve during surgery, infection of implanted components, and failure of the equipment

Other payer policies

1) CMS
    a. The implantation of a phrenic nerve stimulator is covered for selected patients with partial or complete respiratory insufficiency
2) Cigna 2023
    a. Covers phrenic nerve stimulation for patients with severe, chronic respiratory failure requiring mechanical ventilation for either of the following:
        i. stable, high spinal cord injury
        ii. hypoventilation, either primary or secondary to a brainstem disorder
    b. Considers phrenic nerve stimulation to be experimental for central sleep apnea, amyotrophic lateral sclerosis (AL), temporary respirator insufficiency
3) Wellmark BCBS 2023

   a. Covers phrenic nerve stimulation as an alternative to mechanical ventilation for patients with central hypoventilation syndrome or ventilatory failure from stable spinal cord injury at or above C3
   b. Experimental for central sleep apnea, motor neuron disease or when respiratory insufficiency is temporary
4) Aetna 2023
   a. Covers phrenic nerve pacing for members with high quadriplegia at or above C3 or central hypoventilation, patients with ALS meeting certain criteria, or moderate to severe central sleep apnea

HERC staff summary

Phrenic nerve stimulation appears to be a standard option for treatment of central hypoventilation syndrome and high spinal cord injury, to allow patients to have a break from mechanical ventilation. Its use requires an intact phrenic nerve and diaphragm. Use of this technology for patients with motor neuron disease such as ALS, severe obstructive sleep apnea, or temporary mechanical ventilation appears to be an area of research. This technology was previously covered with generic nerve stimulation codes, which are Ancillary. HERC staff recommends adding this technology to the dysfunction in breathing line with consideration of adding a new guideline.

HERC staff recommendations:

1) Place the various codes for phrenic nerve pacing on line 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
   1. **33276** Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed
   2. **33277** Insertion of phrenic nerve stimulator transvenous sensing lead
   3. **33278** Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; system, including pulse generator and lead(s)
   4. **33279** Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s) only
   5. **33280** Removal of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator only
   6. **33281** Repositioning of phrenic nerve stimulator transvenous lead(s)
   7. **33287** Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; pulse generator

8. **33288** Removal and replacement of phrenic nerve stimulator, including vessel catheterization, all imaging guidance, and interrogation and programming, when performed; transvenous stimulation or sensing lead(s)
9. **93150** Therapy activation of implanted phrenic nerve stimulator system, including all interrogation and programming
10. **93151** Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system
11. **93152** Interrogation and programming of implanted phrenic nerve stimulator system during polysomnography
12. **93153** Interrogation without programming of implanted phrenic nerve stimulator system

2) Add the following HCPCS codes to line 71
    1. C1778 Lead, neurostimulator (implantable)
    2. C1816 Receiver and/or transmitter, neurostimulator (implantable)
    3. L8680 Implantable neurostimulator electrode, each
    4. L8682 Implantable neurostimulator radiofrequency receiver
    5. L8683 Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
3) Consider adding a new guideline to line 71 as shown below

GUIDLEINE NOTE XXX PHRENIC NERVE STIMULATION
Line 71
Phrenic nerve stimulation is included on this line when all of the following criteria are met

1) The patient has severe, chronic respiratory failure requiring mechanical ventilation due to EITHER
    a. A stable high spinal cord injury; OR
    b. Central alveolar hypoventilation disorder; AND
2) The patient has intact and sufficient function in the phrenic nerve, lungs, and diaphragm; AND
3) Stimulation of the diaphragm either directly or through the phrenic nerve results in sufficient muscle activity to accommodate independent breathing without the support of a ventilator for at least 4 continuous hours and day.

2023 CPT Code Review
Urethral Stricture Dilation with Drug-Coated Balloon Catheter

Plain Language Summary:

Coverage question: Should a procedure that uses a tube coated with medicine to open the urethra be covered?

Should OHP cover this treatment? No, this procedure is not well studied.

Code: **52284** Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed

Information: Urethral strictures are scar tissue that narrows the urethral and can cause lower urinary tract symptoms such as urinary retention. Current available options for recurrent urethral strictures include endoscopic management and urethral reconstruction. While open repair is considered the gold standard, with success rates of 80–95%, minimally invasive therapies are more frequently used. The Optilume® Drug Coated Balloon (DCB) (Urotronic, Inc., Plymouth, MN, USA) is the first drug coated balloon catheter intended for the treatment of male anterior urethral strictures. This technology aims to provide immediate symptomatic relief by widening the urethral lumen using balloon dilation, while maintaining long-term urethral patency via the circumferential and local application of paclitaxel. Paclitaxel is an antimitotic agent that inhibits cell proliferation and migration.

Evidence

Elliot 2022, one year results of the ROBUST III RCT

1) RCT of drug-coated balloon dilation (DCB) vs direct vision internal urethrotomy (DVIU)
2) N=127 patients enrolled (N=79 DCB vs N=48 DVIU)
    a. 100 patients evaluated at 6 months (N=69 DCB group, N=31 DVIU group)
    b. 75 patients evaluated at 1 year (N=60 DCB group, N=15 DVIU group)
    c. Anterior strictures ≤ 12 Fr in diameter and ≤ 3 cm in length with at least 2 prior endoscopic treatments, International Prostate Symptom Score ≥ 11 and maximum flow rate < 15 ml second
    d. Participants with previous urethroplasty, hypospadias repair, lichen sclerosis or unresolved confounding etiologies (eg bladder neck contracture, neurogenic bladder, benign prostatic hyperplasia) were excluded.
    e. Primary endpoint was anatomical success s (≥ 14Fr by cystoscopy or calibration) at 6 months
    f. Secondary end points included freedom from repeat treatment, International Prostatic Symptom Score and peak flow rate
3) At 6 months, anatomical success was 74.6% in the DCB group and 26.8% in the control group

4) Kaplan-Meier estimates of freedom from repeat intervention through 1 year were significantly higher for the DCB group as compared to the control group (83.2% vs 21.7%, p <0.0001)
5) QOL scores for the DCB group remained significantly improved through 1 year, while the DVIU group had deterioration of QOL scores
6) Adverse event types and rates were well matched between groups, except that the DCB group had higher rates of post-procedure hematuria and dysuria compared to controls (11.4% vs 2.1% for both event types).
7) Conclusion: The results of this randomized controlled trial support that Optilume DCB is safe and superior to standard DVIU/dilation for the treatment of recurrent anterior urethral strictures
8) Limitation: DCB was not compared to urethroplasty, the gold standard urethral stricture treatment. Urethroplasty has anatomical success rates of 80%-95% depending on stricture characteristics. However, urethroplasty is more invasive than endoscopic treatment and can be associated with complications of pain, neuropathy and sexual dysfunction.
9) HERC staff evaluation: this is a small trial, with a high drop out rate in the control arm (68.75% drop out rate in the control arm vs 24.05% in the DCB arm). This large mismatch in drop out rates makes the results of this study less reliable. Additionally, this study only included patients who had multiple previous endoscopic dilations, which gives no information on how DCB performs when done as for first time treatment of strictures.

DeLong 2022, 1 year results of the ROBUST II study

1) Cohort study of patients with a single anterior urethral stricture ≤ 3 cm in length and at least 2 prior stricture treatments.
2) N=16 patients enrolled, N=9 completed 1 year follow up
3) The primary safety endpoint was the rate of treatment-related serious complications at 90 days post-procedure. Efficacy outcomes included symptomatic assessments, erectile function measured using the International Index of Erectile Function (IIEF), Qmax, and anatomic success
4) The anatomic success rate at 6 months was 73.3% (11/15). The average IPSS decreased from 18.4 at baseline to 7.5 at 90 days, 7.0 at 6 months, and 6.0 at 1 year (P < 0.001). The IPSS responder rate was 75.0% (12/16) at 30 days and 61.5% (8/13) at 1 year. The average PROM score also improved after the procedure, decreasing from 10.8 at baseline to 3.6 at 90 days, 4.2 at 6 months, and 4.3 at 1 year (P < 0.001). Quality of life as measured by IPSS QOL improved from 4.4 at baseline to 1.4 at 1 year (P < 0.001).
5) Results of the ROBUST II study showed that treatment of recurrent anterior urethral stricture with the minimally invasive Optilume DCB was safe and achieved durable anatomic results at 6 months, with sustained reduction in severity of LUTS through 1 year

Virasoro 2022: 3 year results from the ROBUST I study

1. Single arm open-label study, N=53 patients enrolled, N=33 patients actually followed for 3 years
    a. Adult men with a single bulbar stricture <12F and ≤ 2 cm long
    b. Protocol exclusions included prior urethroplasty, radical prostatectomy, lichen sclerosus, penile prosthesis or artificial urinary sphincter, and history of pelvic radiation
2. At 3 years, 67% (29/43) of subjects achieved functional success based on an improvement in IPSS ≥50% without retreatment

3. The average International Prostate Symptom Score (IPSS) improved from 25.2 at baseline to 5.5 at 3 years (p<0.0001)
4. Freedom from repeat intervention was 77% (33/43) at 3 years
5. A total of 73 adverse events in 35 subjects were reported through 3 years
6. Symptomatic improvement after treatment with the Optilume DCB was maintained through 3 years in a population susceptible to high stricture recurrence rate. The therapy is safe with no negative impact on sexual function

Kaplan 2021, interim 2 year results for the EVEREST-I trial evaluating the Optilume BHP catheter system

1) Only available as a poster abstract

Expert guidelines

American Urologic Association 2023, Urethral stricture disease

1. Surgeons may offer urethral dilation or direct visual internal urethrotomy, combined with drug-coated balloons, for recurrent bulbar urethral strictures <3cm in length. (Conditional Recommendation; Evidence Level: Grade B)
2. Drug coated balloons have not been assessed in RCTs for first-time treatment of anterior urethral stricture.
3. Only trial noted to be the ROBUST trial
4. The Panel suggests the following issues in future investigations: The efficacy of injection or balloon-coated antiproliferative or other pharmacological agents at time of endoscopic treatment for penile urethral stricture, previous failed urethroplasty, posterior urethral stenosis, and bladder neck contracture.

Other payer policies

1) Aetna 2023
   a. Drug-coated balloons (e.g., the Optilume paclitaxel-coated balloon) is considered investigational.
2) Cigna 2023
   a. Transurethral balloon dilation of the prostatic urethra is considered investigational
3) Wellmark BCBS 2023
   a. Drug Coated Balloon (Optilume): Based on the current peer reviewed medical literature 1-year outcomes from the EVEREST-I study may show promise, however, study limitations include the lack of a control group, and a randomized clinical trial is currently ongoing to confirm the findings. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.
   b. Considers Optilume to be experimental

Expert input

Dr. Jyoti Chouhan, OHSU urology

Optilume (the drug coated urethral balloon that is noted in the prior e-mail) was FDA approved last year for the management of recurrent bulbar urethral strictures < 3 cm. In my opinion, it is

not experimental. Our national organization (the American Urological Association) updated the urethral stricture guidelines earlier this year due to the FDA approval of Optilume (and the studies behind it) and their recommendation is noted below [cites AUA 2023 guideline as above]

While I agree that this is a conditional recommendation, there are many parts of the guideline that are also conditional recommendations and refer to techniques that have been around for decades and are far from experimental (traditional urethral dilation, direct visualized internal urethrotomy, urethroplasty).

Male reconstruction studies are frought w/ suboptimal study designs- usually small, retrospective cohorts. Therefore, the recommendations in guidelines (such as the one above) are often Grade B or C (and not A). This is to be expected in this field.

HERC staff summary

Treatment of urethral strictures with a drug-eluting balloon dilation has been studied in three small cohort studies and one small RCT. The only RCT available (ROBUST III) compares drug eluting balloon dilation to endoscopic dilation, not the standard of care which is urethroplasty. The RCT also had a much higher drop out rate in the control group, making comparisons difficult. Additionally ROBUST III included only patients with multiple prior stricture dilations. There is no RCT comparing drug eluting balloon dilation to standard therapy (either minimally invasive or open) for first time dilation. The AUA has a conditional recommendation for use with a note that future investigations should be conducted. Oregon experts recommend covering this therapy as a minimally invasive treatment option for urethral stricture. Other treatments for urethral strictures are currently included on the Prioritized List. Private payers surveyed consider this intervention to be experimental.

HERC staff recommendations:

1) Place CPT **52284 (**Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed) on line 662
2) Add an entry to GN173 as shown below
3) Readdress when and RCT is published comparing drug-eluting balloon dilation with other therapies or sham 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:

2023 CPT Code Review
Urethral Stricture Dilation with Drug-Coated Balloon Catheter

Procedure Code	Intervention Description	Rationale	Last Review
52284	Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis	Insufficient evidence of effectiveness	November 2023

2023 CPT Code Review
Transcervical Ablation of Uterine Fibroids

Plain Language Summary:

Coverage question: Should OHP cover a medical procedure to destroy noncancer growths in the uterus?

Should OHP cover this treatment? No, evidence does not support this specific medical procedure.

Code: **58580** Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency

Information: Uterine fibroids are non-cancerous growths in the uterus. Fibroids can cause symptoms such as heavy bleeding, pain, or pelvic fullness. Transcervical ablation of uterine fibroids is a minimally invasive treatment which involves insertion of a device through the cervix into the uterus which causes coagulative necrosis in the fibroid(s). Alternative treatments of fibroids include oral contraceptives, Mirena IUD, hysterectomy, myomectomy, endometrial ablation, and uterine artery embolization. Currently, vascular embolization, myomectomy, and hysterectomy are included on line 404 UTERINE LEIOMYOMA AND POLYPS for treatment of uterine fibroids, with a guideline. Transcervical radiofrequency ablation of fibroids was reviewed in 2021 and found to be experimental.

Previous HERC reviews:
The 2021 review of transcervical RFA for fibroids included a NICE 2021 evidence review, an AHRQ 2017 evidence review, and a 2019 systematic review and meta-analysis of prospective studies (Bradley 2019), as well as the 2021 ACOG practice bulletin on management of symptomatic uterine fibroids. Private payers were covering this technology in 2021. That review concluded that "Transcervical radiofrequency ablation has a small evidence base and has been found by one of our highly trusted sources (NICE) to have insufficient evidence of effectiveness."

Similar codes:
58674 (Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency) is on line 404 UTERINE LEIOMYOMA
0404T (Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency) is on line 662/GN173

Evidence
An updated evidence search was conducted, which found no additional studies, systematic reviews, or practice bulletins since the 2021 review

2023 CPT Code Review
Transcervical Ablation of Uterine Fibroids

Expert guidelines

ACOG 2021 Management of Symptomatic Uterine Leiomyomas

1) The only two minimally invasive interventions for leiomyomas that are recommended by ACOG are uterine artery embolization and laparoscopic radiofrequency ablation. Focused ultrasound and endometrial ablation both had insufficient evidence to make a clinical recommendation

Other payer policies

Private payers are covering this procedure for symptomatic fibroids as noted in the 2021 review

HERC staff summary

Transcervical ablation of uterine fibroids has no additional evidence or expert guideline recommendations to support its use since the 2021 HERC review. ACOG continues to not recommend this procedure. HERC staff recommend continuing non-coverage of this technology.

HERC staff recommendations:

1) Place **58580** (Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency) on line 662
2) Modify the 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
~~0404T~~ 58580	~~Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency~~ Transcervical ablation of uterine fibroid(s)	Insufficient evidence of effectiveness	~~August 2021~~ November 2023

2023 CPT Code Review
Suprachoroidal Injections

Plain Language Summary:

Coverage question: Should OHP cover a certain way to deliver medication to the back of the eye?

Should OHP cover this treatment? Yes, for treatment of a condition where there's swelling in the center part of the eye (the macula) caused by inflammation (uveitic macular edema).

Code: **67516** Suprachoroidal space injection of pharmacologic agent (separate procedure)

Information: Current drug delivery techniques to access the posterior segment of the eye include intra-vitreal injections, peri-ocular injections (i.e., subconjunctival, subtenon, or juxtascleral), and intra-vitreal implants. Drug delivery by injection into the suprachoroidal space is another technique that has recently been proposed in the treatment of posterior segment disease. The suprachoroidal space provides a potential route of access from the anterior region of the eye to the posterior region. The suprachoroidal space (SCS), an anatomical niche nestled between the sclera and the choroid, provides a minimally invasive conduit for precise medication delivery.

Current Prioritized List status:

Uveitis is on line 360 CHORIORETINAL INFLAMMATION

Retinal (macular) edema is on line 449 DEGENERATION OF MACULA AND POSTERIOR POLE

Evidence

Wu 2023, review of suprachoroidal injection

i. N=8 studies on use in macular edema secondary to non-infectious uveitis which represented 2 phase III trials [PEACHTREE—sham controlled RCT; single arm phase III trial AZALEA], and 3 phase I/II trials
    1. PEACHTREE trial—160 eyes randomized to suprachoroidal triamcinolone acetonide (SCTA) or sham injection
        a. showed the significant improvement in visual acuity at 24 weeks and reduction in retinal central subfield thickness (CST), all without increasing the risk of elevated IOP or accelerated cataract progression.
ii. Studies on diabetic macular edema were all phase I/II trials or case series
iii. Studies on macular edema secondary to retinal vein occlusion included mostly phase II trials or case series
    1. One phase III trial showed no benefit compared to sham [SHAPPHIRE]

iv. Studies on post-operative/pseudophakic cystoid macular edema were all phase II trials or case series
v. Studies on photoreceptor loss were animal studies with 3 phase I trials

Expert guidelines
None identified

Other payer policies
1) Aetna 2022
    a. Aetna considers suprachoroidal injection (i.e., triamcinolone acetonide injectable suspension [Xipere]) medically necessary for the treatment of macular edema associated with uveitis when criteria are met. Aetna considers suprachoroidal injection of all other pharmacologic agents experimental and investigational for all indications because the effectiveness of this approach has not been established.
2) Cigna 2023
    a. Covers suprachoroidal injection of triamcinolone acetonide for macular edema associated with uveitis
3) Capital BCBS 2023
    a. Suprachoroidal delivery of a pharmacologic agent is considered investigational, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

HERC staff summary
Suprachoroidal injections or triamcinolone have shown positive results in uveitic macular edema in one RCT as well as phase II trials. Private insurers coverage of these injections vary.

HERC staff recommendations:
a. Add CPT **67516** (Suprachoroidal space injection of pharmacologic agent (separate procedure)) to line 360 CHORIORETINAL INFLAMMATION
b. Add a new guideline as shown below to line 360

GUIDELINE NOTE XXX SUPRACHOROIDAL INJECTION
Line 360
Suprachoroidal space injection (CPT 67516) is only included on this line for treatment of macular edema associated with uveitis with triamcinolone acetonide.

2023 CPT Code Review
Coronary Lithotripsy

Plain Language Summary:

Coverage question: Should OHP cover a medical procedure to help open blocked blood vessels to the heart?

Should OHP cover this treatment? No. It has not been compared to more common treatments and no studies found evidence of it working well.

Code: **92972** Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)

Additional code: HCPCS **C1761** Catheter, transluminal intravascular lithotripsy, coronary

Information: Coronary artery disease (CAD) is a condition in which there is insufficient blood flow in the arteries that feed the heart. CAD can be treated with percutaneous interventions such as coronary artery stenting. Calcium frequently builds up in the coronary arteries and makes interventions like stenting more difficult. To help stent deployment in these cases, several specialty balloons have been developed which cut or score the calcium lining the artery. Intravascular lithotripsy (IVL) is a recently introduced therapeutic modality in managing calcified coronary lesions (CCL). Lithotripsy enhances the fragmentation of CCL via delivery of circumferential sonic pressure waves to the vessel wall and applying pulsatile shockwaves to the surrounding plaque.

A description of this procedure from the NICE review:

> A percutaneous guidewire is passed from the radial or femoral artery into a coronary artery. Then, an intravascular lithotripsy catheter with embedded emitters enclosed in an integrated angioplasty balloon is passed and connected to an external generator with a connector cable. The catheter is advanced to the target lesion guided by radiopaque markers on the catheter. The balloon is then inflated with a saline and contrast solution to ensure contact with vessel wall. The lithotripsy cycle is then activated. For every cycle, the catheter emits localized, high-energy, pulsatile, unfocused, circumferential, acoustic, sonic, pressure waves (lasting microseconds). These waves pass through the inflated balloon into the wall of the coronary artery. As the waves travel along the wall and the connective tissue, they disrupt calcium deposits (both intimal and medial calcium) by microfracturing the calcified lesions. The cycle can be repeated until the lesion has been expanded sufficiently to allow optimal stent placement and optimization. Intravascular lithotripsy during PCI may improve stent delivery and expansion and modify focal intravascular calcium, while limiting localized injury to the endovascular surface.

Evidence

NICE 2020, evidence review intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention

2023 CPT Code Review
Coronary Lithotripsy

1) Included 3 studies
    1. DISRUPT CAD I study, case series of 60 patients
    2. DISRUPT CAD II study, case series of 120 patients
    3. Case series of 71 patients
2) Clinical success found in 94-95% of patients (defined as residual diameter stenosis of less than 50% after stenting without in-hospital major adverse cardiac event)
3) Safety
    1. In the case series of 60 patients, cardiac death (not related to the device) was reported in 3% (2/60) of patients
    2. In the case series of 120 patients, cardiac death (14 days after treating a 95% lesion in the distal right coronary artery because of probable stent thrombosis) was reported in 1 patient
    3. In the case series of 54 patients, cardiac death as a result of ST-elevation myocardial infarction complicated by cardiogenic shock in catheter lab was reported in 1 patient
    4. Deep arterial dissection due to angioplasty (type B according to the National Heart Lung and Blood Institute) occurred in 13% (4/31) of patients in the subgroup analysis of the DISRUPT CAD study of 31 patients
    5. Deep arterial dissection after IVL and stenting (type B and C) was reported in 1 patient each in the case series of 120 patients (DISRUPT CAD II study)
4) Freedom from MACE at 30 days
    1. In the case series of 60 patients, 95% (57/60) of patients did not have MACE at 30 days. However, 5% (3/60) of patients had asymptomatic non-Q-wave periprocedural myocardial infarctions
    2. In the case series of 120 patients, 94% (113/120) of patients reported no MACE in-hospital. However, 6% (7/120) of patients had asymptomatic non-Q-wave periprocedural myocardial infarctions. All these were not related to the device but involved elevated cardiac biomarkers. At 30 days, 8% (9/119) of patients reported non-Q wave myocardial infarctions, 1 patient reported Q wave myocardial infarction and 1 patient needed target vessel revascularisation. Stent thrombosis (definite or probable) was reported in 2% (2/120) of patients
    3. In the case series of 71 patients, 1 patient reported MACE at 30 days and unstable angina was reported in 1 patient after 7 days

Mhanna 2022, systematic review and meta-analysis of intravascular lithotripsy in calcified coronary lesions

1) N=8 studies (980 patients)
    a. 6 prospective cohort studies, 2 retrospective cohort studies
2) The clinical success was achieved in 95.4% of patients (95% CI: 92.9%–97.9%) and angiographic success was achieved in 97% of patients (95% CI: 95%–99%).
    a. clinical success which was defined as the ability of IVL to produce residual diameter stenosis < 50%) after stenting with no evidence of in-hospital major adverse cardiac events and target lesion revascularization

   b. angiographic success which was defined as success in facilitating stent delivery with RDS <50% and without serious angiographic complications
3) Coronary dissections (more than type B) were observed in 0.5% (95%CI: 0.0%–1.0%) and perforations were observed in 0.4% of the cases (95%CI: 0.0%–0.9%), and the 30-days MACE occurred in 4.9% (95%CI: 2.5%–7.3%) of the cases.
4) Conclusion: IVL seems to have excellent efficacy and safety in the management of severe CCL lesions. However, adequately powered RCTs are needed to evaluate IVL compared to other calcium/plaque modifying techniques.

Expert guidelines

ACC/AHA/SCAI 2021 guideline for coronary artery revascularization

1) In patients with fibrotic or heavily calcified lesions, plaque modification with orbital atherectomy, balloon atherotomy, laser angioplasty, or intracoronary lithotripsy may be considered to improve procedural success [2b (weak recommendation), level of evidence B-NR (moderate quality evidence from 1 or more well designed nonrandomized studies)]
2) Despite promising results from hundreds of small mechanistic studies, dozens of large, randomized trials have shown that the routine use of atheroablative devices does not improve clinical or angiographic outcomes. However, the use of atheroablative devices may enhance procedural success in specific circumstances
3) Intracoronary lithotripsy listed as a "potentially emerging modality"

Other payer policies

a. NICE 2020
   a. Evidence on the safety and efficacy of intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention 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. Aetna 2023
   a. Intravascular shockwave lithotripsy for the treatment of coronary artery plaques is experimental
c. Cigna 2023
   a. Percutaneous transluminal coronary lithotripsy is experimental

Expert input:

Dr. Abigail Khan and Dr. David Saenger are not aware of its use in Oregon and do not recommend coverage.

2023 CPT Code Review
Coronary Lithotripsy

HERC staff summary

Intravascular coronary artery lithotripsy has been studied only in cohort studies. No studies exist comparing lithotripsy to other types of coronary artery stenting procedures which report on outcomes such as avoidance of major adverse cardiac events (MACE). A recent NICE review found evidence of harms, although it is unknown how these rates of harm compare to other types of coronary artery interventions. A highly trusted evidence source (NICE) did not find sufficient evidence of effectiveness for this procedure. Private insurers are not covering this procedure currently.

HERC staff recommendations:

a. Place CPT **92972** (Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)) and HCPCS **C1761** (Catheter, transluminal intravascular lithotripsy, coronary) on line 662
b. 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
92972, C1761	Coronary intravascular lithotripsy	Insufficient evidence of effectiveness	November 2023

2023 CPT Code Review
Enhanced Liver Fibrosis (ELF) Test

Plain Language Summary:

Coverage question: Should OHP cover a certain test to check on the health of the liver?

Should OHP cover this treatment? Maybe, this is one good way to test for advanced liver disease but costs more than other tests.

Code: **81517** Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1 [TIMP-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk

Information: Liver diseases can cause liver damage, which is seen as fibrosis. This damage can result in cirrhosis of the liver. The Enhanced Liver Fibrosis (ELF) test is a blood test for fibrosis staging in chronic liver disease. Other testing options to assess for cirrhosis include fibroscan, blood tests, liver ultrasound and liver biopsy. Chronic liver disease can be caused by alcohol, obesity, or viral hepatitis. Liver biopsy is the gold standard test for liver fibrosis and cirrhosis, but it is invasive and can cause complications.

Previous HERC review
ELF was previously reviewed as part of the coverage guidance on non-invasive tests for liver fibrosis in 2016. The coverage guidance included a weak recommendation for coverage of ELF, but only if imaging tests (for example, elastography) were unavailable. The initially approved version of current guideline note 76 DIAGNOSTIC TESTING FOR LIVER FIBROSIS TO GUIDE MANAGEMENT IN CHRONIC LIVER DISEASE included coverage of ELF in that circumstance.

GN76 was addressed again in March 2019. At that time, ELF was reviewed and found to have "reasonable AUROC for distinguishing cirrhosis" but was identified as a proprietary lab test. Due to this proprietary test status, ELF was taken out of the guideline. "Given that there are a variety of good quality non-proprietary blood tests, additional expense associated with proprietary blood tests is not warranted."

Evidence
Sharma 2021, systematic review of accuracy of enhanced liver fibrosis test for diagnosing advanced liver fibrosis and cirrhosis

1) One author is an inventor of the ELF test and has conflicts of interest
2) N=36 studies (10 mixed causes of liver disease, 11 hepatitis C (HCV), 4 hepatitis B (HBV), 9 non-alcoholic fatty liver disease (NAFLD), 2 alcohol related liver disease)
    a. 31 prospective cohorts, 5 retrospective cohorts
    b. Reference standard was liver biopsy

3) HCV
    a. Advanced fibrosis: the AUROCs for detecting advanced fibrosis in HCV patients ranged from 0.773 (95% CI 0.697–0.848) to 0.98 (95% CI 0.93–1.00)
    b. Detecting cirrhosis: the sensitivity ranged from 7% to 100%. The specificity ranged from 53% to 100%
4) Hepatitis B
    a. Advanced fibrosis: the AUROCs ranged from 0.69 (95% CI 0.63–0.75) to 0.86 (95% CI 0.81–0.92)
    b. Cirrhosis: the AUROCs ranged from 0.706 0.68 (95% CI 0.61–0.75) to 0.86 (95% CI 0.81–0.92).
5) NAFLD
    a. The AUROCs for detecting advanced fibrosis in NAFLD patients ranged from 0.78 (0.70–0.89) to 0.97 (no CI reported)
    b. Only 2 studies reported the AUROCs for detecting cirrhosis in NAFLD patients which were 0.852 ± 0.040 in Guillaume et al. and 0.92 (0.88–0.97) in Staufer et al
6) Alcohol liver disease
    a. Advanced fibrosis: The AUROC was excellent ranging from 0.92 (0.89–0.96) in the Thiele et al. study and in the Madsen et al. study (0.88–0.96) to 0.944 (0.836–1.000).
    b. Two studies assessed the diagnostic accuracy of ELF at detecting cirrhosis reporting an excellent AUROC ranging from 0.93 (0.90–0.97) to 0.94 (0.91–0.97)
7) Mixed causes of liver disease
    a. Advanced fibrosis: The AUROCs reported in the included studies ranged widely from 0.63 (no CI) to 0.91 (0.88–0.95)
    b. Cirrhosis: All of the AUROCs reported were above 0.80, with the exception of one article, conducted in 280 patients with viral hepatitis, which reported an AUROC of 0.698 (no sensitivity or specificity reported)
8) In summary, the ELF test showed good diagnostic performance in detecting advanced fibrosis in patients with viral hepatitis and excellent performance in NAFLD and ALD. There is also evidence of good diagnostic performance for detecting cirrhosis in patients with viral hepatitis and excellent performance in patients with ALD. The quality of studies in HBV and ALD patients was very high, but more variable for HCV and NAFLD patients. This review suggests that the ELF test could offer an alternative to biopsy for assessing liver fibrosis in viral hepatitis, NAFLD, and ALD. However, the included studies were significantly heterogeneous, and further comparative studies of high methodological quality are desirable. The ELF test also offers other benefits such as lack of operator variability, excellent pre-analytical and analytical performance, and the very low failure rate

NICE 2016, evidence review for management of non-alcohol fatty liver disease (NAFLD)

1) Ten studies reported diagnostic test accuracy for diagnosing any fibrosis (greater than or equal to F1). Evidence was found on the following tests: enhanced liver fibrosis score (ELF) at thresholds of -0.207 and 9.28; Ferritin at thresholds ranging from 208 to 600; magnetic resonance elastography (MRE) at a threshold of 3.02; NAFLD fibrosis score at thresholds of −1.455 and 0.676; and transient elastography at thresholds ranging from 4.3 to 7.4

<u>Expert guidelines</u>

American Association for the Study of Liver Diseases 2023, practice guideline for management of nonalcoholic fatty liver disease

1) ELF listed as an option for detection of advanced fibrosis and diagnosis of cirrhosis
2) ELF ≥11.3 is associated with increased risk of hepatic decompensation among patients with cirrhosis
3) FIB-4 is the most validated biomarker for estimation of liver fibrosis on patients with NAFLD
4) Although FIB-4 is statistically inferior to other serum-based fibrosis markers such as the ELF panel, FIBROSpect II, and imaging-based elastography methods to detect advanced fibrosis, FIB-4 is still recommended as a first-line assessment for general practitioners and endocrinologists based on its simplicity and minimal, if any, added cost
5) An ELF score of ≥9.8 reliably identifies patients with NAFLD at increased risk of progression to cirrhosis and liver-related clinical events
6) Such serum-based fibrosis tests [including ELF] may be good options as secondary risk assessments when elastography is not available
7) If FIB-4 is ≥ 1.3, VCTE, MRE, or ELF may be used to exclude advanced fibrosis
8) Highly elevated liver stiffness, FIB-4, and ELF scores can predict an increased risk of hepatic decompensation and mortality.

American Association of Clinical Endocrinology and the American Association for the Study of Liver Diseases 2022 guideline on the management of NAFLD

1) Clinicians should use liver fibrosis prediction calculations to assess the risk of NAFLD with liver fibrosis. The preferred noninvasive initial test is the FIB-4. Grade B; Intermediate Strength of Evidence; Best evidence level (BEL) 2
2) Clinicians should consider persons belonging to the "high-risk" groups (as defined under R2.1.1) who have an indeterminate or high FIB-4 score for further workup with an LSM (transient elastography) or ELF test, as available. Grade B; Intermediate Strength of Evidence; BEL 2

American Association for the Study of Liver Diseases and infectious Diseases Society of America 2022 recommendations on managing hepatitis C

1) Available at https://www.hcvguidelines.org/evaluate/testing-and-linkage
    a. Accessed October 6, 2023
2) Enhanced liver fibrosis testing is not mentioned
3) Recommends FIB4, APRI blood tests and transient elastography

<u>Other payer policies</u>

1) NICE 2016 management of non-alcoholic fatty liver disease
    a. Consider using the enhanced liver fibrosis (ELF) test in people who have been diagnosed with NAFLD to test for advanced liver fibrosis.
2) Aetna 2023
    a. Aetna considers the Enhanced Liver Fibrosis (ELF) test medically necessary for the detection and prognosis of liver fibrosis in persons with chronic liver diseases. Performance of the Enhanced Liver Fibrosis (ELF) test more than twice per year is considered not medically necessary. Performance of this test within 6

months following a liver biopsy (or other test for liver fibrosis) is considered not medically necessary.

3) Regence BCBS 2023
    a. Considers Enhanced Liver Fibrosis™ (ELF) Test to be investigational
4) Anthem BCBS 2023
    a. Proprietary algorithms evaluating hepatic fibrosis, used to produce a predictive score indicating the probability of liver fibrosis, are considered **investigational and not medically necessary** in the diagnosis and monitoring of individuals with chronic liver disease, including but not limited to hepatitis C, hepatitis B, and nonalcoholic fatty liver disease (NAFLD).

Expert input

Dr. Atif Zaman, hepatologist at OHSU

ELF as a fibrosis assessment tool and an approach to its use in light of all the other non-invasive assessment tools. Since these non-invasive tools to assess hepatic fibrosis have similar performance in most types of liver disease, it should be fine to consider the ELF approach for HCV

2023 CPT Code Review
Enhanced Liver Fibrosis (ELF) Test

HERC staff summary

The ELF test is one option in detecting advanced liver disease from a variety of causes. It was previously reviewed as part of a non-invasive testing for liver fibrosis coverage guidance and found to have evidence of effectiveness and was covered from 2016 to 2019. Coverage was removed a few years later due to the test being proprietary and thus of higher cost that other available similar tests. Of note, there was no CPT category 1 code for the ELF test during this time period.

ELF is recommended as one option for evaluation of NAFLD. Private insurers vary on coverage of this test. Alternative testing (liver biopsy, transient elastography) is covered on the Prioritized List. Expert guidelines recommend the use of the ELF test if elastography is not available to identify patients at increased risk of progression to cirrhosis and liver-related clinical events. A highly respected evidence based source (NICE) recommends using ELF in the management of nonalcoholic fatty liver disease.

HERC staff recommend coverage in certain circumstances based on expert input and previous coverage guidance review. The HERC may consider continued non-coverage due to the proprietary nature of the test and lack of consistent private payer coverage.

HERC staff recommendations:

1) **Option 1:**
    1. Place CPT **81517** (Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1 [TIMP-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk) to line 198 CHRONIC HEPATITIS; VIRAL HEPATITIS
        a. Will pair with ICD-10-CM K75.81 (Nonalcoholic steatohepatitis (NASH)) and other hepatitis diagnosis codes
        b. Liver elastography (CPT 91200) is on line 198
    2. Modify GN76 as shown below

GUIDELINE NOTE 76, DIAGNOSTIC TESTING FOR LIVER FIBROSIS TO GUIDE MANAGEMENT IN CHRONIC LIVER DISEASE

Line 198

The following tests are included on this line because of their ability to effectively distinguish F4 from lower levels of fibrosis:

Non-proprietary blood tests:

- Platelet count
- Hyaluronic acid
- Age-platelet index
- AST-platelet ratio
- FIB-4
- FibroIndex
- Forns index
- GUCI
- Lok index

- Proprietary blood test:
  - Enhanced Liver Fibrosis (ELF™), for patients with indeterminate or high FIB-4 score when liver elastography is not available.

Imaging tests:
- Transient elastography (FibroScan®)
- Acoustic radiation force impulse imaging (ARFI) (Virtual Touch™ tissue quantification, ElastPQ)
- Shear wave elastography (SWE) (Aixplorer®)

The following tests are not included on this line (or any other line):
- Real time tissue elastography
- Proprietary blood tests such as:
  - ~~Enhanced Liver Fibrosis (ELF™)~~
  - Fibrometer™
  - FibroTest®
  - Hepascore®
  - FIBROSpect® II

Noninvasive tests for liver fibrosis are only indicated for the initial assessment or when monitoring progression from F3 to F4, no more than annually.

Magnetic resonance elastography is included on this line for patients when ALL of the following apply:
- In whom at least one imaging test (FibroScan, ARFI, and SWE) has resulted in indeterminant results, a second one is similarly indeterminant, contraindicated or unavailable
- The patient is suspected to have aggressive disease/advanced fibrosis (e.g. in NAFLD based on older age, diabetes, obesity, high FIB-4, or APRI)
- Cirrhosis is not identified on routine imaging (ultrasound, CT)
- A liver biopsy would otherwise be indicated, but MRE would be an appropriate alternative.

Repeat MR Elastography is not indicated.

2) **Option 2**: continue lack of coverage
   1. Place CPT **81517** (Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1 [TIMP-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk) to line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS
   2. Add an entry to GN172 as shown below

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

Line 502

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

Procedure Code	Intervention Description	Rationale	Last Review
81517	Enhanced Liver Fibrosis (ELF™)	More costly than equally effective tests	November 2023

2023 CPT Code Review
HIPEC

Plain Language Summary:

Coverage question: Should OHP cover a treatment for certain types of advanced cancer? Doctors heat up a special chemotherapy medicine and put it directly into the abdomen (peritoneum) to treat cancer that might be there. The heat and the medicine together can help fight the cancer.

Should OHP cover this treatment? Yes, the advantages of treatment are greater than the potential harms for certain advanced cancers.

Codes:
96547 Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes (List separately in addition to code for primary procedure)
96548 each additional 30 minutes

Information: Peritoneal carcinomatosis is an advanced form of cancer resulting from the spread of gastrointestinal, gynecological and other malignancies throughout the abdomen. Cytoreduction surgery is done to remove all macroscopic tumors within the abdominal cavity. At the time of cytoreduction surgery, hyperthermic intraperitoneal chemotherapy (HIPEC) can be done. HIPEC is a technique in which chemotherapy is delivered in a heated solution perfused throughout the peritoneal space. The rationale for hyperthermic delivery is that heat can increase penetration of the chemotherapy at the peritoneal surface and enhance the sensitivity of cancer cells to chemotherapy by inhibiting DNA repair.

Evidence
NICE 2021, evidence review of cytoreduction surgery (CRS) with hyperthermic intraoperative peritoneal chemotherapy (HIPEC) for peritoneal carcinomatosis

1) Peritoneal carcinomatosis from ovarian and endometrial cancers
    1. A systematic review of 1,168 patients (in 16 studies) with recurrent ovarian cancer having cytoreduction surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC) reported that overall survival ranged between 26.7 and 30 months. Median overall survival across 6 studies ranged from 25.7 to 45.7 months. A randomized controlled trial (RCT) (Spiliotis 2015) included in the systematic review reported that overall mean survival in the CRS and HIPEC group was significantly longer than for CRS and chemotherapy (26.7 months compared with 13.4 months, p=0.006). An RCT of 245 patients comparing CRS plus HIPEC (n=123) with CRS alone (n=122) for treatment of advanced ovarian cancer reported that CRS plus HIPEC resulted in longer median overall survival by 11.8 months than CRS alone (CRS plus HIPEC group 45.7 months compared with CRS alone 33.9 months). A meta-analysis of 1,608 patients from 26 studies on CRS

and HIPEC in patients with advanced epithelial ovarian cancer (n=534) and recurrent ovarian cancer (n=1,074) reported a median overall survival of 63 months in advanced cancer and 39 months in recurrent cancer. In a systematic review and meta-analysis of 13 studies of HIPEC and CRS for patients with ovarian cancer, a pooled analysis of 12 studies showed a significant improvement in overall survival for patients who had HIPEC, compared with patients who had CRS (HR 0.56, 95% CI 0.41 to 0.76, p<0.01).

2) Peritoneal carcinomatosis from gastric cancer
    1. A systematic review and meta-analysis of 620 patients (14 studies) with peritoneal carcinomatosis from gastric cancer who had CRS and HIPEC reported that the overall survival rate was higher, but not statistically significant, for the CRS and HIPEC group compared with the control group at 1-year follow up (risk ratio [RR]=0.67, 95% CI 0.52 to 0.86), 2-year follow up (RR=0.87, 95% CI 0.73 to 1.04, p=0.12) and 3-year follow-up (RR=0.99, 95% CI 0.93 to 1.06, p=0.85)
3) Peritoneal carcinomatosis from colorectal cancer
    1. A systematic review and meta-analysis of 10,036 patients (in 76 studies including 15 controlled and 61 non-controlled studies) who had treatments for peritoneal carcinomatosis from colorectal cancer reported that the mean overall survival rate for CRS plus HIPEC was 29.2 (±11.3) months. Meta-analysis of 15 controlled studies (including 3,179 patients) reported that the mean overall survival for the CRS plus HIPEC treatment group was 34.3 (±14.8) months and the traditional therapy group was 18.8 (±8.8) months. The summarized hazard ratio for overall survival was 2.67 (95% CI 2.21 to 3.23, I2=0%, p <0.00001).
4) Safety
    1. Systematic reviews and meta-analysis of HIPEC for gynecologic cancer found a perioperative mortality rate of 1-5%, for gastric cancer found perioperative mortality rate of 0-7%, and for colorectal cancer the perioperative mortality rate was 3%
    2. The systematic review of 13 studies of people with ovarian cancer reported an overall postoperative morbidity rate of 20% to 30%. The most frequent events were bone marrow depression, gastrointestinal fistulation, anemia, renal failure or acute kidney injury. Other adverse events included pleural effusion, post-operative bleeding, abdominal abscess, urinary tract infection, leucopenia, thrombocytopenia, neutropenia, lymphocyst needing drainage, infected central catheter, transient hematological toxicity, transient confusional syndrome, prolonged ileus, wound infection, abdominal collection and pancreatic leak, unilateral ureteric injury, sepsis and electrolyte imbalance. Reoperation was needed for ureteric necrosis, staple line bleeding and thoracic empyema
    3. A systematic review and meta-analysis of 620 patients (14 studies) with peritoneal carcinomatosis from gastric cancer reported a statistically significantly higher risk of developing postoperative complications in the HIPEC group compared with the control group (RR=2.15, 95% CI 1.29 to 3.58, p< 0.01) and this was consistent among RCTs (RR=2.88, 95% CI 1.04 to 7.97, p=0.04) and NRCTs (RR=1.86, 95% CI 1.04 to 3.33, p=0.04). HIPEC is related to a high risk of developing respiratory failure (RR=3.67, 95% CI

2.02 to 6.67, p< 0.001) and renal dysfunction (RR=4.46, 95% CI 1.42 to 13.99, p=0.01) and it is related to systemic drugs toxicity

4. In the systematic review and meta-analysis of 10,036 patients (in all 76 studies) with peritoneal carcinomatosis from colorectal cancer, the morbidity rate for CSR plus HIPEC was 33% (±13.4).

Expert guidelines

- **a. NCCN 2.2023 Ovarian Cancer**
  - **a.** Hyperthermic intraperitoneal chemotherapy (HIPEC) with cisplatin (100 mg/m2) can be considered at the time of interval debulking surgery (IDS) for stage III disease treated with neoadjuvant chemotherapy (NACT)
- **b. NCCN 3.2023 Colon Cancer**
  - **a.** Patients with metastatic disease deemed possible surgical candidates should be evaluated at a high-volume center for candidacy for hyperthermic intraperitoneal chemotherapy (HIPEC). These candidates are suggested to receive chemotherapy up to 6 months, preferably in the neoadjuvant setting. Additional chemotherapy may be considered for patients who are not resectable at initial diagnosis with the possibility of converting to resectable disease
  - **b.** Cytoreductive surgery (CRS) and HIPEC are associated with morbidity and mortality, and it is imperative that a capable multidisciplinary medical team perform extensive preoperative tests to deem a patient fit for this combination therapy
- **c. NCCN 2.2023 Gastric Cancer**
  - **a.** Hyperthermic intraperitoneal chemotherapy (HIPEC) or laparoscopic HIPEC may be a therapeutic alternative for carefully selected stage IV patients in the setting of ongoing clinical trials and is under further clinical investigation
- **d. NCCN 2.2023 Peritoneal mesothelioma**
  - **a.** Cytoreductive surgery (CRS) + hyperthermic intraperitoneal chemotherapy (HIPEC) is recommended for unicavitary epithelioid peritoneal mesothelioma or well-differentiated papillary mesothelial tumor
- **e. NCCN 1.2023 Small Bowel Adenocarcinoma**
  - **a.** Based on this lack of evidence, HIPEC cannot be recommended for this population
- **f. NCCN 5.2023 Rectal Cancer**
  - **a.** HIPEC is not mentioned
- **g. NCCN 1.2024 Uterine Cancer**
  - **a.** HIPEC is not mentioned

Other payer policies

a. NICE 2021

1) Evidence on the safety of cytoreduction surgery with hyperthermic intraoperative peritoneal chemotherapy for peritoneal carcinomatosis shows frequent and serious but well-recognized complications.

Evidence on its efficacy is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research

b. UHC 2023
    1) When performed in conjunction with Cytoreductive Surgery (CRS), intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) is proven and medically necessary for treating the following conditions:
        a. Ovarian cancer following neoadjuvant chemotherapy
        b. Peritoneal mesothelioma
        c. Pseudomyxoma Peritonei (PMP) resulting from a mucus-producing tumor
        d. Peritoneal Carcinomatosis resulting from the following cancers, provided there are no extra-abdominal metastases:
            a. Adenocarcinoma of the appendix or goblet cell carcinoma
            b. Colon
            c. Rectum
    2) Due to insufficient evidence of efficacy, intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) is unproven and not medically necessary for all other indications, including but not limited to, peritoneal Carcinomatosis resulting from the following cancers:
        a. Gastric
        b. Ovarian, except as noted above
c. Aetna 2023: Aetna considers the following procedures medically necessary:
    1) Cytoreductive surgery combined with hyperthermic intraperitoneal chemotherapy (HIPEC) for the treatment of pseudomyxoma peritonei (including disseminated peritoneal adenomucinosis (DPAM), characterized by histologically benign peritoneal tumors that are frequently associated with an appendiceal mucinous adenoma, as well as peritoneal mucinous carcinomatosis, which are defined as disseminated mucin-producing adenocarcinomas);
    2) Cytoreductive surgery combined with HIPEC for the treatment of peritoneal mesothelioma;
    3) Cytoreductive surgery combined with HIPEC for the treatment of goblet cell carcinoid tumor;
    4) HIPEC for use with cisplatin at the time of interval debulking surgery for FIGO stage III ovarian cancer;
    5) Regional hyperthermic melphalan perfusion in members with stage II, IIIA, and stage III in-transit extremity melanoma;
    6) Sequential radiation and local/regional external hyperthermia only for the treatment of primary or metastatic cutaneous or subcutaneous superficial malignancies (e.g., superficial recurrent melanoma, chest wall recurrence of breast cancers, and cervical lymph node metastases from head and neck cancer).
d. PacificSource 2023

2023 CPT Code Review
HIPEC

1) PacificSource considers Hyperthermic Intraperitoneal Chemotherapy (HIPEC) medically necessary when used at time of or after cytoreductive (debulking) surgery for any of the following:
    a. Malignant peritoneal mesothelioma with metastasis limited to the abdominal cavity
    b. Peritoneal carcinomatosis from gastric cancer (e.g., Appendix, Colon, Rectal, Pancreatic and Gastric Cancers) without extra-abdominal metastases
    c. Pseudomyxoma Peritonei (PMP)
    d. Stage II or Stage III epithelial ovarian cancer

2023 CPT Code Review
HIPEC

HERC staff summary

One highly trusted evidence source (NICE) found that the risks of HIPEC outweighed the benefits for all cancers. The NICE evidence review found the most evidence supported the use of HIPEC for ovarian cancer, with consistent improvement in overall survival, and found some evidence for use in carcinomatosis due to colon cancer. NICE found no improvement in gastric cancer outcomes with HIPEC. NCCN recommends HIPEC only as part of their peritoneal mesothelioma treatment algorithm. NCCN states that HIPEC for ovarian cancer "can be considered at the time of interval debulking surgery (IDS) for stage III disease treated with neoadjuvant chemotherapy (NACT)," can be considered in very limited circumstances for colon cancer, and in carefully selected stage IV gastric cancer patients as a part of a trial.

HERC staff recommendations:

1. Add HIPEC to lines 157 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS, 238 CANCER OF OVARY, and 261 CANCER OF RETROPERITONEUM, PERITONEUM, OMENTUM AND MESENTERY
    a. **96547** Intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) procedure, including separate incision(s) and closure, when performed; first 60 minutes (List separately in addition to code for primary procedure)
    b. **96548** each additional 30 minutes
2. Adopt a new guideline for HIPEC as shown below

GUIDELINE NOTE XXX HYPERTHERMIC INTRAPERITONEAL CHEMOTHERAPY (HIPEC)

Lines 157, 238, 261

Hyperthermic intraperitoneal chemotherapy (HIPEC) is included on these lines only when done as part of chemoreductive surgery and only for

1) Malignant peritoneal mesothelioma with metastasis limited to the abdominal cavity
2) Peritoneal carcinomatosis due to stage III ovarian cancer previously treated with neoadjuvant chemotherapy when HIPEC is done with cisplatin
3) Colon cancer with metastatic disease limited to the abdominal cavity considered to be surgical candidates after evaluation at a high-volume center

2023 CPT Code Review
Low Level Laser Therapy

Codes: **97037** Application of a modality to 1 or more areas; low-level laser therapy (ie, nonthermal and non-ablative) for post-operative pain reduction

Similar code: **S8948** (Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes) is on line 662/GN173

Information: Low level laser therapy (LLLT) is the application of low-level (low-power) lasers or light-emitting diodes (LEDs) to the surface of the body. LLLT is used for a variety of applications, including low back pain, rheumatoid arthritis, neck pain, various tendinopathies, and other chronic pain conditions. LLLT uses narrow-band light source which has an anti-inflammatory effect on the mucous membranes.

Oral mucositis (OM) is one of the most frequent complications arising from the cytotoxic effects of therapies for malignancies. OM results in mouth ulceration, pain, infection, dysphagia, and reduced quality of life. OM can cause treatment interruptions, narcotic analgesia, and enteral or parenteral nutrition with associated additional costs.

Recent HERC reviews:
LLLT was reviewed at several meetings in 2021 and 2022. An AHRQ 2020 systematic review, a Washington HTA 2018 report, a 2010 Cochrane review, and 2 other systematic reviews were included in the evidence considered. The conclusion of that review was "Low level laser therapy as low to very low evidence of efficacy, and most studies do not show clinically significant benefit."

Evidence
Peng 2020, Systematic review and meta-analysis of low-level laser therapy in the prevention and treatment of oral mucositis

i. N=29 studies
    1. Chemotherapy or radiotherapy or hematopoietic stem cell transplant or a combination of these therapies
    2. 26 studies on prophylactic LLLT, 6 studies on therapeutic LLLT
ii. Prophylactic LLLT reduced the overall risk of severe OM (relative risk [RR] = 0.40; 95% confidence interval [CI]: 0.28-0.57; P < .01). Therapeutic LLLT substantially reduced the duration of severe OM (P < .01). LLLT also reduced the overall mean grade of OM, overall incidence of severe pain, mean score of pain, and incidence of severe OM, at the most anticipated time.
iii. Our findings indicate that prophylactic LLLT is effective in preventing OM in patients receiving chemotherapy or radiotherapy and that therapeutic LLLT is effective in reducing severe OM duration. On the basis of the results of our risk of bias assessment and heterogeneity analysis, we believe that more well-designed multicenter RCTs on this subject are needed

Other payer policies

1. Aetna 2023 considers low level laser therapy to be experimental for all indications other than the prevention of oral mucositis in persons undergoing cancer treatment
2. Regence BCBS 2023 considers low level laser therapy to be experimental
3. Cigna 2023 considers low level laser therapy to be experimental for all indications other than the prevention of oral mucositis in persons undergoing cancer treatment
4. Providence Health Plan 2023
    a. Low-level laser therapy for the prevention of oral mucositis may be considered medically necessary for members undergoing cancer treatment associated with increased risk or oral mucositis, including chemotherapy, radiotherapy, and/or hematopoietic stem cell transplantation.
    b. Low-level laser therapy (i.e., cold laser therapy) and high-power laser therapy (i.e., class IV laser) are considered not medically necessary for all other indications

HERC staff summary

A recent HERC review in 2020 found no evidence of effectiveness for low level laser therapy (LLLT). A recent systematic review and meta-analysis found evidence that LLLT is effective at preventing and treating mucositis from cancer treatments, with the majority of the evidence on prophylaxis before mucositis occurs. Most major insurers are now covering LITT for this indication, but not for other indications.

The new CPT code is specific to use of LLLT for post-operative pain. This indication is not supported by evidence. However, the existing HCPCS code for LLLT is used for prophylaxis or treatment of oral mucositis. HERC staff recommending adding the new code to line 662/GN173 and adding coverage for the existing HCPCS code with a new guideline.

HERC staff recommendations:

1. Place CPT 97037 (Application of a modality to 1 or more areas; low-level laser therapy (ie, nonthermal and non-ablative) for post-operative pain reduction) on line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
2. Add an entry to GN173 for CPT 97037
3. Remove HCPCS S8948 (Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes) from line 662 and place on all lines with chemotherapy, radiation therapy or stem cell transplant
4. Delete the entry in GN173 regarding HCPCS S8948
5. Adopt a new guideline as shown below regarding LLLT

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

Line 662

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

Procedure Code	Intervention Description	Rationale	Last Review
~~S8948~~	~~Low level laser therapy and all similar therapies~~	~~Insufficient evidence of effectiveness~~	~~August 2020~~
97037	Application of a modality to 1 or more areas; low-level laser therapy (ie, nonthermal and non-ablative) for post-operative pain reduction	Insufficient evidence of effectiveness	November 2023

GUIDELINE NOTE XXX LOW LEVEL LASER THERAPY

All lines with chemotherapy/radiation therapy/stem cell transplant

Low level laser therapy (HCPCS S8948) is included on these lines only for prevention of oral mucositis for members undergoing cancer treatment associated with increased risk of oral mucositis, including chemotherapy, radiotherapy, and/or hematopoietic stem cell transplantation.

2023 CPT Code Review
Pelvic Examination Practice Expense

Code: **99459** Pelvic examination (List separately in addition to code for primary procedure)

Information: Pelvic exams are done for a variety of reasons, including screening for cervical cancer, testing for STIs, evaluating pelvic pain, and evaluation of abnormal uterine bleeding. The physician portion of the exam is included in the office visit code, as well as any procedures such as collection of a pap smear. The new pelvic examination code was requested by ACOG to capture practice expenses, particularly staff time for chaperoning the exam.

From ACOG:

> At the September 2022 American Medical Association (AMA) CPT® Editorial Panel Meeting, the Panel approved a new code to capture the practice expense (PE) of providing a clinical staff chaperone during a pelvic examination. The new CPT code 9X036 is a PE-only code, and therefore has no physician work (i.e., work relative value unit (RVU)) associated with the service. As such, the code is valued at 0.68 PE RVUs which captures four minutes of clinical staff time when chaperoning a pelvic exam. The code may be reported with evaluation and management (E/M) services in the non-facility/office setting. Note that the medical documentation must support that a pelvic exam was performed. This code should not simply be added to every female medical exam without the proper documentation.

There was no discussion of this code found in the September 2022 AMA CPT meeting minutes.

Other practice expense RVUs include expenses for building space, equipment and supplies. PE values are part of a complicated formula used to calculate physician payment, which also include values for physician work, geographic pricing index, and practice liability insurance.

From the AMA, available at https://www.ama-assn.org/system/files/practice-expense-component.pdf:

> Beginning in January 1999, Medicare began a transition to resource-based practice expense (PE) relative values, which establish PE payment for each Current Procedural Terminology (CPT®) code that differs based on the site of service. Procedures that can be performed in a physician's office, as well as in a hospital have two PE relative values: facility and nonfacility PE relative values. The nonfacility setting includes physician offices, freestanding imaging centers, and independent pathology labs. Facility settings include all other settings, such as hospitals, ambulatory surgery centers, skilled nursing facilities, and partial hospitals. In 2002, PEs were fully transitioned and the practice-expense component of the resource-based relative value scale (RBRVS) is resource-based. In 2007, the Centers for Medicare & Medicaid Services (CMS) implemented a new PE methodology.
>
> Practice expenses make up 52.2% of family physician revenues and 38.8% of obstetrician/gynecologist revenues.

HERC staff summary

Practice expense payments are part of an extraordinarily complicated calculation designed by CMS that takes into account factors such as a percent of useful life of the medical equipment, number of physician owners and employees in a practice, supply pool costs, and administrative labor costs, then multiples these factors by other weighted percentages for physician specialty, geographic location, place of

service, and supply use percentage from an AMA survey of practice overhead, then divides this by a percentage of direct work, calculates in a factor for indirect work, and then result is multiplied by a budget neutrality adjustment fraction. The result of this extremely complicated equation is then put into another extremely complicated equation that includes physician RVUs and the output is a physician payment amount. Taken all of this into account, HERC staff are unsure how this code will be operationalize and whether additional reimbursement is appropriate for this service given the nature of the RVU calculation system.

<u>HERC staff recommendation:</u>

a. Discuss whether to recommend placement on the CPT **99459** (Pelvic examination) on the Diagnostic Procedures file or the Excluded File.

2023 CPT Code Review
Limited PLA Code Review

Issue: 62 new proprietary lab analysis (PLA) codes were published as part of the 2024 new code set. In depth review of each these codes is not feasible with limited HERC staff resources. HERC staff have done a limited review of certain codes of interest. This review focused on tests for obstetrical conditions (of high interest to the OHP population) and tests/treatments substantially similar to tests/treatments previously reviewed by the HERC.

Oncology biomarkers were outside the scope of this review, due to the complex nature of the individual genes involved. Oncology next generation sequencing test PLA codes are included in a separate GAP issue summary.

NOTE: most PLA codes have never been reviewed by the HERC. When a similar PLA code was identified to one in the 2024 set, HERC staff have included that code(s) in this review.

1) **0377U** lipoprotein profile
    a. Similar codes: CPT 83695-83704 (Lipoprotein testing) are on line 662
    b. HERC staff recommendation:
        i. Place **0377U** (Cardiovascular disease, quantification of advanced serum or plasma lipoprotein profile, by nuclear magnetic resonance (NMR) spectrometry with report of a lipoprotein profile (including 23 variables)) on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
        ii. Modify the 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
83700-83704, 0377U	Lipoprotein, blood	Insufficient evidence of effectiveness	October 2006

2) **0380U** Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis, 20 gene variants and CYP2D6 deletion or duplication analysis with reported genotype and phenotype
    a. Similar code CPT 81226 CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *9, *10, *17, *19, *29, *35, *41, *1XN, *2XN, *4XN) is on the DIAGNOSTIC PROCEDURES file
    b. The current non-prenatal genetic testing guideline lists the following criteria for the above tests:

i. 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).

c. HERC staff recommendations:
   i. Place **0308U** (Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis, 20 gene variants and CYP2D6 deletion or duplication analysis with reported genotype and phenotype) on the DIAGNOSTIC PROCEDURES file
   ii. Modify the entry in DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE to read as below

CPT 81225-81227, 81230-81231**,** 81418, 0308U (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).

3) **0390U, 0243U** Maternal serum biomarker for prediction of risk for preeclampsia
   a. Information: preeclampsia is a serious complication of pregnancy and can cause maternal and perinatal morbidity and mortality. Standard screening for preeclampsia is monitoring blood pressure, urinalyses, and blood tests. Maternal serum biomarker testing is proposed as an adjunct to standard screening to identify women at risk of preeclampsia
   b. Codes
      i. Older code
         1. 0243U Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia
            a. PGIF Preeclampsia Screen
      ii. 2024 code
         1. 0390U Obstetrics (preeclampsia), kinase insert domain receptor (KDR), Endoglin (ENG), and retinol-binding protein 4 (RBP4), by immunoassay, serum, algorithm reported as a risk score
            a. PEPredictDx
   c. Expert guidelines
      i. **ACOG 2020**, practice bulletin on gestational hypertension and preeclampsia
         1. Several studies have evaluated the role of biochemical markers or a combination of biochemical and biophysical markers in the prediction of preeclampsia in the first and second trimesters of pregnancy (79). Regardless of the parameters used, screening for preeclampsia in low-risk women is associated with very low positive predictive values ranging from 8% to 33%

2. However, no single test reliably predicts preeclampsia and further prospective investigation is required to demonstrate clinical utility
3. Thus, biomarkers and ultrasonography cannot accurately predict preeclampsia and should remain investigational.

d. Other payer polcies:
   i. Premara BCBS 2023
      1. The use of maternal serum biomarker tests with or without additional algorithmic analysis for prediction of preeclampsia is considered investigational.
   ii. Aetna 2023 considers PEPredictDx to be experimental
e. HERC staff summary: maternal serum biomarkers for preeclampsia risk are not recommended for use by ACOG
f. HERC staff recommendation
   i. Place **0390U, 0243U** on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
   ii. 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
0390U, 0243U	Maternal serum biomarker tests with or without additional algorithmic analysis for prediction of preeclampsia	Insufficient evidence of effectiveness	November 2023

4) **0392U, 0411U, 0419U** Drug metabolism testing for psychiatric conditions
   a. Codes
      i. 0392U Drug metabolism (depression, anxiety, attention deficit hyperactivity disorder [ADHD]), gene-drug interactions, variant analysis of 16 genes, including deletion/duplication analysis of CYP2D6, reported as impact of gene-drug interaction for each drug
      ii. 0411U Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6
      iii. 0419U Neuropsychiatry (eg, depression, anxiety), genomic sequence analysis panel, variant analysis of 13 genes, saliva or buccal swab, report of each gene phenotype
   b. Current Prioritized List status/older codes

i. 0173U Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes
ii. 0175U Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes
iii. 0345U Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6
iv. General gene testing for cytochrome P450 testing is covered, with an entry in the non-prenatal genetic testing guideline stating that such testing cannot be for psychiatric medications when not required in the FDA labeling

DIAGNOSTIC GUIDELINE D21, PHARMACOGENETICS TESTING FOR PSYCHIATRIC MEDICATION MANAGEMENT
Pharmacogenetics testing for management of psychiatric medications is not a covered service.

c. HERC staff recommendation
   i. Place **0173U, 0175U, 0345U, 0392U, 0411U, and 0419U** on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
   ii. 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
0173U, 0175U, 0345U, 0392U, 0411U, 0419U	Pharmacogenetics testing for management of psychiatric medications	Insufficient evidence of effectiveness	November 2023

5) **0396U** Pre-implantation genetic testing
   a. Infertility and IVF is an excluded service
   b. Older similar PLA codes
      i. 0253U Reproductive medicine (endometrial receptivity analysis), RNA gene expression profile, 238 genes by next-generation sequencing, endometrial tissue, predictive algorithm reported as endometrial window of implantation (eg, pre-receptive, receptive, post-receptive)
      ii. 0254U Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for

aneuploidy, and a mitochondrial DNA score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploidy, per embryo tested

c. HERC staff recommendations:
    i. Place **0396U** (Obstetrics (pre-implantation genetic testing), evaluation of 300000 DNA single-nucleotide polymorphisms (SNPs) by microarray, embryonic tissue, algorithm reported as a probability for single-gene germline conditions) on the Excluded file
    ii. Place **0253U, 0254U** on the Excluded file

6) **0408U** Omnia COVID test
    a. All other COVID tests are considered diagnostic
    b. 0408U codes for the Qorvo Biotechnologies Omnia COVID antigen test, which tests for COVID antigen directly from a nasal swab without the use of transport media
    c. The Omnia test received an EUA from the FDA in July 2022
    d. HERC staff recommendation:
        i. Place 0408U (Infectious agent antigen detection by bulk acoustic wave biosensor immunoassay, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19])) on the Diagnostic Procedures file

Breast Reduction for Macromastia

Plain Language Summary:

Coverage question: Should OHP cover surgery to reduce the size of breasts when they cause back and/or neck pain?

Should OHP cover this treatment? Yes, when there are no other reasons for the neck and back pain, and in situations where the surgery seems likely to help with the neck and back pain this surgery should be covered.

Coverage Question: Should coverage be added for breast reduction surgery for macromastia?

Question source: OHP Ombuds office

Background: The ombuds office has had multiple cases in which women were seeking breast reduction for treatment of back or neck pain or other painful conditions related to large breasts.

Currently, macromastia is on an unfunded line on the Prioritized List, Line 653 MACROMASTIA/BREAST REDUCTION. There is a guideline on the Prioritized List that prohibits coverage for breast reduction (Guideline Note 166). Breast reduction is covered on the breast cancer line for symmetry of the reconstructed breast and natural breast; this coverage is mandated by federal rule. Breast reduction is also covered for gender affirmation.

Macromastia is defined as large breasts, generally considered larger than a D cup although various other definitions may be used. Macromastia can cause various physical symptoms, including headache, neck pain, back pain, and shoulder pain. Breast reduction is used to reduce the size of the breasts and is one of the most commonly performed cosmetic surgeries in the US.

This topic was discussed at the March 2023 VBBS and HERC meetings. The VBBS requested that staff obtain expert input on the evidence regarding effectiveness of this procedure and bring back for further consideration.

The topic was again discussed at the August 2023 VBBS and HERC meetings. The VBBS agreed that coverage should be added as a two step process: 1) change the breast reduction guideline to allow coverage as a co-morbid condition to neck and back pain and to include adolescents in this guideline based on wording from other state Medicaid program coverage; then 2) reprioritize the macromastia line as part of the 2026 biennial review. The HERC requested consideration of wording regarding the expected amount of tissue to be removed to be included in the guideline. HERC members were also interested in having OMT and acupuncture included as conservative therapy options.

Macromastia was again discussed at the September 2023 VBBS and HERC meetings. At the September meeting, both VBBS and HERC agreed that macromastia should be covered for 1) shoulder pain, 2) back and neck pain, and 3) intertrigo when guideline criteria are met. To make this coverage clear, VBBS

members directed staff to draft a proposal to add all of the diagnosis and procedure codes from the current macromastia line to the covered back pain, shoulder issue, and inflammatory skin disease lines, effective 1/1/24. During the 2026 Biennial Review, the current macromastia line will be reprioritized to have symptomatic macromastia in the funded region and asymptomatic macromastia added to the musculoskeletal conditions with no treatment necessary line, with appropriate modifications to the macromastia guideline, and undo the duplicate coding on the back, shoulder, and skin disease lines.

Current Prioritized List/Coverage status:

CPT 19318 (Reduction mammaplasty) is on lines 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER, 312 GENDER DYSPHORIA/TRANSEXUALISM, and 561 MACROMASTIA.

ICD-10 N62 (Hypertrophy of breast) is on lines 561 MACROMASTIA and 642 GYNECOMASTIA

Line:	**561**
Condition:	MACROMASTIA (See Guideline Notes 196 and 166)
Treatment:	BREAST REDUCTION
ICD-10:	N62
CPT:	19318,98966-98972,99051,99060,99070,99078,99184,99202-99239,99281-99285,99291-99404,99411-99449,99451,99452,99468-99472,99475-99480,99487-99491,99495-99498,99605-99607
HCPCS:	G0068,G0071,G0088-G0090,G0248-G0250,G0406-G0408,G0425-G0427,G0463,G0466,G0467,G0490,G0508-G0511,G2012,G2211,G2212,G2214,G2251,G2252

GUIDELINE NOTE 166, BREAST REDUCTION SURGERY FOR MACROMASTIA

Lines 402,561

Breast reduction surgery for macromastia is not covered as a treatment for neck or back pain resulting from the macromastia due to lack of high quality evidence of effectiveness.

Breast Reduction for Macromastia

HERC staff summary:

VBBS and HERC have directed staff to design a proposal to add the macromastia diagnoses and procedures to the covered back, shoulder, and inflammatory skin disease lines with a new guideline modified based on the discussion at the September, 2023 meetings.

On review, line 561 contains one unique ICD-10-CM code (N62 Hypertrophy of breast) and one CPT code specific to breast reduction (19318 Breast reduction). The other CPT and HCPCS codes on line 561 are generic office and hospital codes that already appear on the back, shoulder and inflammatory skin disease lines.

Intertrigo is coded with ICD-10-CM L30.4 (Erythema intertrigo) which is on line 504 ERYTHEMATOUS CONDITIONS.

HERC staff recommendations (effective 1/1/2024):

1) Add ICD-10-CM N62 (Hypertrophy of breast) and CPT 19318 (Breast reduction) to the following lines:
    a. 402 CONDITIONS OF THE BACK AND SPINE
    b. 417 DISORDERS OF SHOULDER, INCLUDING SPRAINS/STRAINS GRADE 4 THROUGH 6
    c. 426 SEVERE INFLAMMATORY SKIN DISEASE
2) Adopt a new guideline for breast reduction for macromastia as shown below
3) Add ICD-10-CM L30.4 (Erythema intertrigo) to line 426 SEVERE INFLAMMATORY SKIN DISEASE

GUIDELINE NOTE 166, BREAST REDUCTION SURGERY FOR SYMPTOMATIC MACROMASTIA

Lines 402,417,426,561

~~Breast reduction surgery for macromastia is not covered as a treatment for neck or back pain resulting from the macromastia due to lack of high quality evidence of effectiveness.~~

Breast reduction surgery is included on these lines 402, 417 or 426 only when ALL of the following conditions are met:

1) The patient is aged 15 or older; AND
2) The patient has a diagnosis of macromastia (size D or higher); AND
3) At least one of the following criteria (a or b) have been met:
    a. Back, neck or shoulder pain
        i. Must be documented to have adverse effects on activities of daily living
        ii. Must be unresponsive to conservative treatments for three months within a year prior. Conservative treatment must include at least three months of
            1. a documented trial of analgesics, AND
            2. physical therapy or chiropractic/osteopathic manipulation treatment or acupuncture, AND
            3. use of support wear for the breast; OR
    b. Persistent severe intertrigo in the inframammary fold unresponsive to documented prescribed medication for at least three months within a year prior; AND
4) The treating surgeon must document that breast reduction has a high likelihood of improving the symptoms that limit activities of daily living caused by the macromastia; AND

Breast Reduction for Macromastia

5) The expected bilateral reduction volume must be greater than 300 grams (1 cup size) per breast; AND
6) Women aged 40 and older are required to have a negative screening mammogram within two years of the planned reduction mammoplasty; AND
7) Member should be a non-smoker or should not have smoked within the 6 weeks prior to surgery as documented by the surgeon.

Additional criteria for patients aged 15-17 years:

1) The patient must have completed puberty (Tanner stage V)
2) The patient must have a one year history of growth stabilization evidenced by a minimum of four visits with documented heights or puberty completion as shown on wrist radiograph read by a radiologist

Otherwise, breast reduction surgery is included on line 561.

Gender Affirming Treatment Standard of Care

Plain Language Summary:

Coverage question: Should OHP pick a "standard of care" for gender affirming treatments?

Should OHP cover this treatment? Yes, OHP should use the World Professional Association for Transgender Health (WPATH) Standards of Care 8.0.

Coverage Question: Should guideline note 127 be modified to reference a specific standard of care for gender affirming treatments?

Question source: Public comment from the August 17, 2023 HERC and VBBS meetings

Previous HERC reviews:

In 2015, HERC approved coverage for puberty-suppressing medications for gender-questioning youth. In 2016, based on a HERC decision, the Oregon Health Plan (OHP) began covering a set of services based on standards of care developed by the World Professional Association of Transgender Health (WPATH; Version 7.0). These standards included a variety of chest and genital surgeries as well as medications.

In late 2022, WPATH published Version 8.0 of its standards of care, which broadened the scope of services and included changes to the assessments required in order to receive certain services. In early 2023, HERC staff was working on an updated evidence review and potential recommended changes to the services covered on OHP and had planned to bring this to the August 17, 2023 meetings of the Value-based Benefits Subcommittee (VbBS) and the Health Evidence Review Commission (HERC), knowing that the discussion may require multiple meetings.

In June of 2023, before this work was completed, the legislature passed HB 2002, which required coverage of gender-affirming treatments and prohibited denials of gender-affirming treatments when prescribed in alignment with accepted standards of care. The bill takes effect January 1, 2024.

During its August 2023, meeting, HERC revised its guideline note 127 to reference HB 2002 and added codes to Line 312 of the Prioritized List based on the services listed in WPATH 8.0. At the same August meeting, several individuals (including patients and a health plan representative) offered written and verbal comment requesting that HERC reference the WPATH 8.0 standards of care as the accepted standard of care for OHP. Staff followed up with legislative research and legal consultation and concluded that reference to WPATH 8.0 is appropriate in order to implement HB 2002.

Professional guidelines:

World Professional Association for Transgender Health. (2022). Standards of Care version 8. Retrieved from https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644

Gender Affirming Treatment Standard of Care

Pending Prioritized List/Coverage status (planned for implementation 1/1/2024):

Line:	312
Condition:	GENDER DYSPHORIA/TRANSEXUALISM (See Guideline Notes 127 and 196)
Treatment:	MEDICAL AND SURGICAL TREATMENT/PSYCHOTHERAPY

GUIDELINE NOTE 127 GENDER AFFIRMING TREATMENT [as it will appear on the 1/1/2024 Prioritized List unless revised]

Line 312

Gender-affirming treatments are included on this line according to the provisions of House Bill 2002 (2023), whether or not the code for the service appears on the line. These services are included for gender affirming treatment or for any condition represented on this line. To simplify administration, the line includes a variety of procedures that may be considered medically necessary and prescribed in accordance with accepted standards of care.

Gender affirming treatments not on this line must also be covered in accordance with the provisions of the bill, which specify criteria for medical necessity, prohibit denying or limiting services considered by plans to be 'cosmetic' and require that any denial or limit be reviewed and upheld by a provider with experience prescribing or delivering gender affirming treatment.

HERC staff recommendation:

1) Revise Guideline note 127 as shown below.

GUIDELINE NOTE 127 GENDER AFFIRMING TREATMENT

Line 312

Gender-affirming treatments are included on this line according to the provisions of House Bill 2002 (2023), when provided according to Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, published by the World Professional Association of Transgender Health (WPATH), whether or not the code for the service appears on the line. These services are included for gender affirming treatment or for any condition represented on this line. To simplify administration, the line includes a variety of procedures that may be considered medically necessary and prescribed in accordance with the WPATH 8.0 standards of care.

Gender affirming treatments billed using CPT or HCPCS codes not on this line must also be covered in accordance with the provisions of the bill.

In addition, the bill prohibits denial or limitation of services determined to be medically necessary by the provider who prescribed the treatment, ~~criteria for medical necessity,~~ prohibits denying or limiting services considered by plans to be 'cosmetic' and requires that any denial or limit be reviewed and upheld by a provider with experience prescribing or delivering gender affirming treatment.

Tobacco Cessation Requirements in Prioritized List Guidelines

Plain Language Summary:

Coverage question: Should OHP members have to stop smoking or using nicotine before they can have certain types of surgery?

Should OHP cover this treatment? Yes, with some changes for spinal fusion and lung surgery for COPD. No, for surgery for erectile dysfunction.

Coverage Question: Should any of the tobacco cessation requirements in Prioritized List guidelines be modified?

Question source: VBBS/HERC

Background: During 2023, the guideline on smoking cessation and elective surgery was extensively edited and became a Statement of Intent. Tobacco cessation should be encouraged before any elective surgery, but it is no longer required. This change was made due to unintended harms of the previous policy, preventing OHP patients from getting specialist consultations or needed treatments.

VBBS and HERC members requested that HERC staff examine the remaining guidelines that have some type of requirement for tobacco cessation. Specifically, HERC staff were directed to determine if tobacco smoking should be the focus of the cessation or whether nicotine cessation is required (which would include nicotine patches). Members noted that the current wording in various guidelines was quite different, and directed staff to see if any standardization of language should be done. If not, staff were directed to review evidence that a particular procedure, such as spinal fusion, had significantly poorer outcomes with smoking and/or using nicotine.

Previous HSC/HERC reviews:

Tobacco cessation for spinal fusion has been discussed multiple times beginning in 2012, when a guideline was added to the prioritized List restricting spinal fusion to non-smokers due to the evidence of non-fusion in smokers. Initially, the guideline simply read that spinal fusion was limited to patients who were non-smoking 6 months prior to the procedure (no mention of nicotine replacement use or objective testing). Objective testing requirements were added later.

The non-smoking requirement was added to the lung volume reduction surgery guideline in 2015 after an evidence review.

During a larger discussion of smoking and elective surgery in November 2015, VBBS members expressed a desire to have a guideline not allowing smoking prior to erectile dysfunction surgery due to member feeling that this surgery was highly affected by smoking. No evidence was reviewed at that time. In

Tobacco Cessation Requirements in Prioritized List Guidelines

October 2016, a new guideline regarding smoking and erectile surgery was added. The rationale was "based on the November VBBS discussion" with no evidence review.

Current Prioritized List/Coverage status:

STATEMENT OF INTENT 8: SMOKING CESSATION AND ELECTIVE SURGICAL PROCEDURES

Tobacco smoking has been shown to increase the risk of surgical complications. It is the intent of the Commission that current tobacco smokers should be given access to appropriate smoking cessation therapy prior to elective surgical procedures. Pharmacotherapy (including varenicline, bupropion and all five FDA-approved forms of nicotine-replacement therapy) and behavioral counseling are included on Line 5 TOBACCO DEPENDENCE.

GUIDELINE NOTE 8, BARIATRIC SURGERY

Line 320

Bariatric/metabolic surgery (limited to Roux-en-Y gastric bypass, sleeve gastrectomy, biliopancreatic duodenal switch, one anastomosis gastric bypass, single anastomosis duodenal-ileal bypass with gastrectomy) is included on Line 320 with specific criteria for adults and adolescents:

A) For adults aged $\geq$ 18 when ALL of the following criteria are met:
   1) The patient has obesity with a:
      a) BMI $\geq$ 35 kg/m^2; OR
      b) BMI $\geq$ 30-34.9 kg/m^2 with Type 2 Diabetes Mellitus which has not met clinical glycemia targets as defined by HbA1c of 8.0% or greater, despite trials of two diabetes medications
   2) Participate in an evaluation by a multidisciplinary team in an MBSAQIP-accredited specialty center[1]:
      a) Psychosocial (conducted by a licensed mental health professional)
      b) Medical (conducted by a primary care clinician/member of the multidisciplinary team to optimize control of comorbid conditions)
      c) Surgical (conducted by a bariatric surgeon)
      d) Nutritional (conducted by a licensed dietician)
   3) Free from active substance use disorder
   4) Free from active use of combustible cigarettes
   5) Not currently pregnant and documented counseling regarding the need for use of effective contraception for at least 18 months postoperatively, where indicated
   6) Agree to adhere to post-surgical evaluation and post-operative care recommendations, some of which may require lifelong adherence

B) For adolescents aged 13 to 17 years old when ALL of the following criteria are met:
   1) The patient has obesity with a:
      a) BMI $\geq$ 35 kg/m^2 or 120% of the 95th percentile for age and sex AND a clinically significant comorbid condition; OR
      b) BMI $\geq$ 40 kg/m^2 or 140% of the 95th percentile for age and sex
   2) Participate in an evaluation by a multidisciplinary team in an MBSAQIP-accredited specialty center with Adolescent accreditation:
      a) Psychosocial (conducted by a licensed mental health professional)

b) Medical (conducted by a primary care clinician/member of the multidisciplinary team to optimize control of comorbid conditions)
c) Surgical (conducted by a bariatric surgeon)
d) Nutritional (conducted by a licensed dietician)

3) Agree to adhere to post-surgical evaluation and post-operative care recommendations, some of which may require lifelong adherence
4) Free from active substance use disorder
5) Free from active use of combustible cigarettes
6) Not currently pregnant and documented counseling regarding the need for use of effective contraception for at least 18 months postoperatively, where indicated

Repeat bariatric surgery is included when it is a conversion from a less intensive (such as gastric band or sleeve gastrectomy) to a more intensive surgery (e.g. Roux-en-Y). Repair of surgical complications (excluding failure to lose sufficient weight) are also included on this and other lines. Reversal of surgical procedures and devices is included on this line when benefits of reversal outweigh harms.

CPT 43999 (Unlisted procedure, stomach) is only included on this line when used for single anastomosis duodenal-ileal bypass with sleeve (SADI-S). It is not included on this line for gastric balloons.

[1] All surgical services must be provided by a program with current accreditation (as a comprehensive center or low acuity center) by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP).

GUIDELINE NOTE 42, SOLID ORGAN TRANSPLANTS [excerpt]

Lines 83,99,162,239-241,250,263,264,307,310,563

Solid organ transplants are included on these lines only when BOTH the general criteria AND the organ specific criteria below are met:

GENERAL TRANSPLANT CRITERIA

A) The patient must have irreversible end-stage organ disease or failure and must have medical therapy optimized; AND

B) The patient is a suitable surgical candidate for transplant surgery, included by ALL of the following:

1) No significant uncontrolled co-morbidities such as (not an all-inclusive list):
a. End-stage cardiac, renal, hepatic or other organ dysfunction unrelated to the primary indication for transplant
b. Uncontrolled HIV infection
c. Multiple organ compromise secondary to infection, malignancy, or condition with no known cure
d. Ongoing or recurrent active infections that are not effectively treated
e. Psychiatric instability severe enough to jeopardize adherence to medical regimen
f. Active alcohol or illicit drug dependency; AND
2) No tobacco smoking as determined by the transplant program unless the transplant is done on an emergent basis (other than for corneal transplants); AND

3) Demonstrated compliance with medical treatments and ability to understand and comply with the post-transplant
immunosuppressive regimen

GUIDELINE NOTE 100, SMOKING AND SPINAL FUSION

Lines 47,150,200,254,346,361,401,478,530,559

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

GUIDELINE NOTE 112, LUNG VOLUME REDUCTION SURGERY

Line 283

Lung volume reduction surgery (LVRS, CPT 32491, 32672) is included on Line 283 only for treatment of patients with radiological evidence of severe bilateral upper lobe predominant emphysema (ICD-10-CM J43.9) and all of the following:

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

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

Tobacco Cessation Requirements in Prioritized List Guidelines

GUIDELINE NOTE 159, SMOKING AND SURGICAL TREATMENT OF ERECTILE DYSFUNCTION

Line 523

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

GUIDELINE NOTE 166, BREAST REDUCTION SURGERY FOR SYMPTOMATIC MACROMASTIA

Lines 402,417,426,561

Breast reduction surgery is included on these lines 402, 417 or 426 only when ALL of the following conditions are met:

1) The patient is aged 15 or older; AND
2) The patient has a diagnosis of macromastia (size D or higher); AND
3) At least one of the following criteria (a or b) have been met:
    a. Back, neck or shoulder pain
        i. Must be documented to have adverse effects on activities of daily living
        ii. Must be unresponsive to conservative treatments for three months within a year prior. Conservative treatment must include at least three months of
            1. a documented trial of analgesics, AND
            2. physical therapy or chiropractic/osteopathic manipulation treatment or acupuncture, AND
            3. use of support wear for the breast; OR
    b. Persistent severe intertrigo in the inframammary fold unresponsive to documented prescribed medication for at least three months within a year prior; AND
4) The treating surgeon must document that breast reduction has a high likelihood of improving the symptoms that limit activities of daily living caused by the macromastia; AND
5) The expected bilateral reduction volume must be greater than 300 grams (1 cup size) per breast; AND
6) Women aged 40 and older are required to have a negative screening mammogram within two years of the planned reduction mammoplasty; AND
7) Member should be a non-smoker or should not have smoked within the 6 weeks prior to surgery as documented by the surgeon.

Additional criteria for patients aged 15-17 years:

1) The patient must have completed puberty (Tanner stage V)
2) The patient must have a one year history of growth stabilization evidenced by a minimum of four visits with documented heights or puberty completion as shown on wrist radiograph read by a radiologist

Otherwise, breast reduction surgery is included on line 561.

GUIDELINE NOTE XXX ENDOBRONCHIAL VALVES

Line 283

Endobronchial valves (CPT 31647-31649 and 31651) are only included on this line when ALL of the following criteria are met:

Tobacco Cessation Requirements in Prioritized List Guidelines

1) The patient has severe heterogeneous or homogeneous emphysema
   a) Severe emphysema is demonstrated by pulmonary function testing showing
      i) Forced expiratory volume in one second (FEV 1) ≤ 45% predicted and, if age 70 or older, FEV 1≥ 15% predicted value
      ii) Total lung capacity (TLC) ≥ 100% predicted post-bronchodilator
      iii) Residual volume (RV) ≥ 150% predicted post-bronchodilator
2) The patient has significant hyperinflation in regions of the lung that have little to no collateral ventilation
3) The patient is receiving optimized medical care
4) The patient is stable with ≤20 mg prednisone (or equivalent) dose a day
5) The patient has participated in pulmonary rehabilitation and has a post-rehabilitation 6-min walk of ≥ 140 m
6) The patient is a non-smoker as determined by the performing provider

Evidence:

Spinal fusion--smoking

1) **Nunna 2022** systematic review and meta-analysis of smoking on spinal fusion rate
   a) N=20 studies (3009 patients)
      i) 1117 smokers (37%)
   b) Pooled analysis found that smoking was associated with increased risk of nonunion compared to not smoking ≥1 year following spine surgery (RR 1.91, 95% CI 1.56 to 2.35). (Strength of Evidence, Moderate)
      i) The absolute RD (excess risk) for nonunion associated with smoking was .13 and the number needed to treat (NNT) for an additional nonunion of 8 (95% CI 6 to 13).
   c) This association was seen both in the cervical spine (10 studies) pooled RR 2.03, 95% CI 1.46 to 2.81, I 2 =36%) and the lumbar spine (9 studies) pooled RR 1.78, 95% CI 1.37 to 2.31, I2 = 16). The RD for cervical and thoracolumbar fusion was .14 and .11, respectively. This relationship held true whether the follow-up was 12- 23 months or ≥24 months (Table 4), or when 9 poor-quality trials were excluded (10 studies, RR 1.74, 95% CI 1.37 to 2.21, I2 = 0%)
   d) Smoking was significantly associated with increased nonunion in those receiving either allograft (RR 1.39, 95% CI 1.12 to 1.73) or autograft (RR 2.04, 95% CI 1.54 to 2.72). Both multilevel and single level fusions carried increased risk of nonunion in smokers (RR 2.30, 95% CI 1.64 to 3.23; RR 1.79, 95% CI 1.12 to 2.86, respectively).
   e) Conclusion: Tobacco smoking status carries a global risk of nonunion for spinal fusion procedures regardless of follow-up time, location, number of segments fused, or grafting material
2) **Li 2021** systematic review and meta-analysis of smoking on spinal fusion rate
   a) N=26 studies (case control and cohort studies), 4409 patients
      i) Cervical, thoracolumbar and lumbar/sacral
   b) the pooled results demonstrated that the fusion rate of smokers after spinal fusion was significantly lower than that of nonsmokers. The odds ratio (OR) was 0.55 (95% confidence interval [CI] 0.45-0.67, P < 0.0001).
      i) There was no heterogeneity detected (I2 ¼ 2 %, P ¼ 0.43)
   c) The present meta-analysis of 26 observational studies revealed that smokers have a lower fusion rate than nonsmokers in spinal fusion surgery (OR 0.55, 95% CI 0.45-0.67, P < 0.00001). This estimate was robust across sensitivity analyses.

Tobacco Cessation Requirements in Prioritized List Guidelines

Spinal fusion—nicotine replacement therapy (NRT)

1) **Khalid 2022**, impact of smoking cessation therapy on **lumbar** fusion outcomes
    a. Matched cohort study of 31,935 patients undergoing single-level lumbar fusion
        i. 10,645 (33%) in each of the following groups: (1) active smokers; (2) patients on smoking cessation therapy; and (3) those without any smoking history
    b. The rate of any complication within 30 days of surgery was significantly higher in the smoking cohort (19%) compared with both the smoking cessation cohort (17%) and the nonsmoking cohort (9.5%). The rate of pseudarthrosis [failure of fusion] within 2.5 years of surgery was no different between the smoking (5.9%) and smoking cessation (6.1%) cohorts but was significantly lower in the nonsmoking (3.9%) cohort. Similarly, the rate of revision surgery within 2.5 years of surgery was not significantly different between the smoking (2.3%) and cessation (2.0%) cohorts but was significantly lower in the nonsmoking (1.6%) group
    c. Conclusion: both smoking and NRT had a negative effect on lumbar fusion rates and on all cause post-operative complications
2) **Khalid 2022**, impact of smoking cessation therapy on **cervical** fusion outcomes
    a. Matched cohort study of 5769 patients undergoing single-level ACDF
        i. 1923 (33.33%) in each of the following groups: (1) nonsmokers; (2) active smokers; and (3) patients undergoing smoking cessation therapy.
    b. Nonsmokers had significantly lower rates of all complications compared to active smokers and those on cessation therapy (3.74% vs 13.05% vs 15.08%).
    c. There was no significant difference in the rate of 30-day readmission (3.07% vs. 3.02% vs. 3.02%), 90-day readmission (4.68% vs. 5.25% vs 5.62%), or pseudarthrosis [failure of fusion] (3.02% vs 3.28% vs 3.17%) between the nonsmoking, active smoking, and smoking cessation groups, respectively
    d. Conclusion: NRT did not affect cervical fusion rates, but had overall complication rates similar to smokers

Lung volume reduction surgery

3) **NETT 2003**, foundational trial of lung volume reduction surgery
    a) National Emphysema Treatment Trial (NETT)
        i) Inclusion criteria
            (a) Prerehabilitation plasma cotinine ≤13.7 ng/ml (if not using nicotine products) or prerehabilitation arterial carboxyhemoglobin ≤2.5% (if using nicotine products)
            (b) Nonsmoker (tobacco products) for 4 months prior to initial interview and patient remains a nonsmoker throughout screening (by history)
4) **Van Agterern 2015**, Cochrane review of lung volume reduction surgery
    a) All studies included in the review had smoking as an exclusion criteria

Erectile dysfunction surgery

No published literature was identified

Tobacco Cessation Requirements in Prioritized List Guidelines

Expert guidelines:

Spinal fusion

Lung volume reduction surgery

1) American Lung Association:
    a. Candidates for lung volume reduction surgery should "Have not smoked for at least six months"

Erectile dysfunction surgery

1) **American Urological Association 2018** guideline on erectile dysfunction
    a. Counseling on smoking cessation was recommended for all men with erectile dysfunction
    b. No mention of smoking cessation in their recommendations for any type of erectile dysfunction surgery

Other payer policies:

Spinal fusion

1) Aetna 2023
    a. For spinal fusion (cervical, lumbar and thoracic), the member should be nicotine-free (including smoking, use of tobacco products, and nicotine replacement therapy) for at least 6 weeks prior to surgery. For persons with recent nicotine use (unless there is evidence of spinal cord compression/myelopathy, cauda equina syndrome, severe weakness (graded 4 minus or less on MRC scale) or progressive weakness), documentation of nicotine cessation should include a lab report (not surgeon summary) showing blood nicotine level of less than or equal to 10 ng/ml, drawn within 6 weeks prior to surgery.
2) Cigna 2023
    a. For non-surgent spinal fusion surgery, Cigna requires a statement that the individual is a non-smoker or will refrain from use of tobacco products for at least six (6) weeks prior to the planned surgery.
3) Regence BCBS 2023
    a. The patient is not a tobacco user OR there is clinical documentation that the patient has been abstinent from tobacco use for at least six weeks prior to fusion
4) Washington Bureau of Labor and Industries
    a. abstain from nicotine for at least 4 weeks prior to surgery, as demonstrated by two negative urine cotinine tests during this time period. Abstinence from nicotine is required for all fusion and repeat fusion procedures.

Lung volume reduction surgery

1) CMS NCD for lung volume reduction surgery
    a. Tobacco related requirements:
        i. Plasma cotinine level ≤13.7 ng/mL (or arterial carboxyhemoglobin ≤ 2.5% if using nicotine products)
        ii. Nonsmoking for 4 months prior to initial interview and throughout evaluation for surgery
        iii. These requirements are the inclusion criteria for the NETT trial

Tobacco Cessation Requirements in Prioritized List Guidelines

Erectile dysfunction surgery

1) Aetna, Cigna, and Capital BCBS advise counseling on smoking cessation. Aetna requires no active smoking before vascular surgical interventions for ED. Cigna and Capital BCBS have no smoking cessation requirement before any ED procedure

Tobacco Cessation Requirements in Prioritized List Guidelines

HERC staff summary:

Spinal fusion: Smoking is consistently associated with lower fusion rates, with about 12.5% higher failure rate compared to non-smokers. Nicotine replacement therapy (NRT) has been shown to lead to higher fusion failure rates for lumbar fusions, but not for cervical fusions. All payers surveyed require at least 4 weeks of smoking cessation prior to spinal fusion, with the industry standard appearing to be 6 weeks. Most payers require cessation of NRT as well. Most require confirmatory cotinine testing (which would detect both smoking and NRT). HERC staff recommend reducing the requirement of abstinence from tobacco and NRT from 6 months down to 6 weeks in the spinal fusion guideline, and require only one negative cotinine test.

Lung volume reduction surgery: This surgery has never been studied in current smokers. All trials required smoking cessation. The foundational NETT trial allowed nicotine replacement, with a carboxyhemoglobin level test to prove abstinence from combustible cigarettes. This requirement is also contained in the CMS NCD regarding this surgery. HERC staff recommend removing the requirement for abstinence from all nicotine in the current guideline, as this is not consistent with the evidence. However, abstinence from combustible cigarettes should continue to be in the guideline, as all trials included this as a criteria; therefore, there is no evidence on the effectiveness of this surgery on current smokers.

Erectile dysfunction surgery: staff were unable to find published evidence on the impact of smoking on erectile dysfunction surgery outcomes. Smoking cessation is not mentioned in the expert guidelines on ED surgery and is not required by other payers surveyed. This guideline was added without any evidence review. HERC staff recommend deleting this guideline and allowing the general smoking and elective surgery statement of intent to be the only guidance.

HERC staff recommendations:

1) Modify GN 100 as shown below
    a. Reduce the period of abstinence to 6 weeks, reduce the required number of cotinine tests to one
2) Modify GN112 as shown below
    a. Changes requirement to the NETT study inclusion requirements/CMS NCD requirements
3) Delete GN159 as shown below

GUIDELINE NOTE 100, SMOKING AND SPINAL FUSION

Lines 47,150,200,254,346,361,401,478,530,559

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

Tobacco Cessation Requirements in Prioritized List Guidelines

GUIDELINE NOTE 112, LUNG VOLUME REDUCTION SURGERY

Line 283

Lung volume reduction surgery (LVRS, CPT 32491, 32672) is included on Line 283 only for treatment of patients with radiological evidence of severe bilateral upper lobe predominant emphysema (ICD-10-CM J43.9) and all of the following:

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    1) Forced expiratory volume in one second (FEV 1) ≤ 45% predicted and, if age 70 or older, FEV 1≥ 15% predicted value
    2) Total lung capacity (TLC) ≥ 100% predicted post-bronchodilator
    3) Residual volume (RV) ≥ 150% predicted post-bronchodilator
D) PCO_2, ≤ 60 mm Hg (PCO 2, ≤ 55 mm Hg if 1-mile above sea level)
E) PO_2, ≥ 45 mm Hg on room air (PO 2, ≥ 30 mm Hg if 1-mile above sea level)
F) Post-rehabilitation 6-min walk of ≥ 140 m
~~G) Non-smoking and abstinence from all nicotine products for 6 months prior to surgery, as shown by negative cotinine levels at least 6 months apart, with the second test within 1 month of the surgery date.~~
H) Non-smoking for 4 months prior to initial surgical evaluation and throughout the pre-surgical process
    1) This must be demonstrated by a negative serum or urine cotinine level (if not using nicotine replacement products), or an arterial carboxyhemoglobin ≤ 2.5% if using nicotine replacement) prior to surgical authorization

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

~~GUIDELINE NOTE 159, SMOKING AND SURGICAL TREATMENT OF ERECTILE DYSFUNCTION~~

~~*Line 523*~~

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

PET Scan for Prostate Cancer

Plain Language Summary:

Coverage question: Should OHP cover a specific type of imaging test to see whether prostate cancer has spread to other parts of the body?

Should OHP cover this treatment? Yes, for people diagnosed with more severe forms of prostate cancer.

Note: This issue summary is identical to what appeared in the August 17, 2023 and September 28, 2023 meeting materials, except that an additional related code (C9156) for the necessary medication was added to the recommendation after the August meeting. This medication is necessary for PSMA PET scans.

Coverage Question: Should limited coverage of PET scan for evaluation of prostate cancer in certain clinical scenarios be added?

Question source: Dr. Steve Kornfeld, urology

Background: PET scans are used in many cancers to aid in diagnosis, staging, restaging and monitoring. PET scans are only covered for a limited subset of cancers based on Diagnostic Guideline D22. Dr. Kornfeld asked that currently lack of coverage for PET scans in prostate cancer be re-evaluated based on newer NCCN guidelines.

PSMA-PET refers to a growing body of radiopharmaceuticals that target prostate specific membrane antigen (PSMA) on the surface of prostate cells. Because of the high density of PSMA receptors on the surface of cancer cells relative to adjacent prostate, PSMA-PET has the advantage of high signal-to-noise relative to adjacent tissues.

Previous HSC/HERC reviews:

PET scans have been extensively reviewed over the past 20 years. The most recent changes were adding PET scan coverage for initial staging of breast cancer in 2018, and expanding this indication to monitoring treatment of metastatic breast cancer in 2021. PET scan coverage was added for use in management of active therapy of classic Hodgkin's lymphoma in 2021. Coverage for Alzheimer's disease for patients being considered for treatment with aducanumab or similar FDA approved medications for treatment of Alzheimer's disease was added in 2021.

The most recent PET scan review was conducted in November, 2022. Prostate cancer was not discussed as an indication during that review.

PET Scan for Prostate Cancer

Current Prioritized List/Coverage status:

Diagnostic Procedure File
• CPT 78815 Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
• CPT 78816 Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body

ICD-10-CM C61 (Malignant neoplasm of prostate) is on line 329 CANCER OF PROSTATE GLAND

DIAGNOSTIC GUIDELINE D22, PET SCANS
Diagnosis:
PET Scans are covered for diagnosis only when:
A) The PET scan is for evaluation of either:
1) Solitary pulmonary nodules, small cell lung cancer and non-small cell lung cancer, OR
2) Evaluation of cervical lymph node metastases when CT or MRI do not demonstrate an obvious primary tumor, AND
B) The PET scan will
1) Avoid an invasive diagnostic procedure, OR
2) Assist in determining the optimal anatomic location to perform an invasive diagnostic procedure.

Initial staging:
PET scans are covered for the initial staging when:
A) The staging is for one of the following cancers/situations:
1) Cervical cancer only when initial MRI or CT is negative for extra-pelvic metastasis
2) Head and neck cancer when initial MRI or CT is equivocal
3) Colon cancer
4) Esophageal cancer
5) Solitary pulmonary nodule
6) Non-small cell lung cancer
7) Lymphoma
8) Melanoma
9) Breast cancer ONLY when metastatic disease is suspected AND standard imaging results are equivocal or suspicious
10) Small cell lung cancer
11) Neuroendocrine tumors
12) Multiple myeloma
13) Thyroid cancers; AND
B) Clinical management of the patient will differ depending on the stage of the cancer identified and either:
1) the stage of the cancer remains in doubt after standard diagnostic work up, OR
2) PET replaces one or more conventional imaging studies when they are insufficient for clinical management of the patient.

Monitoring:

PET Scan for Prostate Cancer

For monitoring tumor response during active therapy for purposes of treatment planning, PET is covered for

A) classic Hodgkin's lymphoma treatment

B) metastatic breast cancer ONLY when a change in therapy is contemplated AND PET scan was the imaging modality initially used to find the neoplasm being monitored.

Restaging:

Restaging is covered only when:

A) the cancer has staging covered above, AND

B) initial therapy has been completed, AND

C) the PET scan is conducted for

1) detecting residual disease, or
2) detecting suspected recurrence, or
3) determining the extent of a known recurrence.

Other indications:

PET scans are covered for preoperative evaluation of the brain in patients who have intractable seizures and are candidates for focal surgery. PET scans are covered for patients being considered for treatment with aducanumab or similar FDA approved medications for treatment of Alzheimer's disease.

Non-covered conditions/situations:

A) PET scans are NOT covered to monitor tumor response during the planned course of therapy for any cancer other than classic Hodgkin's lymphoma or the limited indication described above for metastatic breast cancer.

B) PET scans are NOT covered for routine follow up of cancer treatment or routine surveillance in asymptomatic patients.

C) PET scans are NOT covered for cardiac evaluation.

Evidence:

1) **Jadvar 2022**, appropriate use criteria for prostate-specific membrane antigen PET imaging
    a. Expert consensus
    b. Appropriate use of PSMA PET
        i. Newly diagnosed unfavorable intermediate-, high-risk, or very-high-risk prostate cancer [high level evidence]
        ii. Newly diagnosed unfavorable intermediate-, high-risk, or very-high-risk prostate cancer with negative/equivocal or oligometastatic disease on conventional imaging [supportive evidence]
        iii. PSA persistence or PSA rise from undetectable level after radical prostatectomy [high quality evidence]
        iv. PSA rise above nadir after definitive radiotherapy [high quality evidence]
        v. nmCRPC (M0) on conventional imaging
            1. There was some discussion by the panel regarding final scoring for this scenario, primarily because it was unclear how PSMA PET would change management, as all drugs approved in the M0 CRPC space are also

approved for the metastatic setting. Overall, there is an appreciation that external beam radiation is being used to treat patients with oligometastatic CRPC, with some preliminary data on its effectiveness; therefore, PSMA PET is important for correctly characterizing disease in these patients. On this basis, the panel decided to support PSMA PET as appropriate in this clinical scenario

Expert guidelines:

1) **NCCN 1.2023** Prostate Cancer
    a. Initial clinical assessment and staging evaluation
        i. For symptomatic patients and/or those with a life expectancy of greater than 5 years, bone and soft tissue imaging is appropriate for patients with unfavorable intermediate-risk, high-risk, and very-high-risk prostate cancer:
            1. Bone imaging can be achieved by conventional technetium-99m-MDP bone scan.
                a. Plain films, CT, MRI, or PET/CT or PET/MRI with F-18 sodium fluoride, C-11 choline, F-18 fluciclovine, Ga-68 prostate-specific membrane antigen (PSMA)-11, or F-18 piflufolastat PSMA can be considered for equivocal results on initial bone imaging.
            2. Soft tissue imaging of the pelvis, abdomen, and chest can include chest CT and abdominal/pelvic CT or abdominal/pelvic MRI. mpMRI is preferred over CT for pelvic staging.
            3. Alternatively, Ga-68 PSMA-11 or F-18 piflufolastat PSMA PET/CT or PET/MRI can be considered for bone and soft tissue (full body) imaging.
                a. Because of the increased sensitivity and specificity of PSMA-PET tracers for detecting micrometastatic disease compared to conventional imaging (CT, MRI) at both initial staging and biochemical recurrence, the Panel does not feel that conventional imaging is a necessary prerequisite to PSMA-PET and that PSMA-PET/CT or PSMA-PET/MRI can serve as an equally effective, if not more effective front-line imaging tool for these patients.
    b. Work up for progression
        i. Castrate levels of testosterone should be documented if clinically indicated in patients with signs of progression, with adjustment of ADT as necessary. If serum testosterone levels are <50 ng/dL, the patient should undergo disease workup with bone and soft tissue imaging:
            1. Bone imaging can be achieved by conventional technetium-99m-MDP bone scan.
                a. Plain films, CT, MRI, or PET/CT or PET/MRI with F-18 sodium fluoride, C-11 choline, F-18 fluciclovine, Ga-68 PSMA-11, or F-18 PyL PSMA can be considered for equivocal results on initial bone imaging.
            2. Soft tissue imaging of pelvis, abdomen, and chest can include chest CT and abdominal/pelvic CT or abdominal/pelvic MRI.

3. Alternatively, Ga-68 PSMA-11 or F-18 PyL PSMA PET/CT or PET/MRI can be considered for bone and soft tissue (full body) imaging.
    a. Because of the increased sensitivity and specificity of PSMA-PET tracers for detecting micrometastatic disease compared to conventional imaging (CT, MRI) at both initial staging and biochemical recurrence, the Panel does not feel that conventional imaging is a necessary prerequisite to PSMA-PET and that PSMA-PET/CT or PSMA-PET/MRI can serve as an equally effective, if not more effective frontline imaging tool for these patients.

c. The use of these PET tracers can lead to changes in clinical management. The FALCON trial showed that results of F-18 fluciclovine PET/CT in 104 patients with biochemical recurrence after definitive therapy resulted in a change in management for 64%. In addition, the LOCATE trial demonstrated that fluciclovine frequently changed management plans in patients with biochemical recurrence. In a similar fashion, data also show that PSMA PET has the ability to change radiation treatment planning in 53% (N = 45) of patients with high- and very-high-risk prostate cancer using PSMA-11 as well as change management in over half of a prospective cohort of 635 patients with BCR. However, whether changes to treatment planning because of PET tracers have an impact on long-term survival remains to be studied

2) **Lowrance 2023**, American Urological Association guideline for advanced prostate cancer
    a. Patients diagnosed with aggressive cancer defined by D'Amico risk factors (cT3a or greater, Grade Group 4/5, or PSA>20ng/mL) should undergo routine bone scan and cross-sectional imaging (CT or MRI) or PET imaging at the time of diagnosis. Utilization of PSMA PET may lead to the diagnosis of metastatic disease not previously detected with conventional imaging. While this detection of metastases at lower PSA levels is helpful in guiding therapy, it is important to note that the clinical trials for treatment did not use PET imaging; therefore, it is unknown if volume of disease on PET imaging can accurately classify patients into high- and low-risk groups
    b. In patients with PSA recurrence after failure of local therapy who are at higher risk for the development of metastases (e.g., PSADT <12 months), clinicians should perform periodic staging evaluations consisting of cross-sectional imaging (CT, MRI) and technetium bone scan, and/or preferably PSMA PET imaging. (Clinical Principle)
    c. Clinicians should utilize PSMA PET imaging preferentially, where available, in patients with PSA recurrence after failure of local therapy as an alternative to conventional imaging due to its greater sensitivity, or in the setting of negative conventional imaging. (Expert Opinion)
    d. Clinicians should assess non-metastatic CRPC patients for development of metastatic disease using conventional or PSMA PET imaging at intervals of 6 to 12 months. (Expert Opinion)
    e. In metastatic CRPC patients with disease progression (PSA or radiographic progression or new disease-related symptoms) having previously received docetaxel and androgen pathway inhibitor, who are considering 177Lu-PSMA-617, clinicians should order PSMA PET imaging. (Expert Opinion)
    f. Clinicians should offer 177Lu-PSMA-617 to patients with progressive metastatic CRPC having previously received docetaxel and androgen pathway inhibitor with a positive PSMA PET imaging study. (Strong Recommendation; Evidence Level Grade: B)
    g. Discussion

PET Scan for Prostate Cancer

i. The prostate cancer community has witnessed considerable developments in the detection of disease with next generation prostate cancer imaging. PET-CT has emerged as a sensitive and specific imaging test to detect prostate cancer metastases, particularly among men with biochemical recurrence after primary therapy.

Other payer policies:

1) Aetna 2023
    a. Aetna considers fluciclovine f-18 PET or choline c-11 PET medically necessary for restaging of men with a suspected recurrence of prostate cancer who meet *all* of the following criteria:
        i. Member has previously been treated with prostatectomy and/or radiation therapy; *and*
        ii. Member has a consecutive rise in PSA; *and*
        iii. PSA ≥ 1 ng/mL; *and*
        iv. CT scan and bone scan are negative for metastatic disease.
    b. Aetna considers Ga-68 PSMA-11 and piflufolastat F-18 (Pylarify) medically necessary for newly diagnosed and suspected recurrence of prostate cancer
2) Evicore/Cigna 2023
    a. PET scan is not covered for the initial work up or staging of prostate cancer
        i. PET/CT with any radiotracers are considered experimental/investigational for initial evaluation of prostate cancer
    b. PET scan is covered for restaging or recurrence of prostate cancer when a patient has all of the following:
        i. Prior treatment with prostatectomy and/or radiation therapy and
        ii. Consecutive rise in PSA and
        iii. PSA ≥1 ng/mL and
        iv. Recent CT scan and bone scan are negative for metastatic disease and
        v. Individual is a candidate for salvage local therapy

Expert input:

Jen-Jane Liu, OHSU urology

It [PSMA PET] definitely enhances detection of disease, and per NCCN guidelines is listed as a staging option with anyone with Gleason grade group 3 (4+3) and above and for biochemical recurrence after treatment of primary prostate cancer.

I think that the data for staging is strong in terms of enhanced sensitivity. It enhances detection, and this can potentially change management (change # of places you decide to radiate, opt out of surgery if widely metastatic disease). Whether that results in long term progression free or overall survival I do not think we know yet. For biochemical recurrence it can be useful to determine whether disease is localized and help direct therapy from that standpoint.

I use it frequently for staging now if insurance will approve, and most of the time for recurrence if PSA is high enough.

PET Scan for Prostate Cancer

If I had to prioritize, I think coverage for biochemic recurrence is more important because this does affect choice of local therapy. For staging, it would be nice, but since we don't know if it enhances survival and there is conventional imaging available (bone scan, CT/MRI), it may not be as crucial in changing patient outcomes.

Chris Amling, OHSU urology

PSMA PET is currently covered for restaging (evaluation of recurrent disease after treatment), but often not approved for initial staging. As I understand it, this is in large part because it is FDA approved for the former but not the latter. The bottom line is that most of us who treat prostate cancer patients think that is should be covered for initial staging of higher risk prostate cancers (the ones listed), because it is more sensitive and specific in detecting metastatic disease (which could alter treatment approach), and because it could eliminate the need for pre-treatment bone scan and CT scan (current standard of care).

Steve Kornfeld, urologist

I can provide a summary based on NCCN. Note NCCN for prostate is quite old. I suspect when they update PSMA PET will be pushed even more. In general I feel that Oncologists over use PET. Especially to further stage known stage 4 and to follow metastatic disease on tx.

WE are not talking about standard PET, but PET directed toward PSMA. This is a specific Prostate Cancer only PET

Prostate has a number of unique features. Only in Prostate is a rising PSA after definitive local therapy considered a biochemical recurrence (vs rising tumor marker). M0 (biochemical recurrence) is treated differently than M1 (metastatic recurrence). Prostate is one of a very few cancers that has a radiopharmaceutical tx requiring specific PET imaging positivity.

PET Scan for Prostate Cancer

HERC staff summary:

PSMA PET imaging is listed by NCCN as an alternative imaging modality for the initial evaluation of intermediate and high risk prostate cancer. Expert imaging guidelines give PSMA PET imaging for newly diagnosed unfavorable intermediate-, high-risk, or very-high-risk prostate cancer a high level evidence. However, AUA guidelines note that PSMA PET as initial imaging for this group was not included in treatment studies and the impact on outcomes is not yet known. Additionally, the private payers surveyed generally did not cover PET for this indication. Local experts recommend covering for both staging and restaging.

NCCN also lists PSMA PET as one imaging option for recurrent disease. The AUA guidelines recommend PSMA PET imaging as the preferred imaging modality for recurrent disease. PET for recurrent disease is generally covered by private insurance and is the more highly recommended use of PET by local experts.

HERC staff recommends adding coverage of PSMA PET imaging for staging and restaging of prostate cancer in intermediate and high risk disease based on expert guidelines and expert input.

HERC staff recommendations:

1) Modify Diagnostic Guideline D22 as shown below
2) Advise HSD to add HCPCS C9156 (Flotufolastat f 18, diagnostic, 1 millicurie) to the Ancillary file for use in PSMA PET scanning

DIAGNOSTIC GUIDELINE D22, PET SCANS

Diagnosis:

PET Scans are covered for diagnosis only when:

A) The PET scan is for evaluation of either:
   1) Solitary pulmonary nodules, small cell lung cancer and non-small cell lung cancer, OR
   2) Evaluation of cervical lymph node metastases when CT or MRI do not demonstrate an obvious primary tumor, AND

B) The PET scan will
   1) Avoid an invasive diagnostic procedure, OR
   2) Assist in determining the optimal anatomic location to perform an invasive diagnostic procedure.

Initial staging:

PET scans are covered for the initial staging when:

A) The staging is for one of the following cancers/situations:
   1) Cervical cancer only when initial MRI or CT is negative for extra-pelvic metastasis
   2) Head and neck cancer when initial MRI or CT is equivocal
   3) Colon cancer
   4) Esophageal cancer
   5) Solitary pulmonary nodule
   6) Non-small cell lung cancer
   7) Lymphoma
   8) Melanoma

9) Breast cancer ONLY when metastatic disease is suspected AND standard imaging results are equivocal or suspicious
10) Small cell lung cancer
11) Neuroendocrine tumors
12) Multiple myeloma
13) Thyroid cancers
14) PSMA PET for unfavorable intermediate, high-risk, or very-high-risk prostate cancer

AND

B) Clinical management of the patient will differ depending on the stage of the cancer identified and either:
1) the stage of the cancer remains in doubt after standard diagnostic work up, OR
2) PET replaces one or more conventional imaging studies when they are insufficient for clinical management of the patient.

Monitoring:
For monitoring tumor response during active therapy for purposes of treatment planning, PET is covered for
A) classic Hodgkin's lymphoma treatment
B) metastatic breast cancer ONLY when a change in therapy is contemplated AND PET scan was the imaging modality
initially used to find the neoplasm being monitored.

Restaging:
Restaging is covered only when:
A) the cancer has staging covered above, AND
B) initial therapy has been completed, AND
C) the PET scan is conducted for
1) detecting residual disease, or
2) detecting suspected recurrence, or
3) determining the extent of a known recurrence

Other indications:
PET scans are covered for preoperative evaluation of the brain in patients who have intractable seizures and are candidates for focal surgery. PET scans are covered for patients being considered for treatment with aducanumab or similar FDA approved medications for treatment of Alzheimer's disease.

Non-covered conditions/situations:
A) PET scans are NOT covered to monitor tumor response during the planned course of therapy for any cancer other than classic Hodgkin's lymphoma or the limited indication described above for metastatic breast cancer.
B) PET scans are NOT covered for routine follow up of cancer treatment or routine surveillance in asymptomatic patients.
C) PET scans are NOT covered for cardiac evaluation.

Cardiac Resynchronization Therapy

Plain Language Summary:

Coverage question: Should OHP clarify the requirements for treatments that helps the heart beat with the right rhythm (pacemaker and heart defibrillator).

Should OHP make this change? Yes.

Coverage Question: Should cardiac resynchronization therapy indications on the Prioritized List be modified?

Question source: Tracy Muday, CCO medical director

Background: Cardiac resynchronization therapy (CRT) involves the insertion of an atrial and a ventricular pacemaker as well as a cardiac defibrillator. It is indicated in patients with heart failure and also left bundle branch block (LBBB) or prolonged QT interval.

There are a number of biventricular pacemakers designed to provide cardiac resynchronization therapy (CRT). Individuals meeting selection criteria for CRT therapy frequently are also considered candidates for an implantable cardioverter defibrillator (ICD). These persons may receive combined therapy with a combined CRT/ICD device. A biventricular pacemaker is designed to resynchronize the pumping action of the left ventricle. This type of pacing is called cardiac resynchronization therapy (CRT). Standard pacemakers pace the right side of the heart. In contrast, biventricular pacemakers pace both the right and left sides of the heart enabling the left ventricle to pump blood more efficiently. Biventricular pacemakers use three leads (one in the right atrium, and one in each ventricle) and have been investigated as a technique to coordinate the contraction of the ventricles, thus, improving the individual's hemodynamic status

Currently, cardiac resynchronization therapy is limited to patients requiring a bridge to transplant based on guideline note 95. Dr. Muday received a request for CRT for a patient who was not a transplant candidate and requested that the HERC reconsider current CRT coverage.

Previous HSC/HERC reviews:

The current wording regarding cardiac resynchronization was added to guideline note 95 in March 2018 as part of a review of implantable cardiac defibrillator (ICD) coverage. The wording was added based on what was then the CMS national coverage determination for ICDs. However, there was no specific discussion of cardiac resynchronization therapy in 2018, and it is unclear whether the added clause was mean to imply that CRT was ONLY covered for patients awaiting heart transplant or was ALSO covered for these patients.

Cardiac Resynchronization Therapy

Current Prioritized List/Coverage status:

CPT 33224 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)) is on lines 69 ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION, 97 HEART FAILURE, 98 CARDIOMYOPATHY, 110 CONGENITAL HEART BLOCK; OTHER OBSTRUCTIVE ANOMALIES OF HEART, 189 CHRONIC ISCHEMIC HEART DISEASE, 281 LIFE-THREATENING CARDIAC ARRHYTHMIAS, 347 CARDIAC ARRHYTHMIAS

CPT 33225 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (eg, for upgrade to dual chamber system)) is on lines 69,97,98,110,189,281,347

CPT 33226 (Repositioning of previously implanted cardiac venous system (left ventricular) electrode (including removal, insertion and/or replacement of existing generator)) is on lines 69, 97, 98, 110, 189, 281, 285, 347

CPT 33230 (Insertion of implantable defibrillator pulse generator only; with existing dual leads) is on lines 97,98,110,281,285

CPT 33249 (Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber) is on lines 97,98,110,281,285

GUIDELINE NOTE 95, IMPLANTABLE CARDIAC DEFIBRILLATORS

Lines 97,98,110,281,285

Implantable cardiac defibrillators are included on these lines for patients with one or more of the following:

A) Patients with a personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation. Patients must have demonstrated one of the following:
   1) Documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause
   2) Documented sustained ventricular tachyarrhythmia (VT), either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction

B) Patients with a prior myocardial infarction and a measured left ventricular ejection fraction (LVEF) ≤ 0.30. Patients must not have:
   1) New York Heart Association (NYHC) classification IV heart failure; or
   2) Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; or
   3) Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary intervention (PCI) with angioplasty and/or stenting, within past 3 months; or
   4) Had a myocardial infarction in the past 40 days; or
   5) Clinical symptoms or findings that would make them a candidate for coronary revascularization

C) Patients who have severe ischemic dilated cardiomyopathy but no personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation, and have New York Heart Association (NYHA) Class II or III heart failure, left ventricular ejection fraction (LVEF) ≤ 35%. Additionally, patients must not have:

1) Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
2) Had a myocardial infarction within the past 40 days; or
3) Clinical symptoms and findings that would make them a candidate for coronary revascularization.

D) Patients who have severe non-ischemic dilated cardiomyopathy but no personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation, and have New York Heart Association (NYHA) Class II or III heart failure, left ventricular ejection fraction (LVEF) ≤ 35%, been on optimal medical therapy (OMT) for at least 3 months. Additionally, patients must not have:
   1) Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
   2) Had a myocardial infarction within the past 40 days; or
   3) Clinical symptoms and findings that would make them a candidate for coronary revascularization.

E) Patients with documented familial, or genetic disorders with a high risk of life-threatening tachyarrhytmias (sustained ventricular tachycardia or ventricular fibrillation), to include, but not limited to, long QT syndrome or hypertrophic cardiomyopathy.

F) Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, elective replacement indicator (ERI) or device/lead malfunction.

For these patients identified in A-E, a formal shared decision making encounter must occur between the patient and a physician or qualified non-physician practitioner using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.

All indications above in A-F must meet the following criteria:

A) Patients must be clinically stable (e.g., not in shock, from any etiology);

B) Left ventricular ejection fraction (LVEF) must be measured by echocardiography, radionuclide (nuclear medicine) imaging, or catheter angiography;

C) Patients must not have:
   1) Significant, irreversible brain damage; or
   2) Any disease, other than cardiac disease (e.g., cancer, renal failure, liver failure) associated with a likelihood of survival less than 1 year; or
   3) Supraventricular tachycardia such as atrial fibrillation with a poorly controlled ventricular rate.

Exceptions to waiting periods for patients that have had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months, or had a myocardial infarction within the past 40 days:

A) Cardiac Pacemakers: Patients who meet all CMS coverage requirements for cardiac pacemakers and who meet the criteria in this national coverage determination for an ICD may receive the combined device in one procedure at the time the pacemaker is clinically indicated;

B) Replacement of ICDs: Patients with an existing ICD may receive a ICD replacement if it is required due to the end of battery life, elective replacement indicator (ERI) or device/lead malfunction.

Cardiac Resynchronization Therapy

Other Indications:
For patients who are candidates for heart transplantation on the United Network for Organ Sharing (UNOS) transplant list awaiting a donor heart, coverage of ICDs, as with cardiac resynchronization therapy, as a bridge to transplant to prolong survival until a donor becomes available.

Expert guidelines:

1) **Heidenreich 2022**, AHA/ACC/HRSA guideline for the management of heart failure
   a) Recommends cardiac resynchronization therapy for patients with NYHA II-III or ambulatory IV, LVEF ≤ 35%, LBBB and QRS ≥ 150ms
      i) Class I (strong) recommendation
   b) Recommends cardiac resynchronization therapy for patients with NYHA II-III or ambulatory IV, LVEF ≤ 35%, QRS ≥ 150ms without LBBB
      i) Classa 2a (moderate) recommendation
   c) Recommends cardiac resynchronization therapy for patients with NYHA II-III or ambulatory IV, LVEF ≤ 35%, LBBB and QRS ≥ 120-149 msec
      i) Classa 2a (moderate) recommendation
   d) Recommends cardiac resynchronization therapy for patients with NYHA II-III or ambulatory IV, LVEF ≤ 35%, QRS ≥ 120-149 msec without LBBB
      i) Classa 2b (weak) recommendation
   e) Most of the relevant data for the guidelines of CRT in HF come from seminal trials published from 2002 to 2010. The first of these was the MIRACLE (Multicenter InSync Randomized Clinical Evaluation) trial, which took patients with LVEF ≤35%, moderate to severe HF, and QRS duration ≥130 ms.16 There was a benefit in the 6-minute walk test, QOL, functional HF classification, and LVEF. The COMPANION (Comparison of Medical Therapy, Pacing and Defibrillation in Heart Failure) trial, which enrolled NYHA class III to IV patients with QRS ≥120 ms, included 3 arms: GDMT, CRT-D, and CRT pacemaker (CRT-P).17 The primary end-point of death or hospitalization was decreased with CRT-P and CRT-D. The CARE-HF (Cardiac Resynchronization Heart Failure) trial included a similar group with NYHA class III to IV, LVEF ≤35%, QRS >120 ms, and showed a significant reduction in primary and endpoint of death or hospitalization.18 In the REVERSE (Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction) trial, patients with NYHA class I to II and LVEF ≤40% were randomized to CRT-D on for 1 year and CRT-D off for 1 year or vice versa.19 A HF composite endpoint was less common when CRT was activated. MADIT-CRT enrolled NYHA class I and II HF with LVEF ≤30% and QRS ≥130 ms and compared CRT-D with ICD.20 The primary endpoint of death or HF was reduced by CRT-D. The RAFT (Resynchronization-Defibrillation for Ambulatory Heart Failure) trial randomized patients with NYHA class II to III HF, LVEF ≤30%, QRS >120 ms, or paced QRS ≥200 ms and compared CRT-D with ICD.2 Again, there was a reduction in the primary endpoint of death or HF hospitalization.
   f) Extension of benefit to patients with narrow QRS has been attempted but has generally failed. In the RETHINQ (Cardiac Resynchronization Therapy in Patients with Heart Failure and Narrow QRS) trial, patients with QRS duration < 130 ms were randomized to CRT or not. There was no benefit from CRT, but subgroup analysis showed there was a benefit with QRS durations between 120 and 130 ms. In the ECHO-CRT (Echocardiography Guided Cardiac Resynchronization Therapy) trial, patients with NYHA class III to IV HF,

LVEF ≤35% and a QRS duration ≤130 ms, and mechanical dysynchrony on echocardiography underwent randomization to CRT. There was no benefit to CRT in this trial. And in the LESSER-EARTH (Evaluation of Resynchronization Therapy for Heart Failure) trial, patients with severe LV dysfunction and QRS < 120 ms derived no benefit from CRT.51 The NARROW-CRT (Narrow QRS Ischemic Patients Treated With Cardiac Resynchronization Therapy) was the only trial that showed a benefit in a clinical composite score in patients with an indication for an ICD and QRS < 120 ms.

g) Subgroup analysis of the CRT trials has shown no benefit for those with LVEF ≤35%, non-LBBB 120 to 149, and NYHA class I-II HF

Other payer policies:

2) CMS LCD Cardiac resynchronization therapy
   a) CRT will be considered medically necessary when the following criteria for a given beneficiary are met:
      i) LVEF ≤ 35%, with ischemic or non-ischemic cardiomyopathy, on maximally tolerated guideline-directed medical therapy (GDMT) for at least 3 months and with no reversible causes; *and*
         (a) QRS ≥ 150 ms; and
         (b) Any type bundle branch block with evidence of dyssynchrony; and
         (c) NYHA class III or ambulatory IV HF
      ii) LVEF ≤ 35%, on maximally tolerated GDMT for at least 3 months and with no reversible causes; *and*
         (a) QRS ≥ 150 ms; and
         (b) LBBB; and
         (c) NYHA classes II, III or ambulatory IV HF
      iii) LVEF ≤ 35%, on maximally tolerated GDMT for at least 3 months and with no reversible causes; *and*
         (a) QRS 130-149 ms; and
         (b) LBBB; and
         (c) NYHA class II, III or ambulatory IV HF
      iv) In patients with atrial fibrillation (AF) or in sinus rhythm who have an indication for pacemaker implant for second or third degree atrioventricular (AV) block (including those who have or will have AV nodal ablation), or very prolonged first degree block with PR > 300 ms, *and*:
         (a) with an EF < 50%; and
         (b) with NYHA I, II or III class; and
         (c) anticipated frequent ventricular pacing
      v) Patients who are being paced from the RV frequently (generally considered at least > 40% of the time) and who develop worsening HF symptoms (NYHA class II-IV) with a decline in LVEF to a value < 40% may be considered for upgrade to CRT.*
         (a) *For an upgrade from standard pacing to CRT, this A/B Medicare Administrative Contractor (MAC) would expect documentation narrative regarding the risk-benefit balance for that individual patient and his/her degree of HF, QRS duration/morphology, etc. A "stand-alone" upgrade in patients with an existing pacemaker or implanted cardiac defibrillator should be considered carefully and based on the individual patient's unique circumstances. Upgrades to CRT from

conventional RV pacing at the time of a needed generator change will be covered per the usual criteria as noted in all preceding coverage bullets.

b) Patients who meet all CMS coverage requirements for cardiac pacemakers, and who meet the criteria in the NCD for Implantable Automatic Defibrillators (20.4), may receive the combined devices in 1 procedure, at the time the biventricular pacemaker is clinically indicated.
c) Patients with an existing CRT device may receive a generator replacement if it is required due to the end of battery life, elective replacement indicator (ERI), or device/lead malfunction.
d) **Limitations:**
    i) Noncovered Services: (CRT is unlikely to offer benefit and is probably associated with harm)
        (a) Patients with a QRS < 130 ms (Exception to this non-coverage criterion would be in the case of patients undergoing AV nodal ablation or in need of RV pacing (due to second- or third-degree block or very long first degree block) that is expected to occur a majority of the time.)
        (b) Patients with an EF ≥ 50%
        (c) CRT in patients with non-ambulatory NYHA IV HF symptoms or on chronic inotropic HF therapy or with LV assist devices in place

3) Anthem BCBS 2022
    a) Biventricular pacemakers for cardiac resynchronization therapy (CRT) are considered **medically necessary** for individuals who meet **all** of the following criteria:
        i) NYHA functional Class II, III, or ambulatory Class IV symptoms* secondary to heart failure who remain symptomatic despite recommended, Guideline-directed medical therapy (GDMT) (which may include use of medications from the following drug classes, either individually or in combination for at least 3 months, unless contraindicated: renin-angiotensin system inhibition with angiotensin receptor-neprilysin inhibitors, angiotensin-converting enzyme inhibitors, or angiotensin [II] receptor blockers; beta blockers; mineralocorticoid receptor antagonists; and sodium-glucose cotransporter-2 inhibitors, when appropriate); **and**
        ii) Have either:
            (i) Left bundle branch block (LBBB) morphology and QRS duration of 120 to 149 ms; **or**
            (ii) Any QRS morphology and QRS duration greater than or equal to 150 ms; **and**
            (b) Left ventricular ejection fraction (LVEF) less than or equal to 35%; **and**
        iii) In either:
            (a) Sinus rhythm; **or**
            (b) Atrial fibrillation when AV nodal ablation or pharmacologic rate control will allow near 100% ventricular pacing.

Expert input:

Dr. Eric Stecker from OHSU cardiology assisted HERC staff in drafting the guideline wording change recommendations

Cardiac Resynchronization Therapy

HERC staff summary:

The current wording in GN95 is unclear about intent of coverage for cardiac resynchronization therapy. CRT has never been explicitly discussed by HERC. The current guideline wording should be modified to clarify when CRT is a covered service.

HERC staff recommendation:

1) Modify GN95 as shown below
    a. Based on current ACC/AHA recommendations and expert input
    b. Additional edits are recommended by staff to clean up certain section

GUIDELINE NOTE 95, IMPLANTABLE CARDIAC DEFIBRILLATORS

Lines 97,98,110,281,285

Implantable cardiac defibrillators are included on these lines for patients with one or more of the following:

A) Patients with a personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation. Patients must have demonstrated one of the following:
    1) Documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause
    2) Documented sustained ventricular tachyarrhythmia (VT), either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction

B) Patients with a prior myocardial infarction and a measured left ventricular ejection fraction (LVEF) ≤ 0.30. Patients must not have:
    1) New York Heart Association (NYHC) classification IV heart failure; or
    2) Cardiogenic shock or symptomatic hypotension while in a stable baseline rhythm; or
    3) Had a coronary artery bypass graft (CABG) or percutaneous transluminal coronary intervention (PCI) with angioplasty and/or stenting, within past 3 months; or
    4) Had a myocardial infarction in the past 40 days; or
    5) Clinical symptoms or findings that would make them a candidate for coronary revascularization

C) Patients who have severe ischemic dilated cardiomyopathy but no personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation, and have New York Heart Association (NYHA) Class II or III heart failure, left ventricular ejection fraction (LVEF) ≤ 35%. Additionally, patients must not have:
    1) Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
    2) Had a myocardial infarction within the past 40 days; or
    3) Clinical symptoms and findings that would make them a candidate for coronary revascularization.

D) Patients who have severe non-ischemic dilated cardiomyopathy but no personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation, and have New York Heart Association (NYHA) Class II or III heart failure, left ventricular ejection fraction (LVEF) ≤ 35%, been on optimal medical therapy (OMT) for at least 3 months. Additionally, patients must not have:

1) Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
2) Had a myocardial infarction within the past 40 days; or
3) Clinical symptoms and findings that would make them a candidate for coronary revascularization.

E) Patients with documented familial, or genetic disorders with a high risk of life-threatening tachyarrhytmias (sustained ventricular tachycardia or ventricular fibrillation), to include, but not limited to, long QT syndrome or hypertrophic cardiomyopathy.

F) Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, elective replacement indicator (ERI) or device/lead malfunction.

For these patients identified in A-E, a formal shared decision making encounter must occur between the patient and a physician or qualified non-physician practitioner using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.

All indications above in A-F must meet the following criteria:

A) Patients must be clinically stable (e.g., not in shock, from any etiology);

B) Left ventricular ejection fraction (LVEF) must be measured by echocardiography, radionuclide (nuclear medicine) imaging, or catheter angiography;

C) Patients must not have significant contraindications~~:~~

~~1) Significant, irreversible brain damage; or~~

~~2) Any disease, other than cardiac disease (e.g., cancer, renal failure, liver failure) associated with a likelihood of survival less than 1 year; or~~

~~3) Supraventricular tachycardia such as atrial fibrillation with a poorly controlled ventricular rate.~~

Exceptions to waiting periods for patients that have had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months, or had a myocardial infarction within the past 40 days:

A) Cardiac Pacemakers: Patients who meet all CMS coverage requirements for cardiac pacemakers and who meet the criteria in this guideline ~~national coverage determination~~ for an ICD may receive the combined device in one procedure at the time the pacemaker is clinically indicated;

B) Replacement of ICDs: Patients with an existing ICD may receive a ICD replacement if it is required due to the end of battery life, elective replacement indicator (ERI) or device/lead malfunction.

Other Indications:

For patients who are candidates for heart transplantation on the United Network for Organ Sharing (UNOS) transplant list awaiting a donor heart, ~~coverage of~~ ICDs~~, as with cardiac resynchronization therapy~~, are only included on these lines as a bridge to transplant to prolong survival until a donor becomes available.

Cardiac resynchronization therapy (CRT) ICD is only covered for patients with NYHA Class II-III and ambulatory IV heart failure with an ejection fraction ≤ 35% as well as one of the following:

1) left bundle branch block (LBBB) and a QRS complex over 120 msec; OR
2) QRS complex ≥ 150ms

CRT-pacemaker is covered for the following:

Cardiac Resynchronization Therapy

1) patients for whom CRT-ICD is covered
2) patients for whom CRT-ICD is excluded only due to high risk of competing mortality, or NYHA Class I heart failure, or hospitalized NYHA Class IV heart failure, or EF 35-40%

Nasal Fracture Coverage Clarification

Plain Language Summary:

Coverage question: Should OHP cover treatments for a broken nose?

Should OHP cover this treatment? Yes, fixing a broken nose may need adjusting by hand, with or without using splints. This should be done within 14 days after the break happened. Rhinoplasty (a nose surgery) is needed when the nose is blocked and causing breathing problems.

Coverage Question: When should treatment of nasal fractures be included on a covered line and when on an uncovered line?

Question source: Holly Jo Hodges, CCO medical director

Background: The diagnosis codes and the treatment codes for nasal fracture appear on two lines, line 228 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES and line 557 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT. There is no guideline or other indication regarding when nasal fractures are on the covered line and when on the uncovered.

There are guidelines regarding nasal surgery, but the lines for acute nasal fractures are not included in these guidelines. The coverage for treatment of acute nasal fractures needs to be clarified.

Previous HSC/HERC reviews:
Rhinoplasty was discussed in 2006 as part of cleft palate repair. Coverage was eventually added to the cleft palate line. In a larger discussion regarding repair of nose deformities at that time, the minutes state "The group did not want coverage for nasal deformities with only social impacts. The deformity must have significant physical impacts." A guideline was adopted in 2006 that read "GUIDELINE NOTE XXX RECONSTRUCTION OF THE NOSE Line 273 ICD-9 code 748.1 (Other anomalies of the nose) is on Line 273 only for reconstruction of absence of the nose and other severe nasal anomalies which significantly impair physical or social functioning." At a later discussion in 2010, it was reiterated that the HOSC members only wanted to cover repair of a nasal fracture that resulted functional problems rather than cosmesis.

Repairing nasal issues was again discussed in 2015. The reconstruction of the nose guideline was deleted. In 2016, fracture of the nasal bones that were closed and healing normally were moved from the covered upper line to the uncovered lower line as a consent item.

Nasal Fracture Coverage Clarification

Current Prioritized List/Coverage status:

ICD-10-CM Code	Code Description	Current Placement
S02.2XXA	Fracture of nasal bones, initial encounter for closed fracture	577 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT
S02.2XXB	Fracture of nasal bones, initial encounter for open fracture	228 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
S02.2XXD	Fracture of nasal bones, subsequent encounter for fracture with routine healing	577
S02.2XXG	Fracture of nasal bones, subsequent encounter for fracture with delayed healing	577
S02.2XXK	Fracture of nasal bones, subsequent encounter for fracture with nonunion	443 MALUNION AND NONUNION OF FRACTURE
CPT Code	**Code Description**	**Current Placement**
21315	Closed treatment of nasal bone fracture with manipulation; without stabilization	228
21320	Closed treatment of nasal bone fracture with manipulation; with stabilization	228
21325	Open treatment of nasal fracture; uncomplicated	228,577
21330	Open treatment of nasal fracture; complicated, with internal and/or external skeletal fixation	228,577
21335	Open treatment of nasal fracture; with concomitant open treatment of fractured septum	228,577
21336	Open treatment of nasal septal fracture, with or without stabilization	228
21337	Closed treatment of nasal septal fracture, with or without stabilization	228
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip	466 CHRONIC SINUSITIS 506 NASAL POLYPS, OTHER DISORDERS OF NASAL CAVITY AND SINUSES 577
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip	466,506,577
30420	Rhinoplasty, primary; including major septal repair	228,466,506,577
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)	228,466,506

Nasal Fracture Coverage Clarification

GUIDELINE NOTE 118, SEPTOPLASTY

Lines 42,119,246,287,466,506,525,577

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 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 216, RHINOPLASTY

Lines 42,119,202,246,287,466,506,525

Rhinoplasty is included on these lines when

A) It is performed to correct a nasal deformity secondary to congenital cleft lip and/or palate or other severe congenital craniofacial anomaly; OR

B) It is performed as part of reconstruction after accidental or surgical trauma or disease (e.g., Wegener's granulomatosis, choanal atresia, nasal malignancy, abscess, septal infection with saddle deformity, or congenital deformity) AND
   1) There is prolonged, persistent obstructed nasal breathing unresponsive to a six week trial of conservative management (e.g. nasal corticosteroids, decongestants, antibiotics); AND
   2) Airway obstruction will not respond to septoplasty and turbinectomy alone; AND
   3) Photographs demonstrate an external nasal deformity; AND
   4) There is significant obstruction of one or both nares, documented by nasal endoscopy, computed tomography (CT) scan or other appropriate imaging modality; OR

C) There is nasal airway obstruction causing chronic rhinosinusitis when all of the following are met:
   1) The criteria for sinus surgery are met in Guideline Note 35, SINUS SURGERY; AND
   2) Airway obstruction will not respond to septoplasty and turbinectomy alone; AND
   3) Photographs demonstrate an external nasal deformity; AND
   4) There is significant obstruction of one or both nares), documented by nasal endoscopy, computed tomography (CT) scan or other appropriate imaging modality

Nasal Fracture Coverage Clarification

Line 42 CLEFT PALATE WITH AIRWAY OBSTRUCTION
Line 119 CHOANAL ATRESIA
202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER
246 LIFE-THREATENING EPISTAXIS
287 CANCER OF ORAL CAVITY, PHARYNX, NOSE AND LARYNX
466 CHRONIC SINUSITIS
506 NASAL POLYPS, OTHER DISORDERS OF NASAL CAVITY AND SINUSES
525 BENIGN NEOPLASM OF NASAL CAVITIES, MIDDLE EAR AND ACCESSORY SINUSES

Expert guidelines:

1) **American Academy of Otolaryngology-Head and Neck Surgery 2021**, clinical indicators: nasal fracture
    a. Nasal fractures are common. If no airway obstruction or nasal deformity has occurred due to the fracture, surgical treatment may not be needed. For nasal fractures resulting in deformity or airway obstruction, surgery may be indicated to open the nasal passage and/or improve appearance. Surgery for nasal trauma may not be able to completely correct the traumatic deformity and/or may not correct preexisting deformities. Nasal infection, bleeding, or hematoma are possible, yet infrequent complications.

Nasal Fracture Coverage Clarification

HERC staff summary:

Acute nasal fracture should be on a covered line for either ED or primary care evaluation and initial treatment. Acute treatment may require manual realignment with or without internal or external splinting, which should be done within 14 days from when the fracture occurred. Rhinoplasty is only required when there is nasal blockage causing airway obstruction and is generally not done with acute nasal fractures.

All acute nasal fracture diagnosis codes should be moved to the covered line. All procedure codes for acute treatment should also be on the covered line. The rhinoplasty guideline should be modified to clarify that acute nasal fracture treatment is included on line 228, but treatment more than 14 days after the injury falls on line 577 unless criteria for nasal obstruction are met.

Other changes need to be made to GN 216. This guideline is attached to line 246 LIFE-THREATENING EPISTAXIS, which only has septoplasty CPT codes. Line 246 should only be attached to the septoplasty guideline.

HERC staff recommendations:

1) Add the following ICD-10-CM codes to line 228 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES and remove from line 577 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT
    a. S02.2XXA Fracture of nasal bones, initial encounter for closed fracture
    b. S02.2XXD Fracture of nasal bones, subsequent encounter for fracture with routine healing
    c. S02.2XXG Fracture of nasal bones, subsequent encounter for fracture with delayed healing
2) Add the following ICD-10-CM codes to line 228 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES and remove from line 443 MALUNION AND NONUNION OF FRACTURE
    a. S02.2XXK Fracture of nasal bones, subsequent encounter for fracture with nonunion
3) Remove the following CPT codes from line 577 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT
    a. 21325 Open treatment of nasal fracture; uncomplicated
    b. 21330 Open treatment of nasal fracture; complicated, with internal and/or external skeletal fixation
    c. 21335 Open treatment of nasal fracture; with concomitant open treatment of fractured septum
4) Remove the following CPT codes from line 228 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
    a. 30420 Rhinoplasty, primary; including major septal repair
    b. 30450 Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
5) Modify GN118 as shown below
    a. Add line 202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER
6) Modify GN216 as shown below
    a. Remove line 202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER and line 246 LIFE-THREATENING EPISTAXIS from this guideline as it does not apply to diagnoses on these lines
    b. Add line 577 to the guideline

Nasal Fracture Coverage Clarification

c. Clarify which lines various sections refer to

GUIDELINE NOTE 118, SEPTOPLASTY

Lines 42,119,202,246,287,312,466,506,525,577

Septoplasty is included on line 312 for gender affirming treatment.

Septoplasty is included on lines 42, 119, 202, 246, 287,466, 506, 525 and 577 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 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 216, RHINOPLASTY

Lines 42,119,~~202~~,~~246,~~287,312,466,506,525,577

Rhinoplasty is included on line 312 for gender affirming treatment.

Rhinoplasty is included on lines ~~42, 119, 202, 246, 287, 466, 506 and 525~~ 42 and 119, when A) it is performed to correct a nasal deformity secondary to congenital cleft lip and/or palate or other severe congenital craniofacial anomaly. ~~; OR~~

B) Rhinoplasty is included on lines 228, 287, 506, 525 and 577 when It is performed as part of reconstruction after accidental or surgical trauma or disease (~~e.g.,~~ for example Wegener's granulomatosis, ~~choanal atresia,~~ nasal malignancy, abscess, septal infection with saddle deformity~~, or congenital deformity~~) AND

   1) There is prolonged, persistent obstructed nasal breathing unresponsive to a six week trial of conservative management (e.g. nasal corticosteroids, decongestants, antibiotics); AND
   2) Airway obstruction will not respond to septoplasty and turbinectomy alone; AND
   3) Photographs demonstrate an external nasal deformity; AND
   4) There is significant obstruction of one or both nares, documented by nasal endoscopy, computed tomography (CT) scan or other appropriate imaging modality. ~~; OR~~

C) Rhinoplasty is included on line 466 when t~~T~~here is nasal airway obstruction causing chronic rhinosinusitis when all of the following are met:

   1) The criteria for sinus surgery are met in Guideline Note 35, SINUS SURGERY; AND

Nasal Fracture Coverage Clarification

2) Airway obstruction will not respond to septoplasty and turbinectomy alone; AND
3) Photographs demonstrate an external nasal deformity; AND
4) There is significant obstruction of one or both nares), documented by nasal endoscopy, computed tomography (CT) scan or other appropriate imaging modality

Treatment of Liver Metastases

Plain Language Summary:

Coverage question: Liver metastases are tumors that started out in some other part of the body and have spread to the liver. Should OHP cover treatments for this condition?

Should OHP cover these treatments? Yes, certain types of treatments should be covered in limited cases.

Coverage Question: What treatments should be covered for cancer that is metastatic to the liver?

Question source: Kristin Garrett, CCO medical director

Background: Many cancers can metastasize to the liver, but the most common liver metastases is colorectal cancer. There are many treatments for cancer that has metastasized to the liver, including chemotherapy, surgical resection, radiofrequency ablation (RFA), microwave ablation (MWA), cryoablation, and electro-coagulation.

Currently, Guideline Note 78 HEPATIC METASTASES limits treatment of liver metastases to hepatectomy/resection of the liver (CPT codes 47120, 47122,47125 or 47130). The CPT codes for other treatments, such as RFA, are on line 315 CANCER OF LIVER, but appear to be reserved for primary hepatocellular carcinoma. Guideline Note 78 was written in 2009, and the field of oncology has made vast strides in treatment of liver metastases since that time.

Dr. Garrett is requesting clarification of what treatments are actually intended to be paired with liver metastases (specifically colorectal cancer metastases).

In addition to Dr. Garrett's question, staff have reviewed the various treatments for liver metastases, and cryoablation of liver tumors (CPT 47383) was last reviewed in 2014 and placed on line 662/GN173 and should be re-reviewed as it has been almost 10 years since the last review.

Dr. Max Kaiser, CCO medical director and HERC member, has asked HERC staff to look at use of Yttrium-90 (Y-90) for treatment of metastatic disease to the liver for indications other than hepatocellular carcinoma (HCC) or colorectal cancer (CRC) metastatic to the liver. Since the last review of Y-90, the CPT code for this treatment has had a major description change. In 2019, CPT 79445 was specific for HCC or CRC metastatic to the liver. Currently, CPT 79445 is "Radiopharmaceutical therapy, by intra-arterial particulate administration."

Previous HSC/HERC reviews:
April 2006

Treatment of Liver Metastases

Discussion

Treatment of Liver Cancer: Little explained that the Commission previously considered embolization for tumor destruction using yttrium and elected not to place it on the list; however, the code for embolization remains. A case at OMAP resulted in her questioning whether appropriate treatments were listed on this line. [Kevin] Olson explained the different treatments, as follows: Radiofrequency ablation is insertion of an ultrasound catheter with use of heat to kill tissue, cryotherapy is the same thing except using a liquid nitrogen probe, chemoembolization is when a catheter is inserted into an artery that feeds the tumor, chemotherapy is infused then the artery is embolized with gel foam. The yttrium procedure does not involve embolization. All of these are used to treat both primary liver cancer and metastatic colon cancer. Saha asked if any of these treatments were controversial except the yttrium. Olson stated that for colon cancer metastatic only to the liver, resection can result in 25% long-term survival. Hepatic artery infusion with 5-FU improved outcomes as well. The data on RFA and cryotherapy is weaker. Chemoembolization results in shrinkage of tumor, but causes severe side-effects. RFA and yttrium have fewer side effects. Hepatic artery infusion is also effective, but systemic chemotherapy has improved to the point that it is rarely done anymore. Saha clarified that the task today is to determine if any of these treatments should be removed from the List. Olson stated that there are some cases where an isolated metastasis is too close to the bile duct to operate, and in those cases it makes sense to use RFA or cryo. He also said that yttrium treatment costs approximately $70,000

Actions: Do not delete any of the following codes from Line 489:
36260 - Insertion of implantable intra-arterial infusion pump
36262 - Removal of implanted intra-arterial infusion pump
37204 - Transcatheter occlusion or embolization
47370 - Laparoscopy, surgical, ablation of one or more liver tumors, RFA
47371 - Laparoscopy, surgical, ablation of one or more liver tumors, cryosurgical
47380 - Ablation, open, one or more liver tumors; RFA
47381 - Ablation, open, one or more liver tumors; cryosurgical 47382 - Ablation, percutaneous, one or more liver tumors; RFA Do not delete CPT code
36261, Revision of implanted intra-arterial infusion pump

Delete 79445 - Radoipharmaceutical therapy, by intra-arterial particulate administration, from Line 489.

June 2009

Discussion

Hepatic metastases Livingston introduced the summary document on liver metastases. The recommendation was to move 197.7 (Secondary malignant neoplasm of the liver) from Line 613 SECONDARY AND ILL-DEFINED MALIGNANT NEOPLASMS to Line 338 CANCER OF LIVER, to pair with 47120-47130 (Hepatectomy, resection of liver), with a coding specification to avoid inappropriate pairings: “Hepatic metastases (ICD-9 code 197.7) are covered in this line only when paired with CPT code 47120-47130 and only when no other extrahepatic metastases are present.” Saha asked whether this diagnosis could have the cancer care statement of intent criteria applied to it. Livingston reported that the 5 year survival is not reported. Historically, survival is 3-25 month survival without treatment and 14-17 months with treatment. Mckelvey asked whether survival was affected by type of primary cancer; Livingston replied that all studies

reviewed were on colorectal cancer. Saha noted that based on the 5 year survival data, it appears that treatment of solitary liver metastases meets the criteria in the SOI of improvement of 30%. Historically, best survival 2 yrs, this data shows 3 years, which is 50% increase in survival. The suggestion was made that solitary liver metastases be moved to the colon cancer line, as this was where the evidence for treatment was strongest. Smits noted that CPT treatment codes would also need to be added to this line. Coffman cautioned that moving CPT codes would allow them to pair with other types of cancer as the ICD-9 code for liver metastases is generic/not specific for metastatic colorectal cancer. Saha asked whether the HSC could make a guideline restricting use of this code for metastatic colon/rectal cancer if this diagnosis was added to the liver cancer line; the answer from HSC staff was yes. Suggested wording for a guideline was: "Hepatic metastases (ICD-9 code 197.7) are covered in this line only for 1) a covered primary cancer treatment of which meets our statement of intent for cancer treatment, 2) when paired with CPT code 47120-47130 and 3) when no other extrahepatic metastases are present." Gubler disagreed, that thought that the solitary liver metastases diagnosis should be left under the liver cancer line, with treatment left to clinical judgment. Saha noted that in this situation, rare cases of other diagnoses could be treated under the exceptions process. Shaffer stated that DMAP don't grant exceptions when the HSC has a clear guideline stating limitations to coverage. Kirk objected as well, noting that the hearings/exceptions process for such exceptions are a strain to the plans. A patient with a terminal cancer below the line who has a hepatic met above the line will get an argument that the lower diagnoses (the terminal cancer) should be covered to help benefit the covered diagnosis (the liver metastases), as counterintuitive as that may be. Saha noted that some cases may involve an unknown primary cancer. He noted that in this case, there is no evidence that you would prolong life by treating the solitary metastasis. The decision was to consider placing on either the colorectal or the liver cancer line, with a guideline to be developed by HSC staff and sent to Saha for comment. This topic will be revisited at the December meeting.

Action: HSC staff to develop a guideline restricting treatment of solitary hepatic metastases to evidence based situations, and to determine whether placement should be on the colorectal or liver cancer lines. Staff will forward this guideline/ recommendation to Saha and return to the December meeting for further discussion

December 2009

Solitary liver metastases Livingston introduced a summary regarding solitary liver metastases. There was minimal discussion.

Action
Move 197.7 (Secondary malignant neoplasm of the liver) from Line 612 to Line 338. Guideline adopted as shown in Appendix A. [This guideline later became Guideline Note 78]

GUIDELINE NOTE XXX, HEPATIC METASTASES
Line 338
Hepatic metastases (ICD-9 code 197.7) are covered in this line only when:
1) Treatment of the primary tumor is covered on a funded line in accordance with the criteria in guideline note XX Treatment of Cancer With Little or No Benefit Provided Near the End of Life;
2) There are no other extrahepatic metastases; and,

Treatment of Liver Metastases

3) The only treatment covered is hepatectomy/resection of liver (CPT codes 47120, 47122, 47125 or 47130)

November 2014

Cryoablation of liver tumors (CPT 47383)

1) Cryoablation of liver tumors is a minimally invasive treatment of either primary hepatocellular carcinoma or metastatic disease to the liver
2) Radiofrequency ablation of liver tumors (CPT 47382) is covered on the liver cancer line
3) Evidence
    a. **NICE 2010,** guidance for treatment of liver metastases
        i. Current evidence on the safety of cryotherapy for the treatment of liver metastases appears adequate in the context of treating patients whose condition has such a poor prognosis, but the evidence on efficacy is inadequate in quality. Therefore cryotherapy for the treatment of liver metastases should only be used with special arrangements for clinical governance, consent and audit or research.
    b. **Bala 2013**, Cochrane review of cryotherapy for liver metastases
        i. 1 RCT, with high risk of bias
            1. 123 patients, randomized to cryotherapy or conventional surgery
            2. The patients were followed for up to 10 years (minimum five months). Mortality at the last follow-up was 81% (51/63) in the cryotherapy group and 92% (55/60) in the conventional surgery group (RR 0.88; 95% CI 0.77 to 1.02); that is, no statistically significant difference was observed.
            3. Recurrence in the liver was observed in 86% (54/63) of the patients in the cryotherapy group and 95% (57/60) of the patients in the conventional surgery group (relative risk (RR) 0.9; 95% CI 0.8 to 1.01); that is, no statistically significant difference was observed.
        ii. **Authors' conclusions** On the basis of one randomised clinical trial with high risk of bias, there is insufficient evidence to conclude if in patients with liver metastases from various primary sites cryotherapy brings any significant benefit in terms of survival or recurrence compared with conventional surgery. In addition, there is no evidence for the effectiveness of cryotherapy when compared with no intervention. At present, cryotherapy cannot be recommended outside randomised clinical trials.
    c. **Awad 2009**, Cochrane review of cryotherapy for hepatocellular carcinoma
        i. No trials identified
        ii. **Authors' conclusions** At present, there is no evidence to recommend or refute cryotherapy for patients with hepatocellular carcinoma. Randomised clinical trials with low-risk of bias may help in defining the role of cryotherapy in the treatment of hepatocellular carcinoma.
4) HERC staff recommendation: **Non-covered List**
    a. Experimental for both hepatocellular carcinoma and metastatic disease

November 2019

Treatment of Liver Metastases

Yttrium 90 therapy was discussed in 11/2019. High level evidence for the use of Yttrium 90 (RCT level evidence) exists only for use of Y90 as first line treatment for HCC. Y-90 treatment was limited to HCC only in GN185. The codes for Y-90 were added to the liver cancer line. Since 2019, the code descriptions have changed. In 2019, CPT 79445 was specific for HCC or CRC metastatic to the liver. Currently, CPT 79445 is "Radiopharmaceutical therapy, by intra-arterial particulate administration."

Current Prioritized List/Coverage status:

Line 157 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS
Contains no liver lesion treatment CPT codes

Diagnosis included on line 315 CANCER OF LIVER:
ICD-10-CM C22.9 Malignant neoplasm of liver, not specified as primary or secondary
ICD-10-CM C78.7 Secondary malignant neoplasm of liver and intrahepatic bile duct

Treatments included on line 315 CANCER OF LIVER:

CPT 36260-36262: placement, revision and removal of implantable intra-arterial infusion pump (eg, for chemotherapy of liver)
CPT 37243 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
CPT 47120-47130: Hepatectomy, resection of liver
CPT 47370 Laparoscopy, surgical, ablation of 1 or more liver tumor(s); radiofrequency
CPT 47371 Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical
CPT 47380 Ablation, open, of 1 or more liver tumor(s); radiofrequency
CPT 47381 Ablation, open, of 1 or more liver tumor(s); cryosurgical
CPT 47382 Ablation, 1 or more liver tumor(s), percutaneous, radiofrequency

GUIDELINE NOTE 78, HEPATIC METASTASES

Line 315

ICD-10-CM C78.7 Hepatic metastases are included on this line only when:

A) Treatment of the primary tumor is covered on a funded line in accordance with the criteria in Guideline Note 12 PATIENT-CENTERED CARE OF ADVANCED CANCER;
B) There are no other extrahepatic metastases; and,
C) The only treatment covered is hepatectomy/resection of liver (CPT codes 47120, 47122,47125 or 47130).

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:

Treatment of Liver Metastases

Procedure Code	Intervention Description	Rationale	Last Review
47383	Ablation, 1 or more liver tumor(s), percutaneous, cryoablation No evidence of effectiveness for both hepatocellular carcinoma and metastatic disease	No evidence of effectiveness for both hepatocellular carcinoma and metastatic disease	November, 2014

GUIDELINE NOTE 185, YTTRIUM-90 THERAPY

Line 315

Yttrium 90 therapy is only included on this line for treatment of hepatocellular carcinoma (HCC) and only when recommended by a multidisciplinary tumor board or team in the following circumstances:

A) Downsizing tumors in patients who could become eligible for curative treatment (transplant, ablation, or resection), OR

B) Palliative treatment of incurable patients with unresectable or inoperable tumors that are not amenable to ablation therapy and

1) who have good liver function (Child-Pugh class A or B) and
2) good performance status (ECOG performance status 0-2), and
3) who have intermediate stage disease with tumors > 5 cm OR advanced stage HCC with unilateral (not main) portal vein tumor thrombus

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

Treatment of Liver Metastases

Evidence:

Ablation vs liver resection

1) NICE 2020, treatment for metastatic colorectal cancer in the liver amenable to treatment with curative intent
    a. Evidence on ablation vs resection
        i. Very low quality evidence from 1 retrospective cohort study (N=138) showed no clinically important difference in overall survival between people who received RFA alone and those who underwent resection alone for metastatic colorectal cancer in the liver.
        ii. Quality of life
            1. No evidence was identified to inform this outcome.

Cryotherapy

1) **Bala 2019**, Cochrane review of cryotherapy for liver metastases
    a. Included only RCTs in their search strategy
    b. We found no randomized clinical trials comparing cryotherapy versus no intervention or versus systemic treatments
    c. We identified one randomized clinical trial comparing cryotherapy with conventional surgery. The trial included 123 participants with solitary, or multiple unilobar or bilobar liver metastases; 63 participants received cryotherapy and 60 received conventional surgery. The primary sites for the metastases were colon and rectum (66.6%), stomach (7.3%), breast (6.5%), skin (4.9%), ovaries (4.1%), uterus (3.3%), kidney (3.3%), intestines (1.6%), pancreas (1.6%), and unknown (0.8%). The trial was not reported sufficiently enough to assess the risk of bias of the randomization process, allocation concealment, or presence of blinding. It was also not possible to assess incomplete outcome data and selective outcome reporting bias. The certainty of evidence was low because of risk of bias and imprecision. The participants were followed for up to 10 years (minimum five months). The trial reported that the mortality at 10 years was 81% (51/63) in the cryotherapy group and 92% (55/60) in the conventional surgery group. The calculated by us relative risk (RR) with 95% Confidence Interval (CI) was: RR 0.88, 95% CI 0.77 to 1.02. We judged the evidence as low-certainty evidence.
    d. Regarding adverse events and complications, separately and in total, our calculation showed no evidence of a difference in recurrence of the malignancy in the liver: 86% (54/63) of the participants in the cryotherapy group and 95% (57/60) of the participants in the conventional surgery group developed a new malignancy (RR 0.90, 95% CI 0.80 to 1.01; low-certainty evidence). The frequency of reported complications was similar between the cryotherapy group and the conventional surgery group, except for postoperative pain. Both insignificant and pronounced pain were reported to be more common in the cryotherapy group while intense pain was reported to be more common in the conventional surgery group. There were no intervention-related mortality or bile leakages. We identified no evidence for health-related quality of life, cancer mortality, or time to progression of liver metastases.
    e. Authors' conclusions: The evidence for the effectiveness of cryotherapy versus conventional surgery in people with liver metastases is of low certainty. We are uncertain about our estimate and cannot determine whether cryotherapy compared with conventional surgery is beneficial or harmful. We found no evidence for the benefits or harms of cryotherapy compared with no intervention, or versus systemic treatments

Treatment of Liver Metastases

2) **Khanmohammadi 2023**, systematic review and meta-analysis of percutaneous cryoablation for liver metastases
    a. N=15 articles (692 patients)
        i. 9 retrospective cohort studies, 6 prospective cohort studies
        ii. Any type of metastatic cancer, colon cancer being the most common diagnosis
    b. Mean overall survival ranged from 14.5–29 months. The rate of local recurrence in the included studies ranged from 9.4% to 78%, and local control progression-free survival ranged from 1 to 31 months. One-year disease-free survival rate ranged from 58.3 to 63.6%, and the mean disease-free survival was between 3.67 and 7.74 months. One-, two-, and three-year overall survival rates were 56.3–92.3%, 31.3–71.9%, and 18.8–41% among the studies, and the mean overall survival ranged from 14.5–29 months
    c. The total QoL decreased one week after the cryoablation procedure (-3.08 [95% Confidence interval: -4.65, -1.50], p-value 7.39], p-value <0.01) and three months (3.75 [2.25, 5.24], p-value <0.01) after the procedure
    d. Increased liver enzymes (144), pain (140), fever (134), thrombocytopenia (59), pleural effusion (31), malaise (6), self-limited liver bleeding (2), grade1/2 complications (2), freezing sensation (1) pneumothorax (1), and biliary leak (1) were among the post-procedure complications
    e. Conclusion: Cryoablation is an effective procedure for the treatment of liver metastases, especially in cases that are poor candidates for liver resection. It could significantly improve QoL with favorable local recurrence.

Expert guidelines:

Colorectal cancer

1) **NCCN 2.2023** Colon cancer
    a. Resection is the standard approach for the local treatment of resectable metastatic disease. However, patients with liver or lung oligometastases can also be considered for tumor ablation therapy, particularly in cases that may not be optimal for resection. Ablative techniques include radiofrequency ablation (RFA), microwave ablation (MWA), cryoablation, and electro-coagulation (irreversible electroporation). There is extensive evidence on the use of RFA as a reasonable treatment option for non-surgical candidates and for recurrent disease after hepatectomy with small liver metastases that can be treated with clear margins.
    b. Data on ablative techniques other than RFA are growing. However, in a comparison of RFA with MWA, outcomes were similar with no local tumor progression for metastases ablated with margins greater than 10 mm (A0) and a relatively better control of perivascular tumors with the use of MWA (P = .021). Similarly, two studies and a position paper by a panel of experts indicated that ablation may provide acceptable oncologic outcomes for selected patients with small liver metastases that can be ablated with sufficient margins. In the same way, a 2018 systematic review confirmed that MWA provides oncologic outcomes similar to resection. Several publications have indicated that the significance of margin creation is particularly important for RAS-mutant metastases.
    c. Yttrium-90
        i. When hepatic metastatic disease is not optimally resectable based on insufficient remnant liver volume, approaches using preoperative portal vein

embolization, staged liver resection, or yttrium-90 radioembolization can be considered. Arterially directed catheter therapy, and in particular yttrium-90 microsphere selective internal radiation, is an option in highly selected patients with chemotherapy-resistant/-refractory disease and with predominant hepatic metastases

2) **Morris 2023**, ASCO guideline on the treatment of metastatic colorectal cancer
    a. Cytoreductive surgery (CRS) plus systemic chemotherapy may be recommended for selected patients with colorectal peritoneal metastases (Type: Evidence-based, benefits outweigh harms; Evidence quality: Moderate; Strength of recommendation: Weak).
        i. This recommendation applies to patients who have been deemed amenable to complete resection of colorectal peritoneal metastases, regardless of previous treatment, and who have no extraperitoneal metastases.
    b. Surgery with or without perioperative chemotherapy should be offered to patients with mCRC who are candidates for potentially curative resection of liver metastases (Type: Evidence-based, benefits outweigh harms; Evidence quality: Moderate; Strength of recommendation: Weak).

Ovarian cancer

1) **NCCN 2.2023** Ovarian Cancer
    a. Does not mention treatment of liver metastases

Neuroendocrine tumors

1) **NCCN 1.2023** Neuroendocrine and adrenal tumors
    a. For patients with locoregional advanced, liver-predominant, progressive disease or patients with poorly controlled carcinoid syndrome, liver-directed therapies are recommended, mainly with the palliative goals of extending life and relieving hormonal symptoms
    b. Cytoreductive surgery or ablative therapies such as radiofrequency ablation (RFA) or cryoablation may be considered if near-complete treatment of tumor burden can be achieved (category 2B). Ablative therapy in this setting is non-curative. Data on the use of these interventions are emerging. For unresectable liver metastases, hepatic regional therapy (arterial embolization, chemoembolization, or radioembolization [category 2B]) is recommended. No single modality of embolization therapy has been shown to be superior to another, but there is a difference in both long-term and short-term toxicities among the different modalities
    c. Liver-directed therapy consists of four categories of treatment:
        i. Surgical resection (which may include intraoperative thermal ablation of lesions);
        ii. Hepatic arterial embolization, including bland transarterial embolization [TAE], chemoembolization [TACE], and radioembolization [TARE]
        iii. Percutaneous thermal ablation
        iv. RT (SBRT/SABR)
    d. Percutaneous thermal ablation, often using microwave energy (radiofrequency and cryoablation are also acceptable), can be considered for oligometastatic liver disease, generally up to four lesions each smaller than 3 cm. Feasibility considerations include safe percutaneous imaging-guided approach to the target lesions, and proximity to vessels, bile ducts, or adjacent non-target structures that may require hydro- or aero-dissection for displacement.

e. Cytoreductive surgery of >90% of metastatic disease may provide symptomatic relief, prevent future symptoms, and improve progression-free survival for patients with functioning tumors. This strategy is particularly appropriate for patients with relatively indolent metastatic small bowel NETs, and less appropriate for patients in whom rapid progression of disease is expected after surgery. Patients who are symptomatic from hormonal syndromes, such as carcinoid syndrome, typically derive palliation from cytoreductive surgery.
f. Liver-directed therapies (eg, liver resection, thermal ablation, chemoembolization) for hepatic metastases from NETs following pancreatoduodenectomy are associated with increased risk for cholangitis and liver abscess.

Hepatocellular carcinoma

1) **NCCN 1.2023** Hepatocellular carcinoma
    a. "In an ablative procedure, tumor necrosis can be induced either by thermal ablation (RFA or MWA) or cryoablation. Ablative procedures can be performed by percutaneous, laparoscopic, or open approaches"
    b. The evidence review included in this NCCN guideline does not include any studies or evaluation of cryoablation. It is noted that that RFA and MWA have largely replaced other ablative techniques

Other payer policies:

1) Aetna 2023

a. Aetna considers the following as medically necessary when the following criteria are met:
b. Cryosurgery, microwave, or radiofrequency ablation for members with isolated colorectal cancer liver metastases or isolated hepatocellular cancer who are not candidates for open surgical resection when the selection criteria specified below are met. Members must fulfill *all* of the following criteria. Particular emphasis should be placed on criteria 2 and 3, which ensure that cryosurgery, microwave, or radiofrequency ablation is performed with curative intent.
    i. Members must either have hepatic metastases from a colorectal primary cancer or have a hepatocellular cancer; *and*
    ii. Members must have isolated liver disease. Members with nodal or extra-hepatic systemic metastases are not considered candidates for these procedures; *and*
    iii. All tumors in the liver, as determined by pre-operative imaging, would be potentially destroyed by cryotherapy, microwave, or radiofrequency ablation; *and*
    iv. Because open surgical resection is the preferred treatment, members must be unacceptable open surgical candidates due to the location or extent of the liver disease or due to co-morbid conditions such that the member is unable to tolerate an open surgical resection; *and*
    v. Liver lesions must be 4 cm or less in diameter and occupy less than 50 % of the liver parenchyma. Lesions larger than this may not be adequately treated by these procedures.
c. Aetna considers cryosurgery, microwave, or radiofrequency ablation of hepatic lesions experimental and investigational when these criteria are not met.

d. The following procedures are considered experimental and investigational because the effectiveness of these approaches has not been established
    i. Cryosurgery, microwave, or radiofrequency ablation as a treatment of hepatic metastases from non-colonic primary cancers;
    ii. Cryosurgical, microwave or radiofrequency ablation as a palliative treatment of either hepatic metastases from colorectal cancer or hepatocellular cancer

2) **Anthem BCBS 2023**, Locoregional Techniques for Treating Primary and Metastatic Liver Malignancies
    a. Medically Necessary:
        i. *Treatment of Hepatic Tumors (Primary or Metastatic)*
            1. Any of the following locally ablative techniques are considered medically necessary for individuals with *any* of the following conditions when *all* of the criteria below have been met:
                a. Techniques
                    i. Cryosurgical ablation; **or**
                    ii. Microwave ablation (MWA); **or**
                    iii. Percutaneous ethanol injection (PEI); **or**
                    iv. Radiofrequency (RFA)
                    and
                b. Conditions
                    i. Hepatocellular carcinoma; **or**
                    ii. Liver metastases from colorectal cancer; **or**
                    iii. Functioning neuroendocrine tumors
                    and
                c. Criteria
                    i. A poor candidate for surgical resection or unwilling to undergo surgical resection; **and**
                    ii. Each lesion measures no more than 5 cm in diameter; **and**
                    iii. No or minimal extra-hepatic metastases; **and**
                    iv. All foci of disease are amenable to ablative therapy or surgical resection.

Expert input:

Dr. Brett Sheppard, OHSU surgery

I just wanted to be sure we are reviewing metastatic disease to the liver (CRC, PNET) [Colorectal cancer, pancreatic/small bowel neuroendocrine tumors] and differentiate this from primary HCC or intra-hepatic cholangiocarcinoma.

For common metastatic disease to the liver (CRC, PNET), I would concur with you that OHP would be providing the best care possible by funding surgical resection and/or ablation (most of us have moved to microwave, some irreversible electroporation).

There is good data that shows even for non-functional PNET and NET that if they are able to have surgical debulking of at least 75% of their tumor they will reap a significant survival benefit.

Treatment of Liver Metastases

This can be completed with surgery +/- microwave ablation (MWA). It would be something to consider for our OHP patients.

I concur with you that cryoablation does not need to be covered. MWA can now generally accomplish the same and has a lower side effect profile than cryoablation and may be less expensive as procedure time may be shorter.

I agree with the revised guidelines. If you agree, after appropriate literature search, about my statement in regards to non-functional PNEt/NET then they would need to be modified

Treatment of Liver Metastases

HERC staff summary:

Expert guidelines recommend various interventions to treat liver metastases for colorectal tumors when a patient is not a good candidate for surgical resection. Such interventions are recommended when there are no metastases outside of the liver. Ablative techniques include radiofrequency ablation (RFA), microwave ablation (MWA), cryoablation, and electro-coagulation (irreversible electroporation). The best evidence for ablative techniques per NCCN is for RFA and MWA.

NCCN mentions ablation of liver metastases from neuroendocrine cancer as a "can be considered" option, noting that it is a palliative rather than curative treatment. However, NCCN mentions ablation of such liver metastases as being helpful for patients who are symptomatic from hormonal syndromes caused by the neuroendocrine tumor. Local experts recommend coverage for neuroendocrine tumors liver metastases that are functional (i.e. producing hormones that are causing symptoms).

The evidence for percutaneous cryotherapy of liver metastases is poor, consisting only of relatively small prospective and retrospective cohorts. There is one small RCT on any type of cryoablation of liver metastases (cryoresection, cryoreduction, croyextirpation).

Private insurers cover treatment of certain types of cancer with liver metastases (colorectal, with some covering neuroendocrine as well) with cryosurgery, microwave, or radiofrequency ablation. This coverage is limited to metastatic disease isolated to the liver when the patient is a poor candidate for surgical resection.

HERC staff recommend clarifying GN78. First, the intent appears to be to allow surgical resection of any type of liver metastases (any primary tumor) as long as the metastases are isolated to the liver. Second, additional ablative procedures (radiofrequency ablation, microwave ablation) should be allowed only for hepatocellular carcinoma, colorectal cancer metastatic to the liver, and functional neuroendocrine tumors metastatic to the liver. In the case of metastatic disease, coverage should be limited to patients who have only liver metastases present and only when the patient is not a candidate for surgical resection.

HERC staff recommend continuing non-coverage of percutaneous cryoablation, and adding surgical cryoablation to the line 662/GN173 entry as the evidence of effectiveness is poor. NCCN notes that RFA and MWA are generally considered the treatments of choice for ablative procedures for hepatocellular carcinoma and colorectal cancer metastatic in the liver.

Yttrium-90 treatment only has high level of evidence of effectiveness for treatment of HCC. NCCN includes as an option in certain clinical scenarios with metastatic colorectal cancer.

HERC staff recommendations:

1) Remove the following CPT codes from line 315 CANCER OF LIVER and add to line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
    a. CPT 47371 Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical
    b. CPT 47381 Ablation, open, of 1 or more liver tumor(s); cryosurgical
2) Modify the GN173 entry regarding cryosurgical treatment of liver tumors as shown below
3) Modify GN78 as shown below

Treatment of Liver Metastases

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
47371, 47381, 47383	Ablation, 1 or more liver tumor(s), percutaneous, cryoablation	No evidence of effectiveness for both hepatocellular carcinoma and metastatic disease	~~November, 2014~~ September 2023

GUIDELINE NOTE 78, HEPATIC METASTASES

Line 315

~~ICD-10-CM C78.7~~ Hepatectomy/resection (CPT codes 47120, 47122,47125 or 47130) of hepatic metastases (ICD-10-CM C22.9 Or C78.7) are included on this line only when there are no other extrahepatic metastases.

A) ~~Treatment of the primary tumor is covered on a funded line in accordance with the criteria in Guideline Note 12 PATIENT-CENTERED CARE OF ADVANCED CANCER;~~
B) ~~There are no other extrahepatic metastases; and,~~
C) ~~The only treatment covered is hepatectomy/resection of liver (CPT codes 47120, 47122,47125 or 47130).~~

Microwave and radiofrequency ablation (CPT 47340, 47389, 47382) are included on this line only when ALL of the following criteria are met:

A) Treatment is for colorectal cancer liver metastases, functioning neuroendocrine tumors or hepatocellular cancer; AND
B) There are no extrahepatic metastases; AND
C) The patient is not a candidate for open surgical resection due to the location or extent of the liver disease or due to co-morbid conditions such that the member is unable to tolerate an open surgical resection; AND
D) All tumors in the liver, as determined by pre-operative imaging, would be potentially destroyed by cryotherapy, microwave, or radiofrequency ablation; AND
E) Liver lesions must be 4 cm or less in diameter and occupy less than 50 % of the liver parenchyma.

Yttrium-90 therapy (CPT 79445) is only covered for treatment of hepatocellular carcinoma as specified in GUIDELINE NOTE 185, YTTRIUM-90 THERAPY.

Foot and Toenail Care for Patients in Facilities

Plain Language Summary:

Coverage question: Should OHP cover nail and foot care for people who live in nursing homes?

Should OHP cover this treatment? Certain conditions should be covered because active fungal infections in a nursing home can be passed from patient to patient and is a public health issue.

Coverage Question: Should foot and toenail care be covered for patients in skilled nursing and similar facilities?

Question source: Dr. Shazad Buksh, podiatrist

Background: HERC staff recently conducted a community listening session. One issue that was raised was regarding lack of coverage for foot and toenail care for patients living in nursing facilities. This issue was also raised last year when staff met with advocates for aging services.

From the June 2023 HERC staff listening session:

> Dr. Buksh, a podiatrist, spoke about lack of access to foot and nail care in skilled nursing facilities, rehabilitation facilities and similar settings. He spoke about the importance of treating nail conditions such as onychomycosis in these settings to both prevent spread and reduce the risk of secondary infections and subsequent adverse outcomes. Dr. Buksh requested consideration of coverage for toenail care, toenail biopsies and lab testing, antifungal medications, and toenail debridement for patients in care facilities. Dr. Buksh argued that fungal infections in facilities can be passed from patient to patient, making non-coverage of treatment a public health issue. Non-treatment also leads to increased risk of abscesses, bleeding, and cellulitis. He specifically was interested in coverage of patients in skilled nursing and rehabilitation facilities, but also noted that this is a problem in homeless shelters and other group settings. Specific codes mentioned for coverage include ICD-0-CM B35.1 (Tinea unguium), toenail biopsy and debridement procedures, and medications such as topical and oral antifungals.

Currently, foot care is covered for patients at high risk for foot complications from diabetes, neuropathy, and similar conditions. Tinea unguium (toenail fungus) is currently only on an uncovered line.

In conversations with other parts of HSD, HERC staff were informed that medications and procedures can be evaluated and approved based on coding indicating place of service, such as a skilled nursing facility. Such evaluation would need to be part of a prior authorization process. There are ICD-10-CM codes such as Y92.10 (Unspecified residential institution as the place of occurrence of the external cause) that could be used as a secondary code to allow automation of claims if that is preferred.

Foot and Toenail Care for Patients in Facilities

This issue was part of the early packet for additional public comment. As part of that process, coverage of dystrophic nails (ICD-10-CM L60.2 and L60.3) was raised as other conditions that cause pain, difficulty ambulation, and increased risk of infection.

Previous HSC/HERC reviews:

Nail care for patients in facilities has not been discussed in at least the past 10 years

Current Prioritized List/Coverage status:

Line:	**165**
Condition:	PREVENTIVE FOOT CARE IN HIGH-RISK PATIENTS
Treatment:	MEDICAL AND SURGICAL TREATMENT OF TOENAILS AND HYPERKERATOSES OF FOOT
ICD-10:	E08.40-E08.42,E08.51-E08.52,E08.621,E09.40-E09.42,E09.51-E09.52,E09.621,E10.40-E10.42,E10.51-E10.52,E10.621,E11.40-E11.42,E11.49-E11.59,E11.621,E11.628,E13.40-E13.42,E13.44,E13.51-E13.52,E13.621,G60.0-G60.8,G61.0-G61.1,G61.81-G61.9,G62.0-G62.2,G62.81-G62.9,I70.201-I70.299,Z86.31
CPT:	11055-11057,11719-11732,11750,98966-98972,99051,99060,99070,99078,99202-99215,99341-99350,99366,99374,99375,99381-99404,99411-99417,99421-99449,99451,99452,99487-99491,99495-99498,99605-99607
HCPCS:	G0068,G0071,G0088,G0090,G0245-G0250,G0318,G0323,G0463,G0466,G0467,G0490,G0511,G2012,G2211,G2214,G2251-G3003

ICD-10-CM B35. 1 (Tinea unguium) is on line 489 DERMATOPHYTOSIS OF NAIL, GROIN, AND FOOT AND OTHER DERMATOMYCOSIS. This code is used for onychomycosis

ICD-10-CM L60.3 (Nail dystrophy) and L60.2 (Onychogryphosis) are on line 587 DISEASE OF NAILS, HAIR AND HAIR FOLLICLES

CPT 11055-11057 (Paring or cutting of benign hyperkeratotic lesion (eg, corn or callus)) are on lines 165,235,555,589,613,625

CPT 11720-11721 (Debridement of nails) are on lines 137 OPPORTUNISTIC INFECTIONS IN IMMUNOCOMPROMISED HOSTS; CANDIDIASIS OF STOMA; PERSONS RECEIVING CONTINUOUS ANTIBIOTIC THERAPY, 165 PREVENTIVE FOOT CARE IN HIGH-RISK PATIENTS, 489 ERMATOPHYTOSIS OF NAIL, GROIN, AND FOOT AND OTHER DERMATOMYCOSIS, 587 DISEASE OF NAILS, HAIR AND HAIR FOLLICLES

CPT 11730-11732 (Avulsion of pail plate, partial or complete) are on lines 165, 205, 207,289,489,587

CPT 11750 (Excision of nail and nail matrix, partial or complete (eg, ingrown or deformed nail), for permanent removal) is on lines 165,205,207,489,587

Foot and Toenail Care for Patients in Facilities

CPT 11755 (Biopsy of nail unit (eg, plate, bed, matrix, hyponychium, proximal and lateral nail folds) (separate procedure)) is on line 587 DISEASE OF NAILS, HAIR AND HAIR FOLLICLES

HCPCS G0127 (Trimming of dystrophic nails, any number) is listed as never reviewed

Evidence:

1) **Leung 2020**, review of onychomycosis
    a. The diagnosis can be confirmed by direct microscopic examination with a Potassium Hydroxide (KOH) wet-mount preparation, histopathologic examination of the trimmed affected nail plate with a Periodic-Acid-Schiff (PAS) stain, fungal culture, or Polymerase Chain Reaction (PCR) assays. The ideal test would identify the fungus and the species, determine its viability, be easy to perform with rapid result and low cost, and be highly specific and sensitive
    b. Treatment options include oral antifungal therapy, topical antifungal therapy, laser therapy, photodynamic therapy, and surgical avulsion (e.g. very thick and chronic fungal nail).
    c. There is an increased risk for bacterial infections such as cellulitis and paronychia, especially in immunocompromised individuals including diabetics [36, 88]. Severe onychomycosis may interfere with standing, walking, nail function, and daily activities [11, 53]. The condition, if left untreated, may cause discomfort, pain, paresthesia, nail deformities such as transverse over-curvature, difficulties in trimming thick nail plates, difficulties in fitting shoes, and low self-esteem

Other payer policies:

1) CMS Routine Foot Care and Debridement of Nails 2021
    a. The Medicare program generally does not cover routine foot care. However, this determination outlines the specific conditions for which coverage may be present.
    b. The following services are considered to be components of routine foot care, regardless of the provider rendering the service:
        i. Cutting or removal of corns and calluses;
        ii. Clipping, trimming, or debridement of nails, including debridement of mycotic nails;
        iii. Shaving, paring, cutting or removal of keratoma, tyloma, and heloma;
        iv. Non-definitive simple, palliative treatments like shaving or paring of plantar warts which do not require thermal or chemical cautery and curettage;
        v. Other hygienic and preventive maintenance care in the realm of self care, such as cleaning and soaking the feet and the use of skin creams to maintain skin tone of both ambulatory and bedridden patients;
        vi. Any services performed in the absence of localized illness, injury, or symptoms involving the foot.
    c. Medicare payment may be made for routine foot care when the patient has a systemic disease, such as metabolic, neurologic, or peripheral vascular disease, of sufficient severity that performance of such services by a nonprofessional person would put the

patient at risk (for example, a systemic condition that has resulted in severe circulatory embarrassment or areas of desensitization in the patient's legs or feet).

d. Treatment of mycotic nails may be covered under the exceptions to the routine foot care exclusion. The class findings, outlined below, or the presence of qualifying systemic illnesses causing a peripheral neuropathy, must be present. Payment may be made for the debridement of a mycotic nail (whether by manual method or by electrical grinder) when definitive antifungal treatment options have been reviewed and discussed with the patient at the initial visit and the physician attending the mycotic condition documents that the following criteria are met:
    i. In the absence of a systemic condition, the following criteria must be met:
        1. In the case of ambulatory patients there exists:
            a. Clinical evidence of mycosis of the toenail, and
            b. Marked limitation of ambulation, pain, and/or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.
        2. In the case of non-ambulatory patients there exists:
            a. Clinical evidence of mycosis of the toenail, and
            b. The patient suffers from pain and/or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.

e. In addition, procedures for treating toenails are covered for the following:
    i. Onychogryphosis (defined as long-standing thickening, in which typically a curved hooked nail (ram's horn nail) occurs), and there is marked limitation of ambulation, pain, and/or secondary infection where the nail plate is causing symptomatic indentation of or minor laceration of the affected distal toe; and/or
    ii. Onychauxis (defined as a thickening (hypertrophy) of the base of the nail/nail bed) and there is marked limitation of ambulation, pain, and/or secondary infection that causes symptoms.

f. The following physical and clinical findings, which are indicative of severe peripheral involvement, must be documented and maintained in the patient record, in order for routine foot care services to be reimbursable.
    i. <u>Class A findings</u>
    Non-traumatic amputation of foot or integral skeletal portion thereof
    ii. <u>Class B findings</u>
    Absent posterior tibial pulse
    Advanced trophic changes as evidenced by any three of the following:
        1. hair growth (decrease or increase)
        2. nail changes (thickening)
        3. pigmentary changes (discoloring)
        4. skin texture (thin, shiny)
        5. skin color (rubor or redness);and
        6. Absent dorsalis pedis pulse
    iii. <u>Class C findings</u>
    Claudication
    Temperature changes (e.g., cold feet)
    Edema

Paresthesias (abnormal spontaneous sensations in the feet)
Burning

g. The presumption of coverage may be applied when the physician rendering the routine foot care has identified:
    i. A Class A finding
    ii. Two of the Class B findings; or
    iii. One Class B and two Class C findings.
h. Note: Benefits for routine foot care are also available for patients with peripheral neuropathy involving the feet, but without the vascular impairment outlined in Class B findings. The neuropathy should be of such severity that care by a non-professional person would put the patient at risk. If the patient has evidence of neuropathy but no vascular impairment, the use of class findings modifiers is not necessary. This condition would be represented by the appropriate ICD-10-CM code being included on the claim.

2) Aetna 2023

a. Routine foot care is not covered under most of Aetna plans. Please check benefit plan descriptions for details. Under plans that exclude routine foot care, foot care is considered non-routine and covered only in the following circumstances when medically necessary:
    i. The non-professional performance of the service would be hazardous for the member because of an underlying condition or disease; *or*
    ii. Routine foot care is performed as a necessary and integral part of an otherwise covered service (e.g., debriding of a nail to expose a subungual ulcer, or treatment of warts); *or*
    iii. Debridement of mycotic nails is undertaken when the mycosis/dystrophy of the toenail is causing secondary infection and/or pain, which results or would result in marked limitation of ambulation and require the professional skills of a provider.

3) Cigna 2023

a. Coverage for routine foot care, including the paring and removing of corns and calluses or trimming of nails, varies across plans. Please refer to the customer's benefit plan document for coverage details. Foot care services are considered medically necessary when EITHER of the following criteria is met:
    i. The foot care services that are associated with systemic conditions that are significant enough to result in severe circulatory insufficiency and/or areas of desensitization in the lower extremities, including, but not limited to, ANY of the following:
        1. diabetes mellitus
        2. peripheral vascular disease
        3. peripheral neuropathy
    ii. Evaluation/debridement of mycotic nails, in the absence of a systemic condition, when BOTH of the following conditions are met:
        1. There is pain or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.
        2. If ambulatory, there is pain to a degree that there is difficulty walking and/or abnormality of gait.

Foot and Toenail Care for Patients in Facilities

Expert input:

Dr. Chris Seuferling, podiatrist
Recommended not requiring biopsy or culture to prove a fungal infection, as typically this condition can be diagnosed clinically and the additional cost of such testing is not necessary and invasive testing caries risks.

Public Comment Disposition

Commenter	Comment	Staff response
Oregon Podiatric Medical Association Board member comments	ICD-10 codes of L60.3 [Nail dystrophy] and L60.2 [Onychogryphosis] should be included and [HCPCS] code G0127 [Trimming of dystrophic nails, any number] Rationale: • Debridement of mycotic nails is undertaken when the mycosis/dystrophy of the toenail is causing secondary infection and/or pain, which results or would result in marked limitation of ambulation and require the professional skills of a provider. • Coverage for routine foot care, including the paring and removing of corns and calluses or trimming of nails, varies across plans….. There is pain or secondary infection resulting from the thickening and dystrophy of the infected toenail plate. • If ambulatory, there is pain to a degree that there is difficulty walking and/or abnormality of gait.	Review of other payer policies finds that these diagnoses and treatment are covered for the same indications as onychomycosis. Staff have revised the recommendations in this issue to include these diagnosis and treatment codes.
Lisa Nakadate Executive Director Oregon Podiatric Medical Association	I am writing to voice the Oregon Podiatric Medical Association's support for the proposed changes to the Oregon Health Plan coverage which would allow nail care for individuals who live in skilled nursing facilities. This is a sensitive population which often lacks access to foot and nail care. Including nail coverage for our elderly patients will have a dramatic effect on their quality of life, keeping them mobile and healthy. In addition, it will help prevent the spread of infection and reduce the risk of secondary infections	Thank you for your comment

	and adverse outcomes. Having access to foot and nail care will lead to better health outcomes and healthier patients. Thank you for considering these changes to OHP coverage. We are in full support of them and appreciate the opportunity to comment.	

Foot and Toenail Care for Patients in Facilities

HERC staff summary:

Two community listening opportunities have brought up problems with lack of coverage for routine foot and toenail care for patients in nursing and other care facilities. In particular, lack of coverage for treatment of toenail fungus has been raised as an issue. Medicare allows coverage for toenail fungus, as well as for routine nail care in certain high risk patient categories. Additional public comment recommended adding coverage for dystrophic nails and onychogryphosis, which lead to pain, difficulty ambulating, and increased risk of infection. Private insurers vary on whether they have any coverage for foot related care.

HERC staff recommendations:

1) Add ICD-10-CM B35. 1 (Tinea unguium), L60.2 (Onychogryphosis), and L60.3 (Nail dystrophy) to line 165 PREVENTIVE FOOT CARE IN HIGH-RISK PATIENTS
    a. Line 165 contains CPT codes for pairing/cutting of corns and calluses, debridement of nails, and avulsion of nail plates
2) Add CPT 11755 (Biopsy of nail unit (eg, plate, bed, matrix, hyponychium, proximal and lateral nail folds) (separate procedure)) to line 165
3) Add HCPCS G0127 (Trimming of dystrophic nails, any number) to line 165
4) Adopt a new guideline regarding testing and treatment of tinea unguium and dystrophic nails as shown below

GUIDELINE NOTE XXX HIGH RISK FOOT CARE

Lines 165, 489

Foot care by a medical professional, including pairing and cutting of corns and calluses, debridement of nails, avulsion of nail plates, trimming of dystrophic nails, and biopsy of nails, is included on line 165 only when:

1) The patient is at high risk for complications from nail and foot problems due to a systemic condition that has resulted in severe circulatory insufficiency and/or areas of desensitization in the lower extremities; OR
2) The patient resides in a skilled nursing facility, rehabilitation facility, group home or similar institutional setting.

Evaluation for and treatment of tinea unguium (ICD-10-CM B35.1) including biopsy of nails, nail paring, and treatment with topical or oral antifungal medications is included on line 165 only when:

1) The patient is in one of the two high risk groups identified above; AND
2) There is clinical evidence of mycosis of the toenail; AND
3) The patient has documented marked limitation of ambulation, pain, and/or secondary bacterial infection resulting from the thickening and dystrophy of the infected toenail plate.

Otherwise, evaluation and treatment of tinea unguium is included on line 489.

Central Auditory Function Testing

Plain Language Summary:

Coverage question: Should OHP cover testing for a condition that makes it difficult for a person to understand speech and follow instructions, especially when there is a lot of noise around.

Should OHP cover this treatment? No. The problem is a bit unclear, and even the experts can't decide on a consistent way to identify it. There are no widely accepted tests, and there are no medications for this condition. Other health plans are not covering this condition.

Coverage Question: Should evaluation of central auditory function be covered?

Question source: Holly Jo Hodges, CCO medical director

Background: According to the American Speech-Language Hearing Association (ASHA), central auditory processing disorder (CAPD), also known as auditory processing disorder, refers to difficulties in the perceptual processing of auditory information in the central nervous system (CNS). CAPD is a complex and heterogeneous group of auditory-specific disorders, usually associated with a range of listening and learning deficits. Children or adults suspected of CAPD may exhibit a variety of listening and related complaints such as difficulty understanding speech in noisy environments, following directions, and discriminating (or telling the difference between) similar-sounding speech sounds.

The diagnosis, management, and even the existence of a modality-specific dysfunction remains controversial. At this time, there is no universally accepted method of screening for CAPD. No pharmacologic agent has been demonstrated as effective specifically for CAPD. Interventions for CAPD focuses on improving the quality of the acoustic signal and the listening environment, improving auditory skills, and enhancing utilization of metacognitive and language resources.

Previous HSC/HERC reviews:

Only one previous review of central auditory function testing was found.

HOSC January 2005

92620/92621 Evaluation of central auditory function: Has been covered for years, but response from expert regarding why/when it is used, states they are no longer doing this test. No response from person question referred to. Per Marsha Becker-Meier, old code rarely used.

Action: Add to non-OHP services list

No discussion was found related to the diagnosis H93.25 (Central auditory processing disorder) in any minutes from HSC/HOSC or VBBS/HERC.

Central Auditory Function Testing

Current Prioritized List/Coverage status:

ICD-10-CM H93.25 (Central auditory processing disorder) is on line 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS

CPT 92620 Evaluation of central auditory function, with report; initial 60 minutes
CPT 92621 Evaluation of central auditory function, with report; each additional 15 minutes

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
92620-92621	Evaluation of central auditory function	Insufficient evidence of effectiveness	January 2005

Evidence:

1) **Moore 2011**, review on the diagnosis and management of auditory processing disorder
    a. Currently, APD is ill defined, and training-based interventions appear to have limited effectiveness
    b. Testing is confounded by issues of attention and memory
    c. I am unaware of any study that has examined the efficacy of auditory training for the management of APD without a concurrent diagnosis of speech and language difficulties, and that appeared to be true also for the 23 papers reviewed by Fey et al. (2011) in the clinical forum
2) **Fey 2011**, systematic review of auditory processing disorder interventions
    a. N=25 studies (121 subjects)
    b. The bases for diagnosis of APD in these studies generally was teacher concern for listening and related academic abilities or low overall performance on one or a battery of tests, usually including the Staggered Spondaic Word Test (SSW; Katz, Basil, & Smith, 1963), the SCAN-C Test for Auditory Processing Disorders in Children—Revised (Keith, 1999), and tests of speech in noise
    c. The interventions included “traditional listening” treatments, AIT, Fast ForWord, and Earobics
    d. Some support exists for the claim that auditory and language interventions can improve auditory functioning in children with APD and those with primary spoken language disorder. There is little indication, however, that observed improvements are due to the auditory features of these programs. Similarly, evidence supporting the effects of these programs on spoken and written language functioning is limited
    e. Conclusion: The evidence base is too small and weak to provide clear guidance to speech-language pathologists faced with treating children with diagnosed APD

Central Auditory Function Testing

Expert guidelines:

1) **Heine 2015**, systematic review of clinical practice guidelines for CAPD
    a. there is currently no universally accepted definition of CAP and CAPD and no consensus regarding assessment, diagnosis or treatment of this disorder.
    b. 6 guidelines identified
        i. American Academy of Audiology Clinical Practice Guidelines (see below); American Speech and Hearing Association (ASHA) (Central) Auditory Processing Disorders technical report; British Society of Audiology, Position Statement Auditory Processing Disorder (APD); Canadian guidelines on auditory processing disorder in children and adults: Assessment and Intervention; Colorado Department of Education, Auditory Processing Disorders: A team approach to screening, assessment & intervention practices; and the British Society of Audiology Practice Guidance
    c. Many guidelines do not reference the level of evidence supporting a recommendation
2) **Iliadou 2017**, European consensus on auditory processing disorder
    a. Auditory processing evaluation in the clinical setting is largely based on psychoacoustic test batteries of verbal and non-verbal stimuli and may be ancillary completed with electrophysiological or objective audiological measures, such as acoustic reflex thresholds, tympanometry, ABR (speech and noise ABR included), or OAEs (suppression included)
    b. The interventions should be as individualized as possible addressing (i) environmental modifications, (ii) use of FM systems, and (iii) systematic auditory training. Management needs to be multidisciplinary, and it is important that this is implemented in the educational environment for affected individuals who are still in education
3) **American Academy of Audiology 2010**, clinical practice guideline for the diagnosis, treatment and management of children and adults with central auditory processing disorder
    a. Expert taskforce developed
    b. Audiologists, related professionals, and clinical scientists generally agree that some of the tests for (C)APD in current clinical use lack rigorous psychometric design, construction, and validation. Populations “suspected” or “presumed” have (C)APD (e.g., those with learning disabilities, reading problems, or attention deficits) cannot be used to determine validity, efficiency, or clinical norms for diagnostic tests of central auditory processing. Similarly, speech-language, psychological, and other tests cannot be used to diagnose (C)APD, even if the term “auditory processing” is included in their titles or subtest descriptions.
    c. Efforts to develop new clinical measures of (C)APD and refine existing procedures must include systematic assessment of test performance and the implementation of accepted principles of psychometric test construction. Substantial evidence regarding test performance (e.g., reliability, validity, sensitivity, and specificity) is lacking for some of the commonly used tests of central auditory processing
    d. Historically, there has been considerable debate as to the appropriate “gold standard” for (C)APD and other disorders (e.g., language) in children
    e. . Given the complexity and redundancy of the central auditory system, accurate diagnosis typically requires the administration of more than one test; however, while sensitivity may be improved by increasing the number of tests in the battery, the administration of too many central auditory tests may compromise specificity

Central Auditory Function Testing

Other payer policies:

1) **Aetna 2023**
    a. Aetna considers any diagnostic tests or treatments for the management of auditory processing disorder (APD) (previously known as central auditory processing disorder (CAPD)) experimental and investigational because there is insufficient scientific evidence to support the validity of any diagnostic tests and the effectiveness of any treatment for APD.
2) **Excellus BCBS 2022**
    a. Based upon our criteria and assessment of the peer-reviewed literature, auditory processing disorder (APD) testing is considered not medically necessary, as it does not improve patient outcomes, and there is insufficient evidence to support the validity of the diagnostic tests utilized in diagnosing an auditory processing disorder

Public comment disposition

No public comments were received during the early packet public comment period.

Central Auditory Function Testing

HERC staff summary: Central auditory processing disorder is a vaguely defined condition with no consensus on diagnostic criteria. There is no universally accepted method of screening for CAPD. No pharmacologic agent has been demonstrated as effective specifically for CAPD. Behavioral and other interventions for CAPD have limited, if any, evidence of effectiveness. No private payer with an identifiable policy on CAPD covered testing or treatment for the condition.

HERC staff recommendations:

1) Make no change to the current placement of evaluation for central auditory function (CPT 92629 and 92621)
    a. Update the date of last review in GN173 as shown below
2) Delete ICD-10-CM H93.25 (Central auditory processing disorder) from line 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS and add to line 655 NEUROLOGIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

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**
92620-92621	Evaluation of central auditory function	Insufficient evidence of effectiveness	~~January 2005~~ November 2023

Photoscreening 2023

Plain Language Summary:

Coverage question: Should OHP cover a test (photoscreening) that checks a child's vision using a special camera instead of an eye chart? It helps find out how well a child can see.

Should OHP cover this test?
Option 1: No. This test is not as cost-effective as using an eye chart for screening.
Option 2: Yes, cover this test because experts recommend it.

Coverage Question: Should coverage be added for instrument-based ocular screening for children?

Question source: Holly Jo Hodges, CCO medical director

Background: Photoscreening is a form of pediatric vision screening that uses a special-purpose camera to determine how well a child can see. It is an alternative to visual acuity-based screening with an eye chart. By detecting special light reflexes from each eye the devices produce images that can help identify refractive errors (like a prescription for glasses) and ocular misalignments (strabismus). When present, these conditions place a child at risk for amblyopia (lazy eye). Photoscreening is particularly useful with pre-verbal children (under age 3 yrs), young children (age 3-5 yrs) and older, non-cooperative or non-verbal children. As such, photoscreening offers an alternative to traditional visual acuity screening, providing earlier detection of potential vision problems than has been possible with traditional testing.

The USPSTF (2011) recommends vision screening for all children at least once between the ages of 3 and 5 years, to detect the presence of amblyopia or its risk factors (grade B recommendation). The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of vision screening for children <3 years of age (I statement). The USPSTF lists photoscreening as one option for vision screening. Per the USPSTF statement from 2017: "Various screening tests are used in primary care to identify vision abnormalities in children, including the red reflex test, the cover-uncover test, the corneal light reflex test, visual acuity tests (such as Snellen, LEA Symbols, and HOTV charts), autorefractors and photoscreeners, and stereoacuity tests."

Previous HSC/HERC reviews:

Photoscreening was reviewed in 2015. An older USPSTF report (Chou 2011) and older AAP guideline (2012) were reviewed at that time. The staff conclusion was "Early vision screening is recommended by major evidence based organizations; however, clinical exam and standard eye chart testing appears to be sufficient. Photoscreening and similar technology needs to be further studied before widespread implementation." Photoscreening was excluded for coverage.

Photoscreening was again discussed in 2019. During that review, the 2017 USPSTF report and the 2016 AAP guidelines were reviewed. The AAP guideline listed instrument-based screening as listed as one option "when available" with other options being physical exam and standard of care being eye chart testing. Based on these recommendations, photoscreening was placed on line 502, as more expensive than other equally effective tests.

Photoscreening 2023

Current Prioritized List/Coverage status:

CPT 99174 Instrument-based ocular screening (eg, photoscreening, automated-refraction), bilateral; with remote analysis and report
CPT 99177 (Instrument based ocular screening (eg, photoscreening, automated-fractions),bilateral; with onsite analysis)

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

Line 502

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

Procedure Code	Intervention Description	Rationale	Last Review
99174, 99177	Photoscreening	More costly than equally effective methods of screening	May 2019

Evidence:

1) **Horwood 2021,** systematic review on photoscreening cost-effectiveness
    a. N=60 papers
    b. Only 13% of studies reported actual amblyopia detection as an outcome
    c. Reporting of follow up rates and long-term outcomes were poor or absent
    d. PPVs even for risk factors, not actual amblyopia or reduced vision, varied widely from 19% to >80%, but were generally lowest in the youngest children. Referral rates were particularly high in very young children e.g. 19% at 6–9 months, 20% at 9–36 months, 16% at < 12 months, but often did not result in immediate treatment. One study reported that only 11% of 123 children under 36 months referred received any intervention, compared to a 74% in children over 36 months
    e. Photoscreening is being widely adopted, and in many different ways, but with poor availability of local, regional or national protocols, audit or monitoring of long-term outcomes or costs. There is weak evidence of optimum timing, frequency, or referral criteria to maximize outcomes whilst minimizing monetary and societal costs. Despite published guidelines there is still no clear evidence what level of refractive error constitutes an amblyopia risk-factor at different ages, or the optimum time to treat risk factors
    f. Evidence that photoscreening reduces amblyopia or strabismus prevalence or improves overall outcomes is weak, as is evidence of cost-effectiveness, compared to later visual acuity (VA) screening. Currently, the most cost-effective option seems to be a later, expert VA screening with the opportunity for a re-test before referral.
2) **Jonas 2017**, Evidence review for the USPSTF report on vision screening
    a. 11 studies reported on photoscreeners (6 studies on MTI photoscreener, 2 on iScreen, 2 on Visiscreen, 2 on Otago Photoscreener, 1 on off-axis-type photoscreener)

   i. Sensitivity for amblyopia ranged from 0.37-0.95
   ii. Specificity for amblyopia ranged from 0.89-1.0
b. Eleven fair-quality studies (6187 observations; n = 63-3121) assessed photoscreeners. Generally, most studies reported moderate positive likelihood ratios and small negative likelihood ratios. Many of the studies evaluating photoscreeners enrolled children younger than 3 y

Expert guidelines:

1) **American Academy of Ophthalmology and the American Association for Pediatric Ophthalmology and Strabismus 2022,** Joint policy statement on vision screening for infants and children
   a. Photoscreening and handheld autorefraction may be electively performed in children 12 months to 3 years of age, allowing earlier detection of conditions that may lead to amblyopia. Photoscreening and handheld automated refraction are recommended as an alternative to visual acuity screening with vision charts (typically used for children 3 through 5 years of age) and in children who are unable or unwilling to cooperate with routine acuity screening with vision charts (but are not superior to vision chart testing for children able to participate). The use of vision charts to assess amblyopia in children 3 to 5 years of age remains a viable practice at the present time.
2) **Donohue 2016**, Committee on Practice and Ambulatory Medicine, American Academy of Pediatrics; Section on Ophthalmology, American Academy of Pediatrics; American Association of Certified Orthoptists; American Association for Pediatric Ophthalmology and Strabismus; American Academy of Ophthalmology. Procedures for the evaluation of the visual system by pediatricians
   a. If available, instrument-based screening can be attempted beginning at age 12 months,11 and a previous study has demonstrated better eventual outcomes for children undergoing their first photoscreening before 2 years of age
   b. Once children can read an eye chart easily, optotype-based acuity should supplement instrument-based testing. The actual age for this is not yet well established and likely varies depending on the child
   c. Photoscreening has been shown to have high sensitivity and specificity in community and office settings.
3) **USPSTF 2017**, Vision Screening in Children Aged 6 Months to 5 Years US Preventive Services Task Force Recommendation Statement
   a. The USPSTF recommends vision screening at least once in all children aged 3 to 5 years to detect amblyopia or its risk factors. (B recommendation) The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of vision screening in children younger than 3 years. (I statement)
   b. Screening tests listed: Various screening tests are used in primary care to identify vision abnormalities in children, including the red reflex test, the cover-uncover test, the corneal light reflex test, visual acuity tests (such as Snellen, LEA Symbols, and HOTV charts), autorefractors and photoscreeners, and stereoacuity tests.

Other payer policies:

Aetna and Cigna both consider photoscreening to be required as a USPSTF level B recommendation

Photoscreening 2023

Expert input:

Lorri Wilson, OHSU pediatric ophthalmology

> I think one important piece of information to consider is eye chart vision screens are not possible (or very difficult) to obtain accurately in children less than 5 (certainly less than 3 years old) or older nonverbal/noncooperative children, but earlier diagnosis and treatment of amblyopia leads to better outcomes.

Leah Reznick, OHSU pediatric ophthalmology

> Anecdotally, the photoscreening has made a huge difference in early detection of amblyopia and strabismus. From being in practice before and after the incorporation of photo-screeners, children from my referring practices who have photoscreening have significantly better visual outcomes (earlier detection of significantly decreased vision, cataracts, and ocular misalignment).

Public comment disposition

No public comments were received during the early packet public comment period.

Photoscreening 2023

HERC staff summary:

Photoscreening is recommended as one option for visual acuity testing in the USPTSF, AAP, and ophthalmology society guidelines. The AAP recommends photoscreening, when available, for screening younger children and visual acuity testing for screening older children. The evidence for the effectiveness of photoscreening for detection of amblyopia or for impacting treatment outcomes is very weak. The AAP guidelines recommend photoscreeners as the test of choice for younger children (younger than age 3); however, vision screening for children under age 3 is a USPSTF "I" recommendation. Ophthalmology society joint recommendations state that "Photoscreening and handheld automated refraction are recommended as an alternative to visual acuity screening with vision charts (typically used for children 3 through 5 years of age) and in children who are unable or unwilling to cooperate with routine acuity screening with vision charts (but are not superior to vision chart testing for children able to participate)." Most private payers consider photoscreening to be required under the USPSTF level B recommendation for visual screening in children under the age of 5.

HERC staff recommendation:

1) Option 1: continue lack of coverage of photoscreening as a less cost-effective option for visual screening and most appropriate for children under age 3, a group not included in the USPSTF "B" recommendation for visual screening
    a. Update the date of last review in GN172

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

Line 502

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

Procedure Code	Intervention Description	Rationale	Last Review
99174, 99177	Photoscreening	More costly than equally effective methods of screening	~~May 2019~~ November 2023

2) Option 2: add coverage for photoscreening due to expert recommendation
    a. Add photoscreening CPT codes to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS and remove from line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS
        i. CPT 99174 Instrument-based ocular screening (eg, photoscreening, automated-refraction), bilateral; with remote analysis and report
        ii. CPT 99177 (Instrument based ocular screening (eg, photoscreening, automated-fractions),bilateral; with onsite analysis)
    b. Remove the entry for photoscreening from GN172

Photoscreening 2023

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

Line 502

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

Procedure Code	Intervention Description	Rationale	Last Review
~~99174, 99177~~	~~Photoscreening~~	~~More costly than equally effective methods of screening~~	~~May 2019~~

Severe Exfoliating Skin Conditions

Plain Language Summary:

Coverage question: Should OHP cover severe shedding of the skin that can affect overall health?

Should OHP cover this treatment? Yes, based on expert input.

Coverage Question: Should multiple diagnosis codes currently on the uncovered erythematous conditions line that represent severe exfoliating skin conditions be moved to a covered line?

Question source: HERC staff

Background: During the revisions to the breast reduction for macromastia topic, staff reviewed line 504 ERYTHEMATOUS CONDITIONS and determined that some diagnoses on that line are serious and require medical treatment. ICD-10-CM L30.4 (Erythema intertrigo) was added to line 426 SEVERE INFLAMMATORY SKIN DISEASE as part of the breast reduction for macromastia review.

One diagnosis on line 504 is ICD-10-CM L26 (Exfoliative dermatitis). Generalized exfoliative dermatitis, or erythroderma, is a severe inflammation of the entire skin surface. This is due to a reaction to certain medicines, a pre-existing skin condition, and sometimes cancer. In approximately 25% of people, there is no identifiable cause. It is characterized by redness and scaling of the skin that begins in patches and spreads. The skin begins to slough off. This leads to problems with temperature regulation, protein and fluid loss, as well as an increased metabolic rate. Treatment is stopping any offending medications, oral steroids for severe cases, rehydration, and comprehensive wound care to prevent infection. This condition frequently requires hospitalization and can be fatal. Erythroderma is coded with either ICD-10-CM L26, L53.8 (Other specified erythematous conditions) or L53.9 (Erythematous condition, unspecified). If caused by cancer, it may be coded with L54 (Erythema in diseases classified elsewhere). All of these diagnoses are on line 504.

Additionally, the ICD-10-CM L49 series (Exfoliation due to erythematous condition) is on line 504. ICD-10-CM L49.1 is <10% of body surface area, but the percent of body surface area increases up to >90% with ICD-10-CM L49.9. Similar burn diagnoses are on line 605 MINOR BURNS (<10% BSA), line 127 MODERATE BURNS (larger surface area or greater depth of burn) or line 57 SEVERE BURNS (highest surface area with greatest depth of burn). Erythoderma would be present if the exfoliation was over 75% of the body surface area (ICD-10-CM codes L49.7-L49.9).

Previous HSC/HERC reviews:
Line 504 was included in the "below the line" review done by HERC staff last year.

Severe Exfoliating Skin Conditions

Current Prioritized List/Coverage status:

Line 504 ERYTHEMATOUS CONDITIONS

ICD-10 Code	Code Description
L26	Exfoliative dermatitis
L49.1	Exfoliation due to erythematous condition involving less than 10 percent of body surface
L49.2	20-29 percent of BSA
L49.3	30-39 percent of BSA
L49.4	40-49 percent of BSA
L49.5	50-59 percent of BSA
L49.6	60-69 percent of BSA
L49.7	70-79 percent of BSA
L49.8	80-89 percent of BSA
L49.9	90 percent or more of BSA
L53.8	Other specified erythematous conditions
L53.9	Erythematous condition, unspecified
L54	Erythema in diseases classified elsewhere

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

Lines 426,482,504,533,542,555,656

Inflammatory skin conditions included in this guideline are:

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

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, 533, 542, 555 and 656.

For severe psoriasis, treatments included on this line are topical agents, phototherapy, targeted immune modulator medications and other systemic medications.

For severe atopic dermatitis/eczema, treatments included on this line are topical moderate- to high-potency corticosteroids, topical calcineurin inhibitors (for example, tacrolimus), narrowband UVB, and

oral immunomodulatory therapy (e.g. cyclosporine, methotrexate, or oral corticosteroids). Targeted immune modulators (for example, dupilumab) are included on this line when:

A) Prescribed in consultation with a dermatologist or allergist or immunologist, AND

B) The patient has failed (defined as inadequate efficacy, intolerable side effects, or side effects that pose a health risk) a 4 week trial of a combination of topical moderate to high potency topical steroids and a topical non-steroidal agent OR an oral immunomodulator.

JAK inhibitor (for example, upadacitinib or abrocitinib) therapy is included on this line when other immunomodulatory therapy has failed to adequately control disease (defined as inadequate efficacy, intolerable side effects, or side effects that pose a health risk).

ICD-10-CM Q82.8 (Other specified congenital malformations of skin) is included on Line 426 only for Darier disease.

Expert input:

Dr. Sarah Leitenberger, OHSU dermatology

> …erythroderma is a severe condition with major implications to systemic health. When acute, it can require hospitalization for fluid/electrolyte balance and acute cardiovascular reasons. When chronic, there are impacts on nutrition, growth and chronic cardiovascular health.
>
> Fortuitously, this ties in directly with our request to reconsider "ichthyosis". Severe ichthyosis such as Harlequin ichthyosis, lamellar ichthyosis and non-bullous congenital ichthyosiform erythroderma all involve exfoliation of >75% BSA.

Severe Exfoliating Skin Conditions

HERC staff summary:

Several severe exfoliating skin conditions currently in the unfunded region of the Prioritized List should be added to line 426 and the inflammatory skin disease guideline should be modified to indicate when these conditions are on the covered line.

HERC staff recommendations:

1) Add the following ICD-10-CM codes to line 426 SEVERE INFLAMMATORY SKIN DISEASE and keep on line 504 ERYTHEMATOUS CONDITIONS

ICD-10 Code	**Code Description**
L26	Exfoliative dermatitis
L49.7	Exfoliation due to erythematous condition involving 70-79 percent of body surface
L49.8	80-89 percent of BSA
L49.9	90 percent or more of BSA
L53.8	Other specified erythematous conditions
L53.9	Erythematous condition, unspecified
L54	Erythema in diseases classified elsewhere

2) Modify GN21 as shown below
    a. Suggested wording from another issue is shown in purple

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

Lines 426,482,504,533,542,555,656

Inflammatory skin conditions included in this guideline are:

A) Psoriasis
B) Atopic dermatitis
C) Lichen planus
D) Darier disease
E) Pityriasis rubra pilaris
F) Discoid lupus
G) Vitiligo
H) Prurigo nodularis
I) Erythema intertrigo

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:

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

Otherwise, these conditions above are included on Lines 482, 504, 533, 542, 555 and 656.

For severe psoriasis, treatments included on this line are topical agents, phototherapy, targeted immune modulator medications and other systemic medications.

Severe Exfoliating Skin Conditions

For severe atopic dermatitis/eczema, treatments included on this line are topical moderate- to high-potency corticosteroids, topical calcineurin inhibitors (for example, tacrolimus), narrowband UVB, and oral immunomodulatory therapy (e.g. cyclosporine, methotrexate, or oral corticosteroids). Targeted immune modulators (for example, dupilumab) are included on this line when:

A) Prescribed in consultation with a dermatologist or allergist or immunologist, AND

B) The patient has failed (defined as inadequate efficacy, intolerable side effects, or side effects that pose a health risk) a 4 week trial of a combination of topical moderate to high potency topical steroids and a topical non-steroidal agent OR an oral immunomodulator.

JAK inhibitor (for example, upadacitinib or abrocitinib) therapy is included on this line when other immunomodulatory therapy has failed to adequately control disease (defined as inadequate efficacy, intolerable side effects, or side effects that pose a health risk).

ICD-10-CM Q82.8 (Other specified congenital malformations of skin) is included on Line 426 only for Darier disease.

ICD-10-CM L26 (Exfoliative dermatitis), L49.7-L49.9 (Exfoliation due to erythematous condition involving 70% to >90% of body surface), L53.8 (Other specified erythematous conditions), L53.9 (Erythematous condition, unspecified), and L54 (Erythema in diseases classified elsewhere) are included on line 426 only when representing erythroderma or when the exfoliation extends over 75% of body surface area. Otherwise, these diagnoses are included on line 504.

Refugee Screening

Plain Language Summary:

Coverage question: Should OHP cover medical screenings for people arriving from other countries who are seeking safety and protection from war or other dangers?

Should OHP cover this treatment? Yes, this screening is a federal requirement.

Coverage Question: Should a new diagnosis code be added to the preventive services line to represent refugee screening?

Question source: Multnomah County Health Department, DHS Refugee Policy Unit, HSD

Background: Programs that provide resettlement services on behalf of the federal government must provide refugee domestic screening. This screening involves a history and physical, screening for various parasites, STIs, and viruses, assessing nutrition and growth, assessing mental health, and providing necessary immunizations.

The CDC has protocols in place for refugee screening, available at https://www.cdc.gov/immigrantrefugeehealth/guidelines/refugee-guidelines.html

Multnomah County Health Department has been receiving multiple denials of claims for refugee screening exams. Providers are using a variety of diagnosis codes, including ICD-10-CM Z02.89 (Encounter for administrative examinations, unspecified) and Z76.89 (Persons encountering health services in other specified circumstances) which are currently informational only.

OHA staff and the refugee screening programs have met and are requesting that ICD-10-CM Z65.5 (Exposure to disaster, war and other hostilities) be added to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS to designate an encounter as refugee screening. This will allow OHA and providers to identify encounters that are part of this program. Line 3 has all of the screening, immunization and exam CPT codes required for this type of screening. Normal preventive exam or office visit codes will not allow identification that these exams were done as part of the federal program.

Current Prioritized List/Coverage status:
ICD-10-CM Z65.5 (Exposure to disaster, war and other hostilities) is currently on the INFORMATIONAL DIAGNOSES file

HERC staff summary:
In order to comply with federally mandated refugee screening, OHA and the refugee screening programs need a unique diagnosis code to identify claims related to refugee screening. Adding the requested code to line 3 will allow all the required screening activities to pair and be reimbursed.

Refugee Screening

HERC staff recommendation:

1) Add ICD-10-CM Z65.5 (Exposure to disaster, war and other hostilities) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
    a. Advise HSD to remove ICD-10-CM Z65.5 from the INFORMATIONAL DIAGNOSES file