Health Evidence Review Commission

November 17, 2022

1:30 PM - 4:30 PM

Online Meeting

Join online meeting here

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Section 1.0

Call to Order

AGENDA

Online meeting
November 17, 2022
1:30-4:00 pm
(All agenda items are subject to change and times listed are approximate)

#	Time	Item	Presenter	Action Item
1	1:30 PM	Call to order	Kevin Olson	
2	1:35 PM	Approval of minutes (October 6, 2022)	Kevin Olson	X
3	1:40 PM	Director's report • Term limits for subcommittee members • Leadership transitions • Vacancies	Jason Gingerich Kevin Olson	X
4	1:50 PM	Early and Periodic Screening, Diagnosis and Treatment (EPSDT) update	Nathan Roberts	
5	2:00 PM	Value-based Benefits Subcommittee report	Ariel Smits	X
6	3:00 PM	HERC Policy on use of Quality-Adjusted Life Years (QALYs)	Jason Gingerich	X
7	3:55 PM	Next steps • Schedule next meeting – January 19, 2023, 1:30-4:30 p.m.	Kevin Olson	
8	4:00 PM	Adjournment	Kevin Olson	

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

MINUTES

HEALTH EVIDENCE REVIEW COMMISSION
Online meeting
October 6, 2022

Members Present: Holly Jo Hodges, MD, MBA, Vice-Chair; Lynnea Lindsey, PhD; Adriane Irwin, PharmD; Kathryn Schabel, MD; Max Kaiser, DO; Mike Collins; Deborah Espesete, LAc, MAcOM, MPH; Cris Pinzon, MPH, BSN, BS, RN; Stacy Geisler, DDS, PhD; Ben Hoffman, MD.

Members Absent: Kevin Olson, MD, Chair; Leslie Sutton; Devan Kansagara, MD.

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

Also Attending: Shauna Durbin & Valerie King, MD MPH, (OHSU Center for Evidence-based Policy); Alison O'Neill; Ambyr Leigh; Ben Chandhok; Brian Wilhelmsen; Carissa Kemp (ADA); Charlene Lai, MD; Chris DeMars, Kristen Darmody, Mina Colon, Kian Messkoub MPH, Mimi Luther & Ellie Solares-Solis, (Oregon Health Authority); Christine Fallabel; Christopher Merkle; CW; D; Dan; Doug DeBen; Dylan Brown; Gene Spader; Jennifer Olson; Jessica Castle; Joe Gardner; Julia Saltzgiver; Justin Hageman; Kevin J.D. Wilson; Kimberly Cleveland, RN, DCES; Lance Christian (ALS Association); Laura Lacey; Linda Nunes; Lorren Sandt (Caring Ambassadors Program); MacKenzie; Marie; Mathieu Pitre; Megan O'Neill; Melissa Smith; Paul Terdal; Rafat Fields; Rebecca McAuliffe; Renee Doan (Care Oregon); Renee Taylor; Sarah Like; Sharon McDowell; Shawn Miller; shcarsley; Stephen Willis, PA-C; twilson.

Call to Order

Holly Jo Hodges, 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 August 11, 2022 meeting as presented. CARRIES 10-0.

Director's Report

Membership
Gingerich announced an upcoming HERC vacancy as Holly Jo Hodges' term will be over at the end of the year. This position will be open for applications soon and all interested persons are invited to apply.

Public comments
Gingerich said public comment that is submitted will be posted on HERC's public webpage going forward.

Prioritized List
Gingerich said the new World Professional Association for Transgender Health (WPATH) Standards of Care 8 guidelines are published for gender affirming care. Staff are reviewing this guideline for discussion at a future meeting.

He said the Center for Medicare and Medicaid Services (CMS) approved the new waiver for the Oregon Health Plan (OHP). The new waiver includes several changes that affect how HERC's work will be implemented. The state's Early and Periodic Screening, Diagnostic and Treatment (EPSDT) waiver will expire on January 1, 2023. A new webpage (https://www.oregon.gov/oha/HSD/OHP/Pages/EPSDT.aspx) contains implementation information about this change. Additional waiver authority related to the Prioritized List will expire January 1, 2027.

Dana Hargunani, Oregon Health Authority's Chief Medical Officer, described Oregon's new 1115 waiver for the Medicaid program. She said the Prioritized List of Health Services remains in effect to define the benefit package for the Oregon Health Plan. In addition, Oregon will be the first state approved to use federal Medicaid funds to pay for items such as housing, food and nutritional support, and items like air conditioners.

The waiver also expands coverage for children. All children under 6 years of age will have continuous coverage under OHP, and the spacing of review for client eligibility for those who are older will be expanded to two years.

She acknowledged and thanked the volunteer members for all their service and said that Oregon will continue to rely on HERC to guide its decisions on efficacy and medical necessity criteria through its transparent public process. After nearly 30 years, Oregon's transparent public process to determine benefits is no longer experimental and will be moved out of the 1115 demonstration waiver and into the Medicaid State Plan. To ensure an appropriate transition to a State Plan Amendment by 2027, the state will complete a detailed regulatory and operational review with the potential for needed changes in law, rules and processes.

In line with OHA's goal of eliminating health inequities in Oregon, we will continue efforts to ensure the HERC processes are broadly accessible to the public, and work products reflect available evidence as well as extensive input from patients, community organizations, caregivers, providers, health plans and others interested in benefit policy in Oregon.

Value-based Benefits Subcommittee (VbBS) Report on Prioritized List Changes
Meeting materials, pages 3-224

Ariel Smits reported the VbBS met earlier in the day, 10/6/2022. She summarized the subcommittee's recommendations.

RECOMMENDED CODE MOVEMENT (changes to the 1/1/2023 Prioritized List unless otherwise noted)

- Add residential therapy treatment codes to the funded generalized anxiety line
- Delete several behavioral health-related diagnoses codes that appear on funded lines from an unfunded line
- Add the diagnosis code for an ear anomaly that impairs hearing (small ear) to a funded line

- Delete several diagnosis codes related to deformities of hands and feet that appear on funded lines from an unfunded line
- Make several other various straightforward coding changes

RECOMMENDED GUIDELINE CHANGES (changes to the 1/1/2023 Prioritized List unless otherwise noted)

- Change the acupuncture guideline to specify that a substance use disorder treatment plan does not have to part of a formal treatment program
- Clarify the requirements for inflammatory skin disease medications.
- Adopt a new guideline showing when to cover microtia (small ear) treatment
- Adopt a new statement of intent regarding public health emergencies
- Make several other straightforward guideline note changes

MOTION: To accept the VbBS recommendations on Prioritized List changes as stated. See the VbBS minutes of 10-6-2022 for a full description. Carries: 10-0.

Chronic disease self-management programs

These are Center for Disease Control (CDC) recognized programs for people living with chronic diseases (for example: asthma, diabetes, multiple illnesses, HIV, disabilities). The Community Integrated Network of Oregon has asked HERC to review and cover these programs. OHP currently covers two of the programs—the Diabetes Prevention Program and a fall-prevention program. VbBS recommended that HERC direct the Evidence-based Guidelines Subcommittee (EBGS) to undertake a multisector intervention review of chronic disease self-management programs.

Pinzon asked a question about scoping direction for the subcommittee. King said it is always best to have specifics as the topics are scoped. She said her impression is that there are both disease-specific and generic self-management programs. Further, King said she does not want to duplicate the work of the CDC to support their recommendations, though she said she had not read that report yet. Smits said the CDC report focuses on the programs and outcomes such as pain, self efficacy, physician visits and functional ability rather than disease specific outcomes.

Lindsey said, as a member of EbGS, she would be concerned if the report was scoped too narrowly but agrees that if the scope was so big it would obscure the evidence.

Cantor said the scope could take two pathways:

- Evidence mapping – a literature search to map disease that rise to the lever of sufficient evidence to inform a decision or
- Managed scoping approach with call outs to some of the more prominent chronic diseases or programs

The scope's direction will be placed in the care of EbGS.

HERC Policy on use of Quality-Adjusted Life Years (QALYs)

Meeting materials, pages 225-234

Cantor said HERC is investigating this issue due to concerns raised by groups such as disability rights advocates and the pharmaceutical industry. She said it is important to discuss the approach for

conducting a policy about the appropriate use of QALYs in the HERC process and decision-making to ensure equity in decisions that inform coverage.

QALYs are a tool used in health services research to estimate the effectiveness of a medical intervention. They combine measurements of effectiveness, including mortality or life years, as well as morbidity and the quality of life as part of the assessment for medical intervention of effectiveness. It allows researchers to compare changes in health status across conditions. These medical interventions have also often been assessed based on the impact they have on mortality. A life years calculation can be evaluated numerically.

Since 2017, all prior HERC considerations for adopting a more central role of the use of QALYs have been either rescinded, not adopted or never implemented due to concerns for their potential discriminatory effects. In recent years, the HERC has used QALYs in a limited fashion to inform decisions about coverage based on cost-effectiveness. When HERC has considered QALY data, it has almost always resulted in expanded coverage.

Testimony:

Paul Terdal, spoke to the Commission, claiming three potential conflicts of interest: 1) as a parent of two children who have disabilities enrolled on the Oregon Health Plan (OHP); 2) was hired to do research related to Medicaid programs nationwide by the National Council on Disability; 3) pharmaceutical and medical device industry related projects for the past 20 years. He read parts of former congressman Tony Coelho's testimony from the VbBS meeting in the morning. Coelho stated that use of discriminatory measures like QALYs in decision-making discriminates against populations with disabilities and people of color. He advocated ending use of evidence that feeds bias in health care. The Americans with Disabilities Act (ADA) – legislation he authored – was enacted to counter bias based on disability. He advocated the end of the use of QALYs, urging the Commission to choose option four.

Hodges said the Commissioners should pick one or two options from the meeting materials to put out for public comment.

Options for the use of QALYs by the HERC

1. HERC staff will incorporate the following adjustments when referencing QALYs as part of their recommendation development for the HERC in order to prevent the inappropriate use of QALYs:
    a) Only use QALYs to compare treatments for the same population. QALYs will not inform scoring used to rank lines for the Prioritized List.
    b) Perform a literature search for alternative measures of cost effectiveness and cite any that are relevant.
    c) Explicitly describe the role of QALYs vis a vis other decision factors considered using a simplified Multi-Criteria Decision Analysis (defined below), including benefits, harms, costs, values and preferences and delivery system issues relevant to the topic at hand.
    d) Offer HERC's consumer advocate members an opportunity to review and comment on meeting materials prior to public meeting material release. These comments will

inform potential modifications and will be shared as part of public meeting materials.

e) Continue to explore opportunities to improve accessibility for public testimony as part of HERC deliberations.

2. Do not mention QALYs in staff-prepared meeting materials and avoid discussion of QALYs at Commission and subcommittee meetings.
3. Do not mention QALYs in staff-prepared meeting materials and do not discuss QALYs at Commission meetings. Staff will also search all studies for "QALY" and redact any mention of QALYs from published articles.
4. Do not mention QALYs in staff-prepared meeting materials and do not discuss QALYs at Commission meetings. Search all studies for "QALY" and exclude from consideration any studies reporting QALYs.

Hoffman said he didn't feel qualified to make a recommendation though, he said, QALYs do provide beneficial information, independent of the quality data.

Irwin said options two and four are not acceptable to her. Further she said she would like HERC staff to provide information about how option one would affect their work. For option three Irwin said she would like us to do more outreach into the disability community to understand their perspective better.

Schabel said we should pick one and see what kind of public feedback we get, then make time for people to present comments.

Pinzon expressed concern that the line rankings may have been influenced by QALYs. Gingerich said while QALYs were not a direct factor in scoring, "impact on healthy life" was. Staff have completed a comprehensive review of all items below the funding line and adjusted as necessary. Pinzon went on to say testifier Paul Terdal had already completed some research and wondered if he would contribute that research to be part of that review. For today's discussion, Pinzon said she supported putting options one and three out for comment.

Espesete agreed with Pinzon and asked for clarification on options two and three around use of QALYs in decision-making. Gingerich said they would not be used in those cases. Hodges asked for clarification of "use them." Gingerich said it could mean they appear in our issue summary, we could discuss them, perhaps base our recommendation on them. He said that is the difficulty because they frequently appear in articles that contain other useful information.

Geisler said, thinking as an epidemiologist, that every measurement in a heath care study has error associated with it. She asked, with this measure, how to you assess the quality? Is there any type of error assessment so that the study can be ranked as a very well-done study? If there is no way of measuring error, there would be a high risk of bias associated with the use of QALYs.

Lindsey said there are challenges with the use of QALYs, sharing that people with serious mental illness die 30 years earlier than people without those conditions. She asked what is a quality-of-life measure for them compared to someone else? Lindsey said there are challenges in using QALYs.

Kaiser said, based on his work in ethics, he had a concern for QALYs' accuracy and potential for bias. He said when he reads studies, he views QALYs very hesitantly. He said he favors option one to put out for public comment.

MOTION: To post options one and three for a 21-day public comment period. Carries 10-0.

Scope statement: Continuous Glucose Monitors (CGM)
Meeting materials, pages 235-243

Cantor said staff would like to amend the scope statement for CGM, noting formatting changes as well as background of the policy landscape and providing a background relevant to the Prioritized List lines and guideline notes. This scope (meeting materials, pages 241-423) excludes people with type 1 diabetes as they already may have a CGM. It includes people with type 2 diabetes, gestational diabetes and those who are pregnant.

Testimony:

Stephen Willis PA-C offered testimony on the FreeStyle Libre 2 and 3 systems. He said both systems demonstrated a reduction in blood glucose of 0.82% in a randomized control trial (RTC). He said in a real-world analysis of patients with type 2 diabetes on basal insulin, an observational study showed a 62% reduction in acute diabetes events and a 32% reduction in hospitalizations following the FreeStyle Libre acquisition.

Kimberly Cleveland, BSN, RN, DCES, a diabetes care and education specialists, testified. She disclosed she works with people who have diabetes. She said she believes CGM promote equity, helping with fewer days off and preventing crises. She asked the Commission to follow the American Diabetes Association (ADA) standards of care which specifies that CGM should be used for people who are on multiple daily doses of insulin and could be used for those who are on any type of insulin. She also asked for the process for Primary Care Providers (PCPs) to get the technology for their patients to be easier.

Charlene Lai, MD, a pediatric endocrinologist at OHSU Doernbecher, declared no conflicts of interest. She said the rates of type 2 diabetes has grown exponentially outside of the Caucasian communities. She said youth onset type 2 diabetes is more severe than in adults. CGM allows for ease of and frequent blood sugar monitoring, which in many cases can be monitored remotely in almost real time by clinicians. This allows for quick recognition of worsening diabetes and medication changes every two to three days, which can help avoid ER visits, hospitalizations, or ICU admissions. She said nationwide, 40% of patients with type two diabetes are from families making less than $25,000 a year.

Julia Saltzgiver, RDN is a registered dietitian working in an FQHC and primary care clinic in Salem, Oregon. She said the patients that she works with experienced disproportionate barriers to care and unfortunately, their health is often negatively impacted by these disparities. She gave several examples of cases where CGM has been useful for her patients.

Jessica Castle, MD is the associate director of the Harold Schnitzer Diabetes Health Center at Oregon Health and Science University and an associate editor at the Diabetes Care Journal. She said

she has completed research with CGM but does not have any current conflicts of interest. Castle talked about the concept of "time in range" and its importance. She also said to consider CGM for patients who are needle-phobic or for other reasons are not able to do finger-sticks.

Pinzon asked if there were temporary monitors available. Castle said there are professional CGM monitors for use over a period of 10 to 14 days, using real time CGM.

Alison O'Neill is a pediatric endocrinologist at OHSU Doernbecher Children's Hospital and declared no conflicts of interest. She said she is advocating for CGM specifically for cystic fibrosis (CF) related diabetes. All patients with CF with or without diabetes require frequent high calorie meals and snacks to meet metabolic demands, and many require overnight tube feedings to achieve adequate caloric intake. Cystic−fibrosis-related diabetes (CFRD) patients on insulin therefore need to monitor blood sugar by fingerstick 12 or more times per day including multiple overnight sticks, a significant burden on top of the many other therapies required for daily care for patients with CF. There is a significant mortality gap between CF patients with CFRD and those without diabetes. She gave an example of a patient with CFRD who had success using a CGM.

Hoffman thanked O'Neill for bringing the CFRD population to his attention. Hodges asked how many patients with this condition are in Oregon. O'Neill said potentially up to about 50 children and young adults.

Cantor said this population is out of scope for this coverage guidance, but we are looking at bringing these issues to VbBS in the near future.

There was some discussion around what items should be on the scope statement. In the end, the Commission asked Cantor to make additional revision as needed based on the evidence that emerges.

MOTION: To delegate remaining scope revisions related to the CGM reports Cantor. Carries 10-0.

Public Comment

There was no public comment.

Adjournment

Meeting adjourned at 4:35 pm. Next meeting will be from 1:30-4:30 pm on Thursday, November 17, online.

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on October 6, 2022

For specific coding recommendations and guideline wording, please see the text of the 10/6/2022 VbBS minutes.

RECOMMENDED CODE MOVEMENT (changes to the 1/1/2023 Prioritized List unless otherwise noted)

- Add residential therapy treatment codes to the funded generalized anxiety line
- Delete several behavioral health-related diagnoses codes that appear on funded lines from an unfunded line
- Add the diagnosis code for an ear anomaly that impairs hearing (small ear) to a funded line
- Delete several diagnosis codes related to deformities of hands and feet that appear on funded lines from an unfunded line
- Make several other various straightforward coding changes

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- No changes were made to the diagnosis codes on an unfunded line for deformities of the knee

RECOMMENDED GUIDELINE CHANGES (changes to the 1/1/2023 Prioritized List unless otherwise noted)

- Change the acupuncture guideline to specify that a substance use disorder treatment plan does not have to part of a formal treatment program
- Clarify the requirements for inflammatory skin disease medications.
- Adopt a new guideline showing when to cover microtia (small ear) treatment
- Adopt a new statement of intent regarding public health emergencies
- Make several other straightforward guideline note changes

VALUE-BASED BENEFITS SUBCOMMITTEE
Online meeting
October 6, 2022
9:00 AM – 1:00 PM

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

Members Absent: Kevin Olson, MD; Brian Duty, MD.

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

Also Attending: Shauna Durbin & Val King (OHSU); Ambyr Leigh; Dana Hargunani, MD (OHA); Ellie Solares-Solis; Emily Rigler-Wright; Jamie Schlarbaum, MD; Jana Peterson-Besse (OHSU); Jennifer Olson; Julie Dhossche, MD (OHSU); Justin Hageman; Kristen Darmody (OHA); Lavinia Goto; Lisa Ashton; Lorren Sandt (Caring Ambassadors Program); MacKenzie; Meghan Moyer (Disability Rights Oregon); Mina Colon (OHA); Nick Budnick (Lund Report); Paul Terdal; Rafat Fields; Renee Taylor; Sara van Geertruyden; Tholanda Newborne; The Honorable Tony Coelho; Tracy Carver (Comagine Health); Tracy Funk, MD; Yvonne Hubbard.

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

The meeting was called to order at 9:00 am and roll was called. A quorum of members was present at the meeting. Minutes from the August 11, 2022 VbBS meeting were reviewed and approved (Irwin abstained due to not attending August meeting).

Gingerich announced the new CMS-approved waiver for the Oregon Health Plan (OHP). The new waiver includes several changes that affect how HERC's work will be implemented. The state's EPSDT waiver will expire on January 1, 2023. A new webpage (https://www.oregon.gov/oha/HSD/OHP/Pages/EPSDT.aspx) contains implementation information about the expiration. Additional waiver authority related to the Prioritized List will expire January 1, 2027.

Dana Hargunani, Chief Medical Officer of OHA, presented on changes to Oregon's 1115 waiver for the Medicaid program. She said that the Prioritized List remains in effect to define the benefit package for the Oregon Health Plan. In addition, Oregon will be the first state approved to use federal Medicaid funds to pay for items such as housing, food and nutritional support, and items like air conditioners. The waiver also expands coverage for children. All children under 6 years of age will have continuous coverage under OHP, and the spacing of review for client eligibility will be expanded to two years. She acknowledged and thanked the volunteer members for all their service and said that Oregon will continue to rely on the HERC to guide its decisions on efficacy and medical necessity criteria through its transparent public process. After nearly 30 years, Oregon's transparent public process to determine benefits is no longer experimental and will be moved out of the 1115 demonstration waiver and into the Medicaid State Plan. To ensure an appropriate transition to a State Plan Amendment by 2027, the state will complete a detailed regulatory and operational review with the potential for needed changes in law, rules and processes. In line with OHA's goal of eliminating health inequities in Oregon, she said staff will continue efforts to ensure the HERC processes are broadly accessible to the public, and work products

reflect available evidence as well as extensive input from patients, community organizations, caregivers, providers, health plans and others interested in benefit policy in Oregon.

Gingerich announced an upcoming HERC vacancy as Holly Jo Hodges is terming off at the end of the year. This position will be open for applications soon and all interested persons were invited to apply.

At its March 2021 meeting, HERC requested that staff conduct a claims utilization query for CPT 87913 (genotype analysis to identify COVID variants) after 6 months; there have been no claims to date.

Gingerich also announced that public comment that is submitted will be posted on HERC's public webpage going forward.

Gingerich stated that the new WPATH Standards of Care 8 guidelines are published for gender dysphoria care and staff are reviewing this guideline for discussion at a future meeting.

- **Topic: Straightforward/Consent Agenda**

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

  Recommended Actions:

  1) Add Z69.021, Z69.12 and Z69.82 (Encounter for mental health services for perpetrator of non-parental child/spousal or partner/other abuse) to line 120 ABUSE AND NEGLECT
  2) Add CPT 15771 and 15772 (Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs) to line 312 GENDER DYSPHORIA/TRANSEXUALISM
  3) Modify GN 127 as shown in Appendix A
  4) Modify GN 154 as shown in Appendix A
  5) Modify GN 24 as shown in Appendix A
  6) Add ICD-10-CM T81.9XXA (Unspecified complication of procedure, initial encounter) to line 573 REDUNDANT PREPUCE
  7) Modify GN73 as shown in Appendix A
  8) Add the following CPT codes to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
     a. 91313 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 50 mcg/0.5 mL dosage, for intramuscular use
     b. 0134A administration of the vaccine represented by 91313
     c. 91314 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 25 mcg/0.25 mL dosage, for intramuscular use
     d. 0144A administration of the vaccine represented by 91314
     e. 91312 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use
     f. 0124A administration of the vaccine represented by 91312
     g. 91315 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, bivalent spike protein, preservative free, 10

mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use

h. 0154A administration of the vaccine represented by 91315

MOTION: To approve the recommendations stated in the consent agenda. CARRIES 6-0.

- **Topic: Behavioral Health Advisory Panel report**

Discussion: There was no substantive discussion about residential treatment for anxiety or the somatization and related disorders topics.

For the guideline revision related to acupuncture for substance use disorder, Pinzon asked who was responsible for documenting the treatment program, and whether this type of documentation would further limit access to these programs. Hodges noted that acupuncture would be part of an individual treatment plan. Documentation could be provided by the PCP, an SUD treatment provider, a therapist, etc.

Recommended Actions:

1) Add HCPCS H0017 (Behavioral health; residential (hospital residential treatment program), without room and board, per diem) and H0018 (Behavioral health; short-term residential (non-hospital residential treatment program), without room and board, per diem) to line 414 OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED
2) Modify GN92 as shown in Appendix A
3) Remove the following ICD-10-CM diagnoses from line 552 SOMATIC SYMPTOMS AND RELATED DISORDERS as they already appear on other funded lines
    i. F44.0 Dissociative amnesia
    ii. F44.1 Dissociative fugue
    iii. F44.2 Dissociative stupor
    iv. F44.81 Dissociative identity disorder
    v. F44.89 Other dissociative and conversion disorders
    vi. F45.22 Body dysmorphic disorder
    vii. F45.42 Pain disorder with related psychological factors
4) Remove ICD-10-CM F52.5 (Unspecified sexual dysfunction not due to a substance or known physiological condition) from line 552 SOMATIC SYMPTOMS AND RELATED DISORDERS and add to line 523 SEXUAL DYSFUNCTION

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

- **Topic: Quality-adjusted life year (QALY) review**

Discussion: Cantor reviewed the summary document.

Public testimony:

1) **Lorren Sandt, Executive Director, Caring Ambassadors**: Sandt testified against the use of QALYs by HERC, stating they are illegal and are not aligned with the agency's health equity goals. She said Options 2 and 3 hide transparency. She said Option 4 would be ideal but is concerned that would leave a lack of evidence to consider and lead to noncoverage of services. She advocated

for considering Option 1 with some merits and some concerns. However, she advocated for a novel measure that HERC would use to evaluate services. She requested that more than 5 minutes be considered for public testimony, especially for sensitive topics. She said QALYs are discriminatory because most evidence is based on clinical trials, which has inclusion criteria that excludes certain groups of people. The results of these trials feed into QALY calculations.

2) **Meghan Moyer, Public Policy Director, Basic Rights Oregon**: Moyer stated that Oregon has used QALYs prior to 2017 and relied on QALYs to create the Prioritized List. She noted that most of the condition-treatment pairs have not been reprioritized since then. She said QALY calculations reduce the importance of treatments that don't bring a person back to perfect health, which discriminates against a person with a disability. Quality of life is multi-factorial and the methodology of assessing the quality of life is fundamentally flawed. She stated QALYs also have validity and reliability concerns. There are alternatives to the use of QALYs, such as value frameworks that use patient preferences. She said it would be difficult, if not impossible, to use QALYs in a non-discriminatory manner.
3) **Tony Coehlo, Chairman, Partnership to Improve Patient Care**: Coehlo said he authored the Americans with Disabilities Act in Congress. He recommended against Options 2 or 3, as these options only hide the use of QALYs. He preferred Option 4, and stated that use of discriminatory measures like QALYs in decision-making creates winners and losers. This discriminates against populations with disabilities and people of color. He advocated against the use of evidence that feeds bias in health care. He shared his personal health story and stated the ADA was enacted to counter bias based on disability.

Pinzon asked for clarification about Figure 1.9, previously a part of HERC's ranking methodology. Gingerich said the flowchart in the materials was initially part of the methodology but was never applied during line ranking determinations. Gingerich then presented the HERC's current ranking criteria that is applied to the Prioritized List. Clinical effectiveness, cost effectiveness, population effects, and impact on healthy life are criteria, among others. He noted that, prior to the Affordable Care Act, that last criterion was Impact on Health Life Years, but has since been modified. He said HERC staff conducted a comprehensive review of the unfunded region of the Prioritized List and have moved multiple items to the funded region based on this review.

Pinzon asked Sandt about non-discriminatory measures to replace QALYs. Sandt noted that many of these are included in the staff summary.

Gingerich said that HERC staff do not calculate QALYs, and that articles used to inform HERC decisions often include QALYs along with many other kinds of information that may be important to HERC decisions.

- **Topic: Inflammatory skin disease guideline**

Discussion: Smits reviewed the summary document.

Julie Dhossche, a pediatric dermatologist at OHSU, provided invited testimony. Atopic dermatitis is common but generally mild. Significant eczema that may affect the ability to attend school or results in secondary infection needs to be treated with effective medications. Many of the newer treatments address specific immune dysregulation underlying severe eczema. Many of the medications in the current guideline are broad immunosuppressants, require lab monitoring, and

carry significant risks. Targeted immunomodulators (TIM) are safer and don't require close monitoring. Phototherapy can be time- and cost-prohibitive for patients and can actually worsen eczema. She noted that other state Medicaid programs have TIM on their formularies as first-line treatments. Dhossche stated that JAK inhibitors, an oral immunomodulatory therapy, have emerged as an important and superior treatment to atopic dermatitis, and these are an FDA approved treatment for this condition.

There was minimal discussion. The guideline modifications were approved as presented.

Recommended Actions:
1) Modify GN21 as shown in Appendix A

MOTION: To recommend the guideline note changes as presented in option 2 from the meeting material. CARRIES 8-0.

- **Topic: Corneal collagen cross linkage for keratoconus**

Discussion: Smits reviewed the summary document. There were questions from subcommittee members regarding why the evidence is poor to support this treatment, whether it was due to lack of studies, or whether there was newer evidence. The members requested that staff reach out to experts to have them attend the November VBBS meeting to answer member questions.

Recommended Actions:
1) Staff will work with experts to refine this topic and come to answer member questions at the next VBBS meeting. Tabled until a future meeting

- **Topic: Statement of intent for public health emergencies**

Discussion: There was minimal discussion on this topic.

Recommended Actions:
1) Adopt a new statement of intent as shown in Appendix B

MOTION: To add the statement of intent as presented. CARRIES 8-0.

- **Topic: Solid organ transplant lines review**

Discussion: Smits reviewed the summary document.

There was consensus that the general criteria (for example, smoking cessation and control of other illnesses) were helpful. There were concerns about the requirements for specific transplants, such as heart transplants. Saenger noted that refractory ventricular arrythmias was an indication for cardiac transplant. Members recommended that staff contact the transplant centers at Providence, Legacy and OHSU to have any guideline/criteria/coding changes reviewed by transplant experts.

Recommended Actions:

1) Staff will review the criteria with transplant program staff and bring back a revised guideline. Tabled until a future meeting

- **Topic: Hydrocele repair in adults**

Discussion: Smits reviewed the issue summary.

There was discussion about whether there is evidence of benefit for treatment of hydroceles in adults. Hodges suggested adding language to the guideline requiring the hydrocele to interfere with function or other requirements from the hernia guideline. The group felt that this topic should be tabled until Brian Duty can attend the meeting so that he is able to address member questions.

Recommended Actions:

1) Tabled until a future meeting

- **Topic: Below the line review**

Discussion: There was minimal discussion about these agenda items.

Recommended Actions:

1) Remove the ICD-10-CM codes shown below from line 528 DEFORMITIES OF UPPER BODY AND ALL LIMBS

ICD-10-CM code	Code description
M20.02 family	Boutonniere deformity of finger
M20.03 family	Swan-neck deformity of finger
M20.09 family	Other deformity of finger
M21.0 family	Valgus deformity of elbow, hip, knee, ankle
M21.12-M21.16 families	Varus deformity of elbow, hip, knee
M21.2 family	Flexion deformity, shoulder, elbow, wrist, fingers, hip, knees, toes
M21.37 family	Foot drop
M21.52 family	Acquired clubhand
M21.7 family	Unequal limb length (acquired), arm and leg bones
M21.8 family	Other specified acquired deformities of arm or leg
M21.90-M21.05 families	Unspecified acquired deformity of arm or leg
M24.03-M24.05 families	Loose body in wrist, finger, hip
M24.15 family	Other articular cartilage disorders in hip
M25.15 family	Fistula, hip
Q67.6	Pectus excavatum
Q72.70	Split foot, unspecified lower limb

2) Add ICD-10-CM Q17.2 (Microtia) to line 406 BILATERAL ANOMALIES OF EXTERNAL EAR WITH IMPAIRMENT OF HEARING

3) Rename line 406 ~~BILATERAL~~ ANOMALIES OF EXTERNAL EAR WITH IMPAIRMENT OF HEARING
4) Add CPT 21086 (Impression and custom preparation; auricular prosthesis) to line 406
5) Adopt a new guideline for line 406 as shown in Appendix B
6) Remove ICD-10-CM N91.4 (Secondary oligomenorrhea) and N91.5 (Oligomenorrhea, unspecified) from line 658 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
    - Advise HSD to add to the DIAGNOSTIC WORKUP FILE (DWF)
7) Add ICD-10-CM N93.9 (Abnormal uterine and vaginal bleeding, unspecified) to line 423 MENSTRUAL BLEEDING DISORDERS and remove from line 658 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

MOTION: To recommend the code and guideline note changes as presented. CARRIES 8-0.

- **Topic: CPAP titration**

  Tabled to the November HERC meeting

- **Topic: Congenital foot deformity code review**

  Discussion: There was minimal discussion of this topic.

  Recommended Actions:
  1) Add ICD-10-CM Q66.9x (Congenital deformity of feet, unspecified) to line 543 DEFORMITIES OF FOOT and delete from line 359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS

  MOTION: To recommend the code changes as presented. CARRIES 8-0.

- **Topic: Human growth hormone guideline review**

  Tabled to the November HERC meeting

- **Topic: Chronic disease self-management programs**

  Discussion: Smits reviewed the summary document for chronic disease self-management programs (CDSMP). Pinzon noted that the evidence review supported that these programs have a significant effect on self-efficacy, which is important for engaging patients in their care.

Public testimony
1) Lavinia Goto, operations manager for Oregon Wellness Network (OWN): Goto testified in support of OHA coverage for CDSMP. OWN represents groups on aging. Programs in OWN have been providing these CDSMP for over a decade in Oregon. She noted that 13 community

organizations submitted written testimony in support of this benefit. She personally provides these programs and trains program leaders. CDSMPs support patients to manage their illness and improves self-efficacy. It helps patients feel in control and be confident to effect change. CDSMP does not compete with traditional medicine but complements it. These programs activate the patient so that they engage in their care.

2) Tholanda Newborne, Multnomah County REACH Program contractor: Newborne testified that she is a contracted facilitator to help community members manage their diabetes. The REACH program provides a culturally specific program. She supports CDSMP implementation.

Pinzon stated that these programs address social determinants of health and that this coverage request is coming from the community. These programs have impacts beyond the impact on the individual; these programs develop cultural liaisons and community advocates. She expressed concern that if coverage of these programs are left up to the discretion of the CCOs, they won't be offered uniformly across the state.

Hodges noted that many of these programs are already being funded currently in many ways. She supports EBGS review to allow standardization of what interventions are offered throughout the state.

Gingerich noted that many of these programs cannot bill with traditional billing codes and require clinician supervision, posing implementation challenges to making these a funded benefit. There was also mention that evidence for a specific indication (such as asthma or hypertension) is problematic.

Saenger asked about whether these programs have quality certification or accreditation. Smits noted that these programs are recognized by the CDC. Goto informed members that CDSMP providers use a curriculum originally developed by Stanford that is standardized and updated yearly. The Self-Management Resource Center (SMRC) certifies trainers and requires annual reviews. The curriculum addressed topics such as how to talk to a provider, how to manage medications, and so forth. A master trainer does not need any specific degree or license.

Irwin agreed that these programs have utility in empowering patients. She expressed concern about the heterogeneity of disease conditions that these could be used to treat. Such heterogeneity makes it difficult to map to specific lines. She supported EBGS doing a systematic review to inform next steps.

Schabel asked about the price/cost of these programs. Goto answered that these programs involve 2.5 hour weekly sessions for 6 weeks. The cost ranges based on administrative costs (room rent, etc.) as well as paying for the leaders. Cost is nominal per participant, such as $1000 for the whole group for a session (up to 16 clients). There is also a virtual model which is lower cost.

The group voted to recommend to HERC to direct EBGS to create a multisector intervention review of chronic disease self-management programs.

Recommended Actions:

1) Recommend to HERC to direct EBGS to undertake a multisector intervention review of chronic disease self-management programs.

MOTION: To make the recommendation as presented. CARRIES 8-0.

- **Public Comment:**

  No additional public comment was received.

- **Issues for next meeting:**
  - CPAP titration
  - Human growth hormone guideline
  - Transplant coverage
  - Corneal collagen cross-linkage
  - Hydrocele coverage in adults

- **Next meeting:**

  November 17, 2022, virtual meeting

- **Adjournment:**

  The meeting adjourned at 12:55 PM.

Appendix A

Revised Guideline Notes

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

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

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

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 and 656.

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

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

1) prescribed in consultation with a dermatologist or allergist or immunologist
AND
2) The patient has failed (defined as inadequate efficacy, intolerable side effects, or side effects that pose a health risk) either a
    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

b. 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.

GUIDELINE NOTE 24, COMPLICATED HERNIAS

Lines 168,524

Complicated inguinal and femoral hernias in men are included on Line 168 if the hernia

A) Causes symptoms of intestinal obstruction and/or strangulation; OR
B) Is incarcerated (defined as non-reducible by physical manipulation); OR
C) Causes pain and functional limitations as assessed and documented by a medical professional; OR
D) Affects the patient's ability to obtain or maintain gainful employment.

Otherwise, inguinal and femoral hernias in men are included on line 524.

Repair of inguinal and femoral hernias in women and in children age 18 or younger are included on Line 168 due to the different natural history of disease in these populations.

Ventral hernias are included on Line 524. Incarcerated ventral hernias (including incarcerated abdominal incisional and umbilical hernias) are included on Line 524, because the chronic incarceration of large ventral hernias does not place the patient at risk for impending strangulation. Ventral hernias are defined as anterior abdominal wall hernias and include primary ventral hernias (epigastric, umbilical, Spigelian), paratomal hernias and most incisional hernias (ventral incisional hernias). ICD-10-CM K42.0, K43.0, K43.3, K43.6 and K46.0 are included on Line 524 when used to designate incarcerated abdominal incisional and umbilical hernias without intestinal obstruction or gangrene.

GUIDELINE NOTE 73, PENILE ANOMALIES

Lines 424,~~433~~ 434,~~571~~,573, 658

Congenital anomalies of the penis (ICD-10-CM Q54.4, Q55.5 and Q55.6) are included on Line 434 only when they

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

Otherwise, these diagnoses are included on Line 658

Appendix A

Acquired anomalies of the penis (ICD-10-CM N48.82, N48.83, N48.89 or T81.9XXA) are included on Line 424 only when they are the result of a prior penile procedure AND either

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

Otherwise, these diagnoses are included on Line ~~571~~ 573 or Line 658.

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,4,5,64,65,92,111,112,114,125,129,133,135,157,158,191,199-201,208,210,214,215,229,234, 237,238,258,259,262,271,276,286,287,294,314-316,329,342,361,396,397,402,410,419,435,464,541, 559

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

Line 1 PREGNANCY

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

Hyperemesis gravidarum

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

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

Breech presentation

ICD-10-CM: O32.1

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

Back and pelvic pain of pregnancy

ICD-10-CM: O99.89

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

Line 4 SUBSTANCE USE DISORDER,Line 62 SUBSTANCE-INDUCED MOOD, ANXIETY, DELUSIONAL AND OBSESSIVE-COMPULSIVE DISORDERS,Line 65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL

Acupuncture is included on these lines only when used as part of a ~~program~~ documented broader treatment plan that offers patients a variety of evidence-based interventions including behavioral interventions, social support, and Medication Assisted Treatment (MAT), as appropriate.

Line 5 TOBACCO DEPENDENCE

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

Appendix A

Lines 92, 111, 112, 114, 125, 129, 133, 135, 157, 158, 191, 199, 200, 208, 210, 214, 215, 229, 234, 237, 238, 258, 259, 261, 262, 271, 276, 286, 287, 294, 314, 315, 316, 329, 342, 372, 396, 397, 419, 435 and 559

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

Line 201 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS

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

Line 361 SCOLIOSIS

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

Line 402 CONDITIONS OF THE BACK AND SPINE

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

Line 410 MIGRAINE HEADACHES

Acupuncture pairs on Line 410 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), for up to 12 sessions per year.

Line 464 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 464 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions per year.

*Line 541 TENSION HEADACHES

Acupuncture is included on Line 541 for treatment of tension headaches (ICD-10-CM G44.2), for up to 12 sessions per year.

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

*Below the current funding line.

GUIDELINE NOTE 127, GENDER DYSPHORIA

Line 312

Hormone treatment with GnRH analogues for delaying the onset of puberty and/or continued pubertal development is included on this line for gender questioning children and adolescents. This therapy should be initiated at the first physical changes of puberty, confirmed by pubertal levels of estradiol or testosterone, but no earlier than Tanner stages 2-3. Prior to initiation of puberty suppression therapy, adolescents must fulfill eligibility and readiness criteria and must have a comprehensive mental health evaluation. Ongoing psychological care is strongly encouraged for continued puberty suppression therapy.

Cross-sex hormone therapy is included on this line for treatment of adolescents and adults with gender dysphoria who meet appropriate eligibility and readiness criteria. To qualify for cross-sex hormone therapy, the patient must:

A) have persistent, well-documented gender dysphoria
B) have the capacity to make a fully informed decision and to give consent for treatment
C) have any significant medical or mental health concerns reasonably well controlled

D) have a comprehensive mental health evaluation provided in accordance with Version 7 of the World Professional Association for Transgender Health (WPATH) Standards of Care (www.wpath.org).

Sex reassignment surgery is included for patients who are sufficiently physically fit and meet eligibility criteria. To qualify for surgery, the patient must:

A) have persistent, well documented gender dysphoria
B) for genital surgeries, have completed twelve months of continuous hormone therapy as appropriate to the member's gender goals unless hormones are not clinically indicated for the individual
C) have completed twelve months of living in a gender role that is congruent with their gender identity unless a medical and a mental health professional both determine that this requirement is not safe for the patient
D) have the capacity to make a fully informed decision and to give consent for treatment
E) have any significant medical or mental health concerns reasonably well controlled
F) for breast/chest surgeries, have one referral from a mental health professional provided in accordance with version 7 of the WPATH Standards of Care.
G) For genital surgeries, have two referrals from mental health professionals provided in accordance with version 7 of the WPATH Standards of Care.

Electrolysis (CPT 17380) and laser hair removal (CPT 17110,17111) are only included on this line as part of pre-surgical preparation for chest or genital surgical procedures also included on this line. These procedures are not included on this line for facial or other cosmetic procedures or as pre-surgical preparation for a procedure not included on this line.

Mammoplasty (CPT 15771, 15772, 19316, ~~19324~~-19325, 19340, 19342, 19350) is only included on this line when 12 continuous months of hormonal (estrogen) therapy has failed to result in breast tissue growth of Tanner Stage 5 on the puberty scale OR there is any contraindication to, intolerance of or patient refusal of hormonal therapy.

Revisions to surgeries for the treatment of gender dysphoria are only covered in cases where the revision is required to address complications of the surgery (wound dehiscence, fistula, chronic pain directly related to the surgery, etc.). Revisions are not covered solely for cosmetic issues.

Pelvic physical therapy (CPT 97110,97140,97161-97164, and 97530) is included on this line only for pre- and post-operative therapy related to genital surgeries also included on this line and as limited in Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES.

GUIDELINE NOTE 154, EAR DRUM REPAIR

Lines 311,446,476

Repair of open wounds or perforations of the ear drum (~~codes included on these lines from~~ ICD-10-CM H72~~,~~ and S09.2) are only included on Lines 311 and 446 when there is documented conductive hearing loss greater than or equal to 25dB persistent for more than three months. Otherwise, such repairs are included on Line 476 CHRONIC OTITIS MEDIA; OPEN WOUND OF EAR DRUM.

Appendix B

New Guideline Notes

STATEMENT OF INTENT XX, PUBLIC HEALTH EMERGENCIES

It is the intent of the Commission that If the state Public Health Director determines that there exists a disease outbreak, epidemic or other condition of public health importance in a geographic area of this state or statewide, under ORS 743A.264, then all necessary antitoxins, serums, vaccines, immunizing agents, antibiotics, antidotes and other pharmaceutical agents, medical supplies or other prophylactic measures approved or with emergency use authorization by the United States Food and Drug Administration that the director deems necessary to prevent the spread of the disease, epidemic or other condition of public health importance should be covered.

GUIDELINE NOTE XXX MICROTIA

Line 406, 602

ICD-10-CM Q17.2 (microtia) is included on line 406 for external ear reconstruction when ANY of the following criteria are met:

1) Hearing is expected to improve; OR
2) Reconstruction is necessary to allow for use of a conventional air conduction hearing aid; OR
3) The external ear deformity is preventing the functional ability to use eyewear for the correction of visual loss; OR
4) The patient is under 21 years of age and reconstruction is determined to be medically appropriate and necessary after individual case review.

Otherwise, this diagnosis is included on line 602.

Highlights

Behavioral Health Advisory Panel
Virtual Meeting
October 11, 2022
9:00 am—11:00 am

Members Present: Lynnea Lindsey, PhD Chair; Kathy Savicki, LCSW; John Bischof, MD.

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

Staff Present: Jason Gingerich; Ariel Smits, MD, MPH; Liz Walker, MPH; Michelle Hatfield

Also Attending: Molly Taylor and Kristen Darmody (OHA), Jeanne Savage, Lindsey Phillips, Kristen Darmody, Gordon Clay, Steph Baer, Mina Colon, Allison, Mary Kidd, Yvonne Hubbard, Tami Stump (Polk County), Erin Porter

1. CALL TO ORDER

Lynnea Lindsey called the meeting to order at 9:05 AM. The highlights from the Sepember 2022 BHAP meeting were reviewed and no changes were requested.

Gingerich gave the staff report. He reported that OHA is actively working on resolving issues with the implementation of clubhouse services, a topic discussed at the September BHAP meeting. The issues identified by BHAP were verifying the quality of a program and determining how these programs would be able to bill OHP. Staff suggested that addition of the HCPCS codes for clubhouse services could be delayed until next year, to allow OHA to further determine how to implement these services. Members felt that delay on implementation was reasonable, to allow FFS to run a pilot program. In the interim, CCOs can use grants or other funds to pay for these services currently.

Gingerich reported on a data pull on the number of Medicaid members who are receiving covered treatment for personality disorders despite lack of coverage on the Prioritized List. There was no discussion.

2. PRIORITIZED LIST ISSUES

1) Perpetrator services: Smits reported that HERC had already approved the addition of diagnosis codes for perpetrators of abuse to a covered line. Savicki was concerned that adding coverage for these codes would open the door to offender treatment, which BHAP had not wanted to cover in the past. Gingerich noted that court-ordered treatment cannot be covered by Medicaid. Medicaid coverage would only for non-court ordered, medically necessary treatment. Savicki was concerned that the evidence did not support that treatment of abusers was effective. Lindey also expressed concern. Members requested that HERC staff conduct an

evidence review of the effectiveness of treatment for perpetrators of abuse and work internally at OHA to determine who (corrections, legal, Medicaid) is responsible for payment for such services.

Jeanne Savage noted that QHOC had concerns about the suggested addition of perpetrator of abuse diagnosis codes to the Prioritized List. Court-ordered treatment may or may not be medically necessary, and the CCOs have concerns about covering the treatment at that point. However, the client still needs care. This is an important gap in care. Lindsey commented that CCOs cannot cover care that does not rise to the medically necessary standard, and that BHAP recommends coverage of only evidence supported care.

HERC staff will conduct an evidence review of the effectiveness of treatment on perprators of abuse. Staff will work with other sections of OHA, DOJ, or other relevant agencies to address who (corrections, legal, Medicaid) is responsible for payment for such services. This evidence review, as well as BHAP concerns regarding opening these diagnosis codes, will be brought to the November VBBS/HERC meetings for further discussion and determine if the October HERC decision should be readdressed.

2) <u>2023 Behavioral health related CPT codes</u>

Smits described the new multiple-family group behavior management/modification training codes 96202-96203.

a. The group generally supported pairing these codes with diagnoses that had evidence to support use, such as autism spectrum disorder, ADHD, and conduct disorder. Lindsay expressed concern about whether these groups are support groups or training groups. She felt that there needs to be clarity on the type of service, the license or training of the group leader, and the quality of the program before these should be covered. Lindsey noted that there is good evidence that any program that affects the family system can help children. Savicki recommended looking at asthma, eating disorders, and other conditions that are impacted by the family system.

   Yvonne Hubbard suggested looking at adjustment disorders for possible evidence review. Her program (Oregon Community Programs) works with families in the foster care system. Many of these children have gone through trauma and are having behaviors on the extreme end. Her organization provides care that is not reimbursed by CCOs. Hubbard suggested including coverage for caregivers (biologic or foster parents) of children in the foster system with more extreme behaviors. These trainings could be billed under these codes and are given by qualified mental health professional and are evidence-based programs, specifically, Parent Management Training—Oregon Model (PMTO) and Parent Child Interaction Therapy (PCIT) training and KEEP. Hubbard said they are providing group therapy without the patient. Lindsey noted that young children in many cases cannot be given a specific diagnosis, which might complicate pairing for foster care related issues.

   The final recommendation of BHAP was to add the caregiver training codes to the autism related lines, the ADHD line and the conduct disorder line. HERC staff were directed to look for evidence of effectiveness for eating disorders, adjustment disorder, and support for foster care providers.

3) Intentional self harm: Smits reviewed the evidence summary which reviewed that the diagnosis code for "suicide attempt" was diagnostic and the hudreds of codes for "intentional self harm" were Informational. The OHA Metrics and Scoring group had requested that these codes be moved to a covered location as they are part of upcoming CCO metric measures for social-emotional health. BHAP members reflected that these diagnoses are typically only made in the urgent care/emergency room setting. In these locations, there may not be a provider capable of making a definitive mental health diagnosis. There was also concern that these codes could be used for low level self harm (such as cutting) that does not rise to the level of a diagnosis like major depression. BHAP felt that the current placement of the "intentional self-harm" T and X diagnosis codes as well as ICD-10-CM T14.91 were appropriate and did not require any changes. There was concern about coverage of low-level self harm that did not reach the level of needing urgent/emergent behavioral health care. OHA metrics group had specifically asked about use of these codes in young children who could not be given another diagnosis. BHAP and HERC staff noted that young children do not have "intent" and therefore these codes are inappropriate in this group. Young children would be given the "accidental" or "intentionally harmed by another" version of these codes. If the metrics team feels that there is a need to add one or more of these codes to a covered line, this can be re-addressed at a future BHAP meeting.

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3. Public comment

No additional public comment was received.

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4. ADJOURNMENT

The meeting was adjourned at 10:10 AM.

Highlights

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

Online Meeting
October 4, 2022
8:00 AM – 10:00 AM

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

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

Also Attending: Perry Wagul; Sarah Kowalski and Desma Hopkins (OHA); Manu Chaudhry, DMD.

Roll Call/Minutes Approval/Staff Report

The meeting was called to order at 8:00 am and roll was called. Minutes from October 2021 were reviewed and approved.

- **Topic: 2023 CDT code placement**
  1) Intraoral tomosynthesis codes: Deborah Loy commented that advanced dental imaging is costly, and adoption is not generally followed by increasing funding. Gary Allen noted that tomosynthesis might be more common as dentists replace old x-ray devices in their offices. He notes that tomosynthesis is not widely used in dental offices currently. He also noted that studies are not available yet to evaluate the effectiveness of this technology compared to traditional x-rays.
  2) 3D dental surface scan: Gary Allen noted that this technology is mainly used for crowns and bridges, which are not covered. He noted that this technology would be an advantage for determining eligibility for the orthodontic benefit.
  3) 3D facial surface scan: no discussion
  4) HPV vaccine administration: no discussion
  5) Removal of non-resorbable barrier: Gary Allen agreed placing this code on line 54 URGENT DENTAL SERVICES if the implant was causing pain or infection or irritation. Chaudhry noted that non-resorbable barriers are used to rebuild a bone around an implant structure which is not covered. Covering this code would provide mixed messages about coverage of implants. Dayna Steringer noted that this can be covered as an exception with a co-morbid condition. Karen Nolan agreed with non-coverage and allowing exceptions. Gary Allen noted that there are existing codes for removal of a foreign body.

a. Decision: line 492 ADVANCED PERIODONTICS (E.G., SURGICAL PROCEDURES AND SPLINTING)

6) Guided tissue regeneration/D6197: no discussion
7) Odontogenic cyst: Allen noted that generally odontogenic cysts are seen in relation to an impacted tooth. Loy wondered about why removal of a benign cyst is covered. Allen noted that these are seen on x-ray, and the cyst is removed to send to pathology. Therefore, removal is diagnostic. These lesions can look like an odontogenic cyst but actually be a malignant tumor. These are not very common, but when occur, they should be covered.
8) Guided tissue regeneration: no discussion
9) Reline custom sleep apnea appliance: Gary Allen noted that there is an extensive guideline note around sleep apnea appliances. These services are typically billed to the medical plan.

- **Topic: Dental implant removal**

  Smits reviewed the summary document. OHAP members unanimously felt like the proposed guideline changes were overly broad as proposed. Allen had reviewed private plans and found that most have no benefit at all for dental implants, including removal. Patients with private dental insurance had to pay out of pocket for dental implant removal for any reason. OHP already has broader coverage that most private dental plans by allowing coverage of removal with peri-implantitis, abscess or implant fracture.

  OHAP members were very concerned about inclusion of pain as a criterion. Pain is very subjective. It is also difficult to determine the source of the pain in many cases. Members noted that if the criteria for implant removal were broadened, then this change would need new pricing for contracts. OHAP members did not see any indication for advanced dental imaging for implant removal. The group unanimously agreed that the addition of pain was very problematic and recommended no change to the guideline other than the addition of the new CDT code.

- **Topic: Labial frenectomy review 2022**

  Smits reviewed the summary document. Allen noted that the updated evidence review will help with policy of Dental Care Organizations (DCOs). Staff recommendations were modified to place the correct CDT code in GN48 (D7961 instead of invalid code D7960). Chaudhry noted that lip tie can be covered by exception. He expressed concerns, however, that there will be more requests for labial frenulectomy through the Early and Periodic Screening, Diagnosis and Treatment (EPSDT) program. Loy expressed concern that lip tie and tongue tie are medical, not dental issues.

  Staff noted that the placement of CDT D7962 needs slight housekeeping modifications (placement on the lower line specified in GN139 and explicit comment regarding that code in GN139).

- **Public Comment:**

Perry Wagul, a member of the public, testified about being denied a partial denture. The teeth he has missing are visible to people, and not having a partial denture makes finding employment difficult. Not being able to chew normally limits the types of foods he can eat, which prevents his ability to lose weight. His dental issues affect his major depression. Gary Allen noted that the rules on partial dentures affect many people; lack of coverage for partial dentures for posterior teeth should be taken up at some future point. There is an Oregon Administrative Rule that limits partial dentures to replacement every 5 years and need to have 6 or more missing posterior teeth or one anterior tooth to qualify for a partial denture. Deborah Loy noted that the Dental Care Organizations (DCOs) have requested that this OAR be re-evaluated and possibly changed. Staff will work with OHA to consider possible rule changes regarding partial dentures.

- **Next meeting:**
  - TBD

Highlights
Genetic Advisory Panel (GAP)
Virtual Meeting
October 12, 2022
2:00 PM-4:00 PM

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

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

Also Attending: Devki Nagar (Myriad Genetics); Lauren Siems, Justin Hageman, Flora Days, Val King MD, MPH (CEBP), Annemarie Benton

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The meeting was called to order at 2:00 PM. Roll was called. This is an advisory panel to the Health Evidence Review Commission (HERC). All documents discussed during this meeting were materials prepared by the HERC Medical Director for deliberation by the Value-based Benefits Subcommittee at its 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 2021 GAP meeting were reviewed and no changes were suggested.

1) Routine NCCN reference update for genetics-related guidelines: no discussion on this item.

2) 2023 genetic-related CPT codes
    a. CPT **81418** drug metabolism genomic sequence analysis: Carl Stevens felt that the staff recommendation was appropriate.

    Public comment: Devki Nagar from Myriad Genetics testified regarding CPT 81418. Myriad is supportive of the addition of this code to the Diagnostic File. Myriad would like to have GAP consider covering pharmacologic guidelines based on the Clinical Pharmacogenetics Implementation Consortium (CPIC) guidelines. CPIC is an international body that uses rigorous evidence to recommend pharmacogenetic testing. CMS adopted use of CPIC guidelines for their coverage. Multigene testing is more useful than single gene testing. Medicare issued an LCD in 2020 specifying that pharmacogenetic tests are medically necessary for patients on medications with known gene-drug interactions that are called out by the FDA or CPIC guidelines.

    Stevens asked Nagar what drug classes would be covered and asked about Genesight. Nagar said that some Genesight components would align and is covered under Medicare. indicated Plavix. Stevens said Genesight is not covered now. Nagar said 81418 is not specific to Genesight but Genesight could fall in that code if it met the other criteria. She said she included an attachment from Medicare which lists the medications and genes.

    Staff was directed to research CPIC guidelines to see if these would be useful.

    Smits said that the CPIC guidelines are available at: https://cpicpgx.org/guidelines/. CPIC guidelines include recommendations for genetic testing of P450 enzyme mutations prior to use of various proton pump inhibitors, clopidogrel, voriconazole, phenytoin, warfarin,

atomoxetine, ondansetron, tropisetron, tamoxifen, SSRIs, tricyclic antidepressants, opioids, and tacrolimus. In general, the reviews appeared to be current (within the past 5 yrs), evidence based, and funded by impartial bodies (for example, the NIH). Some authors had conflicts of interest. Staff conclusion was that these reviews are evidence based, but the recommendations went far beyond current standard of care. Staff recommendation is to continue to use FDA guidelines and monitor CPIC and other evidence-based sources going forward.

b. CPT **81441** Inherited bone marrow failure syndromes sequence analysis panel: panel members agreed with staff recommendation with no discussion

3) TPMT gene and enxyme activity testing: Stevens supported moving both gene and phenotype testing to the Diagnostic Procedures file. There was minimal discussion.

4) Next generation sequencing: Stevens noted there is a high volume of these tests requested. FoundationOne [CPT 0037U] is a major test in this area. He approves these tests despite the type or stage of cancer. Caris [Molecular Intelligence, CPT 81479] is another major testing group in this area. Stevens/CareOregon prices these codes similar to CPT 81455. He recommended EbGS look at minimum or maximum number of genes, type of cancer, and state of cancer when they begin to address the cancer biomarkers topic.

   The group felt that the staff recommended guideline wording that included "at least 5 genes" should be removed as that number is not based on evidence. Stevens was concerned about having a guideline for these tests at all, as the guideline review would be very time consuming if the reviewer had to constantly refer to the NCCN guidelines. He recommended making these tests Diagnostic with no guideline. Panel members agreed that the tests should have no guideline. There was discussion about how often then tests should be repeated. This was felt to be dependent on the tumor behavior. There was another suggestion that this testing could be limited to once per patient.

   Staff was directed to discuss this topic with a medical oncologist or an ad hoc group of medical oncologists and pathologist to inform the question of scoping the EbGS biomarker review. The advisory panel agreed with staff recommended 2023 CPT code placement, without the new guideline for cancer biomarker panels.

5) Other topics: Carl Stevens requested that Decipher Prostate RP (CPT 81542) be considered for coverage. This is now an NCCN recommended test with a strong recommendation. Dr. Stevens requested that this code be removed from GN173 and added to coverage. Staff will research this prior to the November VBBS/HERC meeting.

The meeting adjourned at 3:20 pm.

Section 2.0

VBBS Report

Corneal Collagen Cross-Linkage

Plain Language Summary:
Background: Should a treatment for a condition which results in vision problems from thinning of the outer layer of the eye (cornea) be covered on the Oregon Health Plan?

Should OHP cover this treatment? Staff recommends covering this treatment because evidence shows the treatment works for certain conditions and it is recommended by experts.

Question: Should corneal collagen cross-linkage be added as a treatment of keratoconus?

Question source: Holly Jo Hodges, CCO medical director

Issue: Keratoconus is a corneal thinning disorder occurring when the normally round dome-shaped cornea, the clear tissue covering the front of the eye, progressively changes shape to a conical bulge. This causes refractive error, which is usually a myopic shift and is often associated with astigmatism, leading to visual impairment. It commonly affects children and young adults and may be progressive.

In mild to moderate keratoconus, clinical management to correct visual acuity is by glasses or contact lenses. With disease progression, rigid gas permeable contact lenses may be fitted, or corneal ring segment inserts used. However, if the corneal shape deteriorates further, some form of corneal surgery may be required, including deep lamellar keratoplasty or penetrating keratoplasty for severe progressive keratoconus. Corneal collagen cross-linkage (CXL) using riboflavin and ultraviolet A (UV A) radiation was piloted on patients in 2003. It increases corneal biomechanical stiffness thereby strengthening and stabilizing the cornea. This is achieved by increasing the number of 'anchors' that bond collagen fibers together. The aim is to stop disease progression and need for corneal transplant.

This topic was discussed at the October 2022 VBBS meeting. The subcommittee members requested that further evidence review be conducted to better understand the effectiveness of the procedure. The members also requested that an ophthalmologist be invited to come to the November meeting to answer questions.

Current Prioritized List status
Never Reviewed:
CPT 0402T Collagen cross-linking of cornea (including removal or the corneal epithelium and intraoperative pachymetry when performed)

ICD-10-CM H18.6 family (keratoconus) is on line 310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA with various surgical treatments paired

Evidence:

1) **Craig 2014,** systematic review and meta-analysis of corneal collagen cross-linkage for keratoconus
    a. N=71 papers on efficacy, 26 papers on adverse events
        i. 8 RCTs (4 unique trials), 29 prospective case series, 7 retrospective case series, 5 case series
    b. In all cases the estimated change at 12 months follow-up was significant, with max and mean K values reducing by about 1 D and min K by 0.75 D.
    c. Epithelium-off CXL was associated with statistically significant improvement in corrected and uncorrected visual acuity over all time periods
    d. Meta-analyses of studies comparing epithelium-off CXL eyes and control eyes at 12 months follow-up reported significant improvement in corrected visual acuity (-0.19 LogMAR) but reported no improvement in uncorrected visual acuity (-0.45 LogMAR)
    e. Meta-analysis results for the differences between preoperative and postoperative data showed statistically significant improvements in astigmatism at 6, 12, and 24 months (-0.4 D at 6 months, -0.7 D at 12 months, and -0.5 D at 24 months), with absolute benefit increasing to 12 months and stabilizing.
    f. Meta-analysis results for differences between epithelium-off CXL and control groups from 2 RCTs showed no significant differences at 12 months (-1.42 D [-3.85; 1.00])
    g. Forty serious complications in 39 patients undergoing epithelium-off CXL were reported in the 49 efficacy and 26 safety papers. Common side effects were pain, corneal edema, and corneal haze. These and other minor complications resolved usually within a few days after the procedure
2) **NICE 2013** systematic review on photochemical corneal collagen cross-linkage
    a. N=49 papers on efficacy and N=26 papers on safety
        i. Generally given a grade of low or very low quality
    b. Improvements in measures of topography were found for Max K, mean K and Min K, respectively at 6, 12 months and 24 months. Benefit increased to 12 months and then stabilized. This evidence came from a comparison of baselines before and after procedure; no randomized control data were available.
    c. For measures of visual acuity, meta-analysis of change between treated and control groups at 12 months found no significant differences for uncorrected visual acuity but a significant difference of around -0.20 (LogMAR) for corrected visual acuity. One RCT reporting at 18 months only, however, found non-significant differences between the treatment and control groups in corrected visual acuity. The results for differences between post-treatment and baseline values for treated patients showed significant improvements for corrected and uncorrected visual acuity at 6, 12 and 24 months. Improvement was also indicated by the results from all papers reporting this outcome.
    d. No significant differences were found between the treatment and control groups for measures of astigmatism. Differences between post-treatment and baseline values for treated patients showed statistically significant improvements in astigmatism at 6, 12 and 24 months, and for spherical equivalence measures, significant differences at 12 months.
    e. A meta-analysis of 6 papers found a statistically significant reduction in central corneal thickness values between post-treatment and baseline values for treated patients at 12 months. Evidence from 25 papers was supportive of a reduction.
    f. Evidence on intraocular pressure is poor but suggestive of a tendency to higher intraocular pressure after procedure.

g. The procedure is generally reported as safe but serious complications were reported, including the need for 4 patients to have corneal transplant, and a similar number suffering long-term loss in visual acuity. Cause of the events was seldom disclosed. For example, some infections may be due to the patient failing to comply with advice on after care, while other events may be due to operator error. Most events resolved over time with no major consequences for the patient.

Other payer policies:

1) NICE 2013

a. Current evidence on the safety and efficacy of epithelium-off CXL for keratoconus and keratectasia is adequate in quality and quantity. Therefore, this procedure can be used provided that normal arrangements are in place for clinical governance, consent and audit

b. Current evidence on the safety and efficacy of epithelium-on (transepithelial) CXL, and the combination (CXL-plus) procedures for keratoconus and keratectasia is inadequate in quantity and quality. Therefore, these procedures should only be used with special arrangements for clinical governance, consent and audit or research

2) Aetna 2022

a. Aetna considers epithelium-off photochemical collagen cross-linkage using riboflavin (Photrexa) and ultraviolet A medically necessary for keratoconus and keratectasia.

b. Aetna considers photochemical collagen cross-linkage experimental and investigational for all other indications because its effectiveness for other indications has not been established.

c. Aetna considers epithelium-on (transepithelial) collagen cross-linkage experimental and investigational for keratoconus, keratectasia, and all other indications.

d. Aetna considers performance of photochemical collagen cross-linkage in combination with other procedures (CXL-plus) (e.g., intrastromal corneal ring segments, PRK or phakic intra-ocular lens implantation) experimental and investigational.

3) Cigna 2021

a. Conventional, epithelium-off, corneal collagen crosslinking (C-CXL) using a U.S. Food and Drug Administration (FDA) approved drug/device system (e.g., Photrexa® Viscous or Photrexa® with the KXL® System) (CPT Code® 0402T; HCPCS Code J2787) is considered medically necessary for the treatment of EITHER of the following:

i. progressive keratoconus

ii. corneal ectasia following refractive surgery

iii. when ALL of the following criteria are met:

1. age 14–65 years

2. progressive deterioration in vision

3. absence of visual disturbance from a significant central corneal opacity or other eye disease (e.g., herpetic keratitis, neurotrophic keratopathy)

b. C-CXL is considered experimental, investigational or unproven for any other indication including when combined with a second refractive procedure. All other corneal collagen crosslinking procedures (e.g., epithelium-on/trans-epithelial) are considered experimental, investigational or unproven.

4) Blue Cross/Blue Shield

a. Corneal collagen cross-linking using riboflavin and ultraviolet A may be considered medically necessary as a treatment of:

i. progressive keratoconus OR
ii. corneal ectasia after refractive surgery in patients who have failed conservative treatment (e.g., spectacle correction, rigid contact lens).

b. Progressive keratoconus or corneal ectasia is defined as one or more of the following:
i. An increase of 1 diopter (D) in the steepest keratometry value;
ii. An increase of 1 D in regular astigmatism evaluated by subjective manifest refraction;
iii. A myopic shift (decrease in the spherical equivalent) of 0.50 D on subjective manifest refraction;
iv. A decrease ≥0.1 mm in the back optical zone radius in rigid contact lens wearers where other information was not available.

Expert input

Dr. Travis Redd, OHSU ophthalmology

I strongly support OHP providing CXL coverage. It would make a huge positive impact for our patients.

Dr. Winston Chamberlain, OHSU ophthalmology

This is very important topic to us because many of our patients are not getting access to vision saving care because of OHP's current lack of coverage policy for crosslinking. The problem is bad enough that many OHP patients have lost vision or required more expensive and more risky procedures…The procedure is not inexpensive because of J codes required to Cover the medication under the current approval status of the procedure in the United States and the equipment and facility costs. But it is a fraction of the cost of the alternative procedure that OHP has historically forced us to consider which is a corneal transplant with lifelong risks to patients and maintenance.

Corneal Collagen Cross-Linkage

HERC staff summary

Corneal collagen cross linking has evidence of significant improvement in corrected and uncorrected visual acuity as a treatment for keratoconus. This procedure is covered by all major insurers surveyed for progressive keratoconus or corneal ectasia following refractive surgery when there is a progressive deterioration in vision. Experts recommend coverage as vision saving cost-effective care.

HERC staff recommendations:

1) Add CPT 0402T (Collagen cross-linking of cornea (including removal or the corneal epithelium and intraoperative pachymetry when performed)) to line 310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA
2) Adopt a new guideline for line 310 as shown below

GUIDELINE NOTE XXX CORNEAL COLLAGEN CROSS LINKING

Line 310

CPT 0402T is included on this line only when used for conventional epithelium-off corneal collagen cross linking and only for treatment of:

1) progressive keratoconus, OR
2) corneal ectasia following refractive surgery; and

only when there is objective progressive deterioration in vision.

Consent Agenda Issues—November 2022

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
Q67.6	Pectus excavatum	401 BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS 528 DEFORMITIES OF UPPER BODY AND ALL LIMBS	ICD-10-CM Q67.6 was mistakenly removed from line 528 at the October 2022 VBBS/HERC meeting. It belongs on both line 528 and on line 401, governed by guideline 94 PECTUS EXCAVATUM.	Do not remove Q67.6 from line 528 as previously decided

Straightforward Guideline Note Changes
November 2022

Gastric neurostimulator guideline

1) The new gastric neurostimulator guideline does not include the HCPCS code for the actual neurostimulator: E0765 (Fda approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting).
    a. HERC staff recommendation:
        i. Modify GN227 as shown below

GUIDELINE NOTE 227, GASTRIC ELECTRICAL STIMULATION

Line 8,27,529

Gastric electrical stimulation (CPT 43657, 43648, 43881, 43882; HCPCS E0765) is included on these lines only for pairing with diabetic gastroparesis (ICD-10-CM E10.43, E11.43) or idiopathic gastroparesis (ICD-10-CM K31.84) and only when ALL of the following criteria are met:

A) The patient has intractable nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology; AND

B) The patient is refractory or intolerant of prokinetic medications and antiemetic medications; AND

C) The patient is not on opioid medications; AND

D) The patient does not have abdominal pain as the predominant symptom.

Botulinum toxin for bladder chemodenervation

2) The Oregon Surgicenter requested clarification of the guideline regarding botulinum toxin for bladder chemodenervation. Currently, GN219 requires that "Chemodenervation of the bladder (CPT 52287) is included on this line only for treatment of idiopathic detrusor over-activity or neurogenic detrusor over-activity (ICD-10-CM N32.81) in patients who have not responded to or been unable to tolerate at least two urinary incontinence antimuscarinic therapies (e.g. fesoterodine, oxybutynin, solifenacin, darifenacin, tolterodine, trospium)." Oregon Surgicenter desired clarification as to whether beta-3 agonists such as Myrbetriq or Gemtesa would qualify. OHA P&T staff recently reviewed medications for overactive bladder and found no difference in efficacy between antimuscarinics or beta-3 agonists. P&T staff recommend modifying GN219 to allow beta-3 agonists to be one of the two medications required to be tried prior to chemodenervation.

GUIDELINE NOTE 219, CHEMODENERVATION

Lines 292,327,351,362,378,393,410,500,517,526

Inclusion of chemodenervation on the Prioritized List has the following limitations for the lines specified below:

Line 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS

Chemodenervation with botulinum toxin injection (CPT 64642-64647) is included on this line for treatment of upper and lower limb spasticity (ICD-10-CM codes G24.02, G24.1, G35, G36.0, I69.03-I69.06 and categories G71, and G80-G83)

Line 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION

Chemodenervation of the bladder (CPT 52287) is included on this line only for treatment of idiopathic detrusor over-activity or neurogenic detrusor over-activity (ICD-10-CM N32.81) in patients who have not responded to or been unable to tolerate at least two urinary

incontinence antimuscarinic or beta-3 adrenergic therapies (e.g. fesoterodine, oxybutynin, solifenacin, darifenacin, tolterodine, trospium, mirabegron, vibegron). Treatment is limited to 90 days, with additional treatment only if the patient shows documented positive response. Positive response to therapy is defined as a reduction of urinary frequency of 8 episodes per day or urinary incontinence of 2 episodes per day compared to baseline frequency.

Line 351 STRABISMUS DUE TO NEUROLOGIC DISORDER

Chemodenervation with botulinum toxin injection (CPT 67345) is included on this line for the treatment of strabismus due to other neurological disorders (ICD-10-CM H50.89).

Line 362 DYSTONIA (UNCONTROLLABLE); LARYNGEAL SPASM

Chemodenervation with botulinum toxin injection (CPT 64612, 64616) is included on this line only for treatment of blepharospasm (ICD-10-CM G24.5), spasmodic torticollis (ICD-10-CM G24.3), and other fragments of torsion dystonia (ICD-10-CM G24.9).

Line 378 ESOPHAGEAL STRICTURE; ACHALASIA

Chemodenervation with botulinum toxin injection (CPT 43201) is included on this line for treatment of achalasia (ICD-10 K22.0).

Line 393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN

Chemodenervation with botulinum toxin injection (CPT 67345) is included on this line for the treatment of strabismus due to other neurological disorders (ICD-10-CM H50.89).

Line 410 MIGRAINE HEADACHES

Chemodenervation for treatment of chronic migraine (CPT 64615) is included on this line for prophylactic treatment of adults who meet all of the following criteria:

A) have chronic migraine defined as headaches on at least 15 days per month of which at least 8 days are with migraine

B) has not responded to or have contraindications to at least three prior pharmacological prophylaxis therapies (e.g. beta-blocker, anticonvulsant or tricyclic antidepressant)

C) their condition has been appropriately managed for medication overuse

D) treatment is administered in consultation with a neurologist or headache specialist.

Treatment is limited to two injections given 3 months apart. Additional treatment requires documented positive response to therapy. Positive response to therapy is defined as a reduction of at least 7 headache days per month compared to baseline headache frequency.

Line 500 SIALOLITHIASIS, MUCOCELE, DISTURBANCE OF SALIVARY SECRETION, OTHER AND UNSPECIFIED DISEASES OF SALIVARY GLANDS

Chemodenervation with botulinum toxin injection (CPT 64611) is included on this line for the treatment of excessive salivation.

Line 517 DISORDERS OF SWEAT GLANDS

Chemodenervation with botulinum toxin injection (CPT 64650, 64653) is included on this line for the treatment of axillary hyperhidrosis and palmar hyperhidrosis (ICD-10-CM L74.52, R61).

Line 526 CHRONIC ANAL FISSURE

Chemodenervation with botulinum toxin injection (CPT 46505) is included on this line for the treatment of anal fissures.

COVID-19 Related Codes
November 2022

Issues:

1) New COVID vaccine codes were released for the booster of the Novavax vaccine

HERC staff recommendations:

1) Add the following CPT code to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

CPT Code	Code Description
0044A	Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponinbased adjuvant, preservative free, 5 mcg/0.5 mL dosage; booster dose

November 2022 Consent Items

Issue: A dental care organization (DCO) requested consideration of additional diagnosis codes for line 256 DEFORMITIES OF HEAD AND HANDICAPPING MALOCCLUSION for use with the new handicapping malocclusion benefit. These conditions could also be used for people who might need orthodontia that meets the criteria specified in Guideline Note 169.

In addition, clarifications are needed to communicate that orthodontia services not included on line 256 appear on line 618 DENTAL CONDITIONS (E.G. MALOCCLUSION) / ORTHODONTIA (I.E. FIXED AND REMOVABLE APPLIANCES AND ASSOCIATED SURGICAL PROCEDURES) and line 645 DENTAL CONDITIONS WHERE TREATMENT IS CHOSEN PRIMARILY FOR AESTHETIC CONSIDERATIONS, where they are in 2022 to account for other services such as cosmetic orthodontia or cosmetic dentistry.

Staff have consulted with Dr. Stacy Geisler who recommends adding the following ICD-10-CM codes to line 256.

Planned coverage:
Diagnoses to be added to line 256 on 1/1/2023 (previously approved), with guideline note:

ICD-10 Code	Code description	Current placement (10/1/2022 List)
K00.1	Supernumerary teeth	645 DENTAL CONDITIONS WHERE TREATMENT IS CHOSEN PRIMARILY FOR AETHETIC CONSIDERATIONS
K00.2	Abnormalities of size and form of teeth	645
K00.5	Hereditary disturbances in tooth structure, not elsewhere classified	645
K00.6	Disturbances in tooth eruption	645
K00.9	Disorder of tooth development, unspecified	645
M26.211	Malocclusion, Angle's class I	618 DENTAL CONDITIONS (E.G., MALOCCLUSION)
M26.212	Malocclusion, Angle's class II	618
M26.213	Malocclusion, Angle's class II	618
M26.219	Malocclusion, Angle's class, unspecified	618
M26.220	Open anterior occlusal relationship	618
M26.221	Open posterior occlusal relationship	618
M26.23	Excessive horizontal overlap	618
M26.24	Reverse articulation	618
M26.25	Anomalies of interarch distance	618
M26.29	Other anomalies of dental arch relationship	618
M26.31	Crowding of fully erupted teeth	618
M26.33	Horizontal displacement of fully erupted tooth or teeth	618
M26.34	Vertical displacement of fully erupted tooth or teeth	618
M26.35	Rotation of fully erupted tooth or teeth	618
M26.36	Insufficient interocclusal distance of fully erupted teeth (ridge)	618

M26.37	Excessive interocclusal distance of fully erupted teeth	618
M26.4	Malocclusion, unspecified	618
M26.70	Unspecified alveolar anomaly	618
Z46.4	Encounter for fitting and adjustment of orthodontic device	618

GUIDELINE NOTE 169, ORTHODONTICS FOR CRANIOFACIAL ANOMALIES AND HANDICAPPING MALOCCLUSION

Line 256

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

1) Cleft lip and palate, cleft palate or cleft lip with alveolar process involvement, OR
2) Other craniofacial anomalies resulting in significant malocclusion expected to result in difficulty with mastication, speech, or other oral function, OR
3) Severe malocclusions with a Handicapping Labiolingual Deviation Index California Modification score of 26 or higher; AND
4) Free and clear of active decay and periodontal disease, verified by a dental exam in past 6 months

Advanced dental imaging is included on this line only when required for surgical planning for repair of craniofacial anomalies

Staff recommendation:

1. Add the ICD-10-CM codes listed below to the previously approved 1/1/2023 line 256 DEFORMITIES OF HEAD AND HANDICAPPING MALOCCLUSION TREATMENT: CRANIOTOMY/CRANIECTOMY; ORTHODONTIA

ICD-10 Code	**Code Description**	**Current Placement**
M26.01	Maxillary hyperplasia	617 ANOMALIES OF RELATIONSHIP OF JAW TO CRANIAL BASE, MAJOR ANOMALIES OF JAW SIZE, OTHER SPECIFIED AND UNSPECIFIED DENTOFACIAL ANOMALIES
M26.02	Maxillary hypoplasia	617
M26.03	Mandibular hyperplasia	617
M26.04	Mandibular hypoplasia	617
M26.05	Macrogenia	617
M26.06	Microgenia	617
M26.11	Maxillary asymmetry	617
M26.12	Other jaw asymmetry	617
M26.19	Other specified anomalies of jaw-cranial base relationship	617
M26.89	Other dentofacial anomalies	617
M26.9	Dentofacial anomaly, unspecified	617

2. Restore diagnoses previously moved to line 256 to also appear on line 267, 618 or 645 (where they are on the 10/2022 list), so they are present for cosmetic orthodontia. They will be added on line 256 effective January 1, 2023.

ICD-10 Code	Code description	Recommended Placement
K00.1	Supernumerary teeth	256, 645 DENTAL CONDITIONS WHERE TREATMENT IS CHOSEN PRIMARILY FOR AESTHETIC CONSIDERATIONS
K00.2	Abnormalities of size and form of teeth	256, 645
K00.5	Hereditary disturbances in tooth structure, not elsewhere classified	256, 645
K00.6	Disturbances in tooth eruption	256, 267 DENTAL CONDITIONS (TIME SENSITIVE EVENTS)
K00.9	Disorder of tooth development, unspecified	256, 645
M26.211	Malocclusion, Angle's class I	256, 618
M26.212	Malocclusion, Angle's class II	256, 618
M26.213	Malocclusion, Angle's class II	256, 618
M26.219	Malocclusion, Angle's class, unspecified	256, 618
M26.220	Open anterior occlusal relationship	256, 618
M26.221	Open posterior occlusal relationship	256, 618
M26.23	Excessive horizontal overlap	256, 618
M26.24	Reverse articulation	256, 618
M26.25	Anomalies of interarch distance	256, 618
M26.29	Other anomalies of dental arch relationship	256, 618
M26.31	Crowding of fully erupted teeth	256, 618
M26.33	Horizontal displacement of fully erupted tooth or teeth	256, 618
M26.34	Vertical displacement of fully erupted tooth or teeth	256, 618
M26.35	Rotation of fully erupted tooth or teeth	256, 618
M26.36	Insufficient interocclusal distance of fully erupted teeth (ridge)	256, 618
M26.37	Excessive interocclusal distance of fully erupted teeth	256, 618
M26.4	Malocclusion, unspecified	256, 618
M26.70	Unspecified alveolar anomaly	256, 618
Z46.4	Encounter for fitting and adjustment of orthodontic device	256, 618

3. Edit guideline note 169 as follows:

GUIDELINE NOTE 169, ORTHODONTICS FOR CRANIOFACIAL ANOMALIES AND HANDICAPPING MALOCCLUSION

Lines 256,618

Orthodontic treatment is included on ~~this~~ line 256 DEFORMITIES OF HEAD AND HANDICAPPING MALOCCLUSION TREATMENT: CRANIOTOMY/CRANIECTOMY; ORTHODONTIA for persons under the age of 21 with

1) Cleft lip and palate, cleft palate or cleft lip with alveolar process involvement, OR
2) Other craniofacial anomalies resulting in significant malocclusion expected to result in difficulty with mastication, speech, or other oral function, OR
3) Severe malocclusions with a Handicapping Labiolingual Deviation Index California Modification score of 26 or higher; AND
4) Free and clear of active decay and periodontal disease, verified by a dental exam in past 6 months

Advanced dental imaging is included on this line only when required for surgical planning for repair of craniofacial anomalies

All other orthodontic services appear on line 618 DENTAL CONDITIONS (E.G., MALOCCLUSION).

Items Discussed with Leadership with No Changes Recommended
Kyphoplasty

Plain Language Summary:
Background: A procedure in the neck (to vertebra) to treat painful fractures. A device manufacturer said the policy of not covering this treatment should be looked at again.

Should OHP cover this treatment? The Washington Health Technology Assessment report did not find good evidence to cover this procedure. The submitted literature was based expert panel opinion. The staff recommend no change in the current non-coverage of kyphoplasty.

Question: Should kyphoplasty be added as a treatment for vertebral fracture?

Question source: Medtronic

Issue: Kyphoplasty (also known as balloon-assisted vertebroplasty) is a minimally-invasive orthopedic procedure, which has been developed to restore bone height lost due to painful osteoporotic compression fractures. It involves the insertion of 1 or 2 balloon devices into the fractured vertebral body. Once inserted, the surgeon inflates the balloon(s) to create a cavity and to compact the deteriorated bone with the intent to restore vertebral height. The balloon(s) are then removed and the newly created cavity is filled with the surgeon's choice of bone filler material, creating an internal cast for the fractured area.

Kyphoplasty was last reviewed in 2016, when the 2013 coverage guidance VERTEBROPLASTY, KYPHOPLASTY, SACROPLASTY was affirmed. The 2013 review recommended that kyphoplasty only be covered for patients hospitalized with uncontrolled pain related to their vertebral fracture.

Current Prioritized List status
On line 478 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT NEUROLOGIC INJURY OR STRUCTURAL INSTABILITY
CPT 22510-22512 (Percutaneous vertebroplasty)
CPT 22513-22515 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance)

GUIDELINE NOTE 109, VERTEBROPLASTY, KYPHOPLASTY, AND SACROPLASTY
Line 478
Vertebroplasty and kyphoplasty are not included on this line (or any other line) for the treatment of routine osteoporotic compression fractures.

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

A) The patient is hospitalized under inpatient status due to pain that is primarily related to a well-documented acute fracture, and

B) The severity of the pain prevents unassisted ambulation, and
C) The pain is not adequately controlled with oral or transcutaneous medication, and
D) The patient must have failed an appropriate 4-to-6 week trial of conservative management.

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

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

From Medtronic:

> It recently came to our attention that a patient in Oregon who is covered by Medicaid was denied prior authorization for BKP. Our understanding is that prior authorization was denied because the patient is not hospitalized under inpatient status due to back pain. Given that BKP is usually done in a physician office, we reviewed the current coverage guidance which was approved in 2013 and affirmed in 2016. The guidance references outdated Current Procedural Terminology (CPT)® coding for both BKP and a related therapy called vertebroplasty (codes 22520, 22521, 22522 for vertebroplasty and 22523, 22524, and 22525 for BKP). Current coding was adopted in 2015 and utilizes 22510, 22511, 22512 for vertebroplasty and 22513, 22514, and 22515 for BKP. For additional detail, you can access Medtronic's current Reimbursement Coding and Payment Guides for both therapies.
>
> In addition to these coding updates, I wanted to make sure HERC is aware that the RAND™/UCLA Appropriateness Method (RAM), used by a multispecialty expert panel, helped establish a clinical care pathway for patients with vertebral compression fractures (VCF) in 2018. This pathway includes key signs and symptoms of suspected VCF, diagnostic evaluation of patients with suspected VCF, appropriateness criteria for vertebral augmentation or non-surgical management, contraindications, and follow up after treatment recommendations. After reviewing the publication, Medicare and other local commercial plans understood the clinical importance of having vertebral fracture patients treated early. In fact, each of the Medicare Administrative Contractors (MACs) and some commercial payers have used this clinical publication to update their requirements and now require acute treatment of vertebral fractures.

Evidence

1) **Washington HTA 2020**, Vertebroplasty, Kyphoplasty, Sacroplasty: Assessing Signals for Update - https://www.hca.wa.gov/assets/program/signal-search-vertebroplasty-kyphoplasty-sacroplasty-20200708.pdf
    a. HTA 2010 review did not find sufficient evidence to cover kyphoplasty
        i. "the evidence for the procedure remains low and the efficacy, safety and economic impact are not well understood."
        ii. "In addition to typical complications from invasive procedures, cementoplasty techniques include risk of possible increase of subsequent compression fractures near a cemented vertebra due to increased rigidity of the treated vertebrae and risk of cement leakage"

b. This report is an update of a 2016 signal review
c. A total of three unblinded RCTs (2 new) comparing kyphoplasty (KP) with conservative medical care (usual care) in patients with osteoporotic fractures have been identified.
    i. The three RCTs together suggest that KP may be associated with improved pain and function versus CMT but clinical importance is unclear; the two new poor quality trials are not considered pivotal and do not change the conclusions from the previous report (criteria A-1 or A3), nor provide major changes in the evidence (criteria B1-B4).
    ii. Safety: Data on safety were poorly reported in studies comparing KP with CMT specifically; they do not change the conclusions from the previous report for this comparison (criteria Criterion A2).
    iii. Cost-effectiveness: Findings of economic studies do not change the conclusions from the previous report (criteria A-1 or A-3), nor provide major changes in the evidence (criteria B-1).

Medline search for kyphoplasty and RCT from 2020-2022 did not find any trials comparing kyphoplasty to conservative treatment.

Submitted literature

1) **Hirsch 2018**, Management of vertebral fragility fractures: a clinical care pathway developed by a multispecialty panel using the RAND/UCLA Appropriateness Method
    a. Funded by Medtronic, all authors reported funding by Medtronic
    b. 12 member expert panel consensus report
    c. Unclear what literature was reviewed
    d. Vertebral augmentation was considered appropriate in patients with positive findings on advanced imaging and in whom symptoms had worsened and in patients with 2 to 4 unfavorable conditions (eg, progression of height loss and severe impact on functioning), dependent on their relative weight. Time since fracture was considered less relevant for treatment choice.
    e. In conclusion, using the RUAM a multispecialty expert panel established a CCP that may guide clinicians to make informed and reasoned decisions on the detection, diagnostic evaluation, treatment choice, and follow-up of patients with or suspected of having a VFF. The pathway may be helpful to reduce undesirable practice variations and improve quality of care. However, validity of the recommendations and usefulness in daily practice needs further research.

HERC staff summary

A recent Washington HTA evidence search did not find studies that showed that kyphoplasty results in clinically meaningful improvement in pain or function. Submitted literature consists of an expert panel opinion report. Staff recommends maintaining the current prioritization and guideline note.

HERC staff recommendation:

1) Make no change in the current prioritization of kyphoplasty

Neurofeedback and Biofeedback for Trauma

Plain Language Summary:
Background: Techniques and equipment that help you learn to control bodily functions such as heart rate or breathing. A subcommittee member asked if these techniques should be covered for children with a history of trauma.

Should OHP cover this treatment? Staff recommends to not cover this treatment because no new evidence exists to show that biofeedback and/or neurofeedback for PTSD of childhood trauma works.

Question: Should neurofeedback and/or biofeedback be paired with trauma, PTSD, or additional indications?

Question source: Lisa Kouzes, DC

Issue: Dr. Kouzes has requested consideration of neurofeedback and/or biofeedback for children with a history of trauma. Biofeedback is a non-invasive psychophysiological treatment technique with a bio-monitoring system and sensors to measure, amplify, and feedback information that enables an individual to learn how to change physiological activity (such as respiration, heart rate variability, blood flow and blood pressure) and thus improve health and performance. Neurofeedback is a specific type of biofeedback. Biofeedback has been used for the treatment of migraine headaches, urinary incontinence, pelvic floor dysfunction, and cancer pain. Neurofeedback focusses on the central nervous system and the brain to improve neuro regulation and stabilization.

From Dr. Kouzes:

> I came across a person who works in Oregon's foster care system as an administrator. She notes that a lot of families are turning to neurofeedback for their foster kids with significant histories of trauma. She reports good results anecdotally and notes that it is not covered by OHP and families are spending a lot out-of-pocket for it. She has found that once families become proficient at the neurofeedback in-office, they are purchasing a unit for home use...
> I looked at the literature and found this RCT: Rogel, A., et al. (2020).
>
> I also did a lot more searching and found there is gaining momentum for neurofeedback, biofeedback, and computer games/apps as adjunct or supplemental interventions (often for home use) for kids. Given the behavioral health system is strained in OR, I was wondering if the HERC would consider evaluating neurofeedback as a covered services for kids suffering from psychological trauma, and/or look into what in-office and/or at-home electronic devices/apps might benefit OHP members for mental health conditions

Previous HSC/HERC review history
Review of old minutes finds that 90901 was on all the cancer lines at one point. In May 2004, the HSC removed 90901 from all lines and placed on the Never Covered File.

In January 2021, biofeedback was formally reviewed. That review included a CADTH 2017 systematic review of neurofeedback and biofeedback for mood and anxiety disorders and a 2019 evidence review of biofeedback for medical conditions from the VA Evidence Synthesis Program. This topic was reviewed by the Behavioral Health Advisory Panel who advised that biofeedback should not be added to any behavioral health or SUD lines. The HERC staff summary from the 2021 review read in part: "There is no evidence supporting the use of biofeedback for the treatment of mental health conditions, and no

private payer is covering biofeedback for this indication. BHAP does not recommend its use for behavioral health conditions."

Current Prioritized List status

CPT 90875 and 90876 (Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 30/45 minutes) are on lines 410 MIGRAINE HEADACHES, 541 TENSION HEADACHES

CPT 90901 (Biofeedback training by any modality) is on lines 410, 541

Evidence:

1) **Rogel 2020**, RCT on impact of neurofeedback on children with developmental trauma
    a. N=37
        i. N=20 neurofeedback, 17 usual treatment
        ii. Follow up 4 months
    b. This pilot study demonstrated that 24 sessions of NFT significantly decreased PTSD symptoms, internalizing, externalizing, other behavioral and emotional symptoms, and significantly improved the executive functioning of children aged 6 –13 years with severe histories of abuse and neglect who had not significantly benefited from any previous therapy.
    c. Conclusions: NFT offers the possibility to improve learning, enhance self-efficacy, and develop better social relationships in this hitherto largely treatment-resistant population

No additional RCTs or systematic reviews identified

HERC staff summary: No significant new evidence has emerged regarding efficacy of biofeedback and/or neurofeedback for PTSD or childhood trauma.

HERC staff recommendation:

1) Make no change in lack of pairing of biofeedback or neurofeedback with PTSD or related conditions

Items Discussed with Leadership with No Changes Recommended
Pneumatic Compression Devices for Lymphedema Therapy

Plain Language Summary:
Background: A pump with varying pressure which fills an inflatable garment with compressed air used to treat abnormal swelling of the arms or legs. A device manufacturer requested a re-review.

Should OHP cover this treatment? Staff recommends no change in the status of non-coverage of this device because there is no evidence that this treatment adds any additional benefit to standard lymphedema therapy.

Question: Should pneumatic compression devices be included as a treatment for lymphedema?

Question source: BioTAB Healthcare

Issue:
Pneumatic compression devices are used to treatment lymphedema, which is a swelling of the upper or lower extremity. Lymphedema can be idiopathic or caused by surgery, particularly lymph node removal. BioTAB Healthcare is requesting a review of the non-coverage of this technology.

The last review of pneumatic compression devices for lymphedema was conducted in 2019. That review included a 2010 AHRQ and a 2017 CADTH technology review. The conclusion of the 2019 review was "The evidence for the use of pneumatic compression devices for treatment of lymphedema is of low quality. The limited evidence base suggests that intermittent pneumatic compression (IPC) may not provide additional benefits when used in combination with the routine management of lymphedema." The HCPCS codes for these devices were placed on line 662/GN173 as a result of that review.

BioTAB Healthcare is requesting a re-review based on a study of 128 patients that showed reduced hospitalization, a study of 69 patients showing reduced symptoms and hospitalization, and an economic study showing a reduction in medical costs. Biotab's presentation includes an indication of chronic venous insufficiency, but no evidence to support this indication is mentioned.

Items Discussed with Leadership with No Changes Recommended
Pneumatic Compression Devices for Lymphedema Therapy

Current Prioritized List 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
E0650-E0673, E0676	Pneumatic compressors and associated appliances, including intermittent devices	Insufficient evidence of effectiveness	May, 2019

ICD-10-CM I87.2 Venous insufficiency (chronic) (peripheral) is on line 639 VARICOSE VEINS OF LOWER EXTREMITIES WITHOUT ULCER OR OTHER MAJOR COMPLICATION

ICD-10-CM I89.0 Lymphedema, not elsewhere classified is on line 422 LYMPHEDEMA

Evidence

Limited review for studies published in 2019 or later

1) **Desai 2019**
    a. Prospective cohort study
        i. N=128 patients (232 extremities)
        ii. Patients were not described as participating in routine decongestive treatment
        iii. Funded by Bio Compression Systems, Inc
    b. Pneumatic compression therapy was utilized for all patients and led to a 28% decrease in absolute limb volume ($P < 0.001$), decrease in body mass index (BMI) ($P < 0.001$), significant improvement in SF-36 quality of life in 7 out of 8 domains ($P < 0.001$), and a significant improvement in LLCS ($P < 0.001$) at 1 year. A subsequent decrease in hospitalization for lymphedema-associated complications saved over $3,200 per patient per year.
2) **Tastaban 2020**
    a. RCT of decongestive treatment with or without intermittent pneumatic compression
        i. N=76 patients
            1. N=38 standard treatment (complex decongestive therapy)
            2. N=38 complex decongestive therapy + intermittent pneumatic compression
    b. Lymphoedema was similar at baseline, but treatments significantly reduced the excess volume (from 373mL to 203mL in Group 1 (complex decongestive treatment) and 379.5 mL to 189.5mL in Group 2 (complex decongestive treatment + pneumatic compression). Percentage excess volumes (PEVs) decreased in both groups. The percentage reduction of excess volume was better in Group 2 than Group 1, but the intergroup difference was not significant. The clinical scores reflected improvements, but the heaviness and tightness read significantly lower in Group 2 than Group 1.
    c. Conclusion: Intermittent pneumatic compression seems to add no benefit when combined with complex decongestive treatment of lymphoedema, but, may be functional in reducing the sensations of heaviness and tightness for the patients with pitting edema (a clinical sign of fluid overload).
3) **Modanado 2021**
    a. Prospective cohort study
        i. N=74 patients
        ii. Generally older men with phlebolymphdema
        iii. Study participants were withdrawn if they did not use the device at least 3 times a week by the 4th week of enrollment
        iv. Patients did not appear to be in routine decongestive therapy
        v. 81% of patients wore static compression garments during study (not report percent wearing prior to study)
        vi. Study supported by Tactile Medical
    b. No significant difference was seen in QOL at 12 weeks. However, at 52 weeks, the Lymphedema Quality of Life scores had significantly improved from baseline

(6.3 vs 7.4; P < .0001) and the short form-36 had demonstrated significant improvement from baseline in the physical component (38.6 vs 40.8; P = .035), with an effect toward overall improvement in the mental component (49.9 vs 51.3; P = .549).

c. APCD treatment was associated with a significant reduction in cellulitis episodes (24.3% vs 8.1%; P ¼ .005), lymphedema-related clinic visits (2.2 vs 0.7; P ¼ .02), urgent care visits (1.2 vs 0.3; P ¼ .004), and hospital admissions (0.5 vs 0.1; P ¼ .047) per patient.

Other Payer policies

Anthem BCBS 2022

Single or multi-chamber or segment *non-programmable* compression devices for the treatment of upper or lower limb lymphedema are considered **medically necessary** when:

A. The individual's lymphedema is not improving; **and**
B. The individual has been compliant with conservative therapy (that is, elevation of the affected limb, exercise, massage, use of an appropriate compression bandage system or compression garment).

Single or multi-chamber or segment *programmable* (for example, calibrated gradient pressure) compression devices for the treatment of upper or lower limb lymphedema are considered **medically necessary** when criteria above for a non-programmable compression device are met and *either* criteria A or criteria B below have been met:

Criteria A:

1. A single or multi-chamber or segment *non-programmable* compression device has been tried for a minimum of 3 months; **and**
2. There is documentation of compliance with treatment with the *non-programmable* pneumatic compression device; **and**
3. The records provide objective documentation that lymphedema has progressed;

or

Criteria B:

1. There is clear documentation of a condition that prevents the satisfactory treatment of lymphedema with a *non-programmable* device. Such conditions may include, but are not limited to the following:
    a. Contracture; **or**
    b. Sensitive skin; **or**
    c. Significant scarring.

Items Discussed with Leadership with No Changes Recommended
Pneumatic Compression Devices for Lymphedema Therapy

HERC staff summary

The evidence for the use of pneumatic compression devices for treatment of lymphedema continues to be of low quality. The limited evidence base suggests that intermittent pneumatic compression (IPC) may not provide additional benefits when used in combination with the routine management of lymphedema.

Studies published since the last review in 2019 either showed no benefit of intermittent pneumatic compression in addition to standard decompressive therapy, or were cohort studies with no comparison to this standard of care.

For patients who are unable to access standard decompressive therapy, pneumatic compression devices might be considered as an alternative treatment option; however, this would not be standard of care.

HERC staff recommendation

1) Make no change in the current non-coverage of pneumatic compression devices for lymphedema therapy
    a. Update the date of last review in GN173

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

Line 660

The following Interventions are prioritized on Line 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
E0650-E0673, E0676	Pneumatic compressor Segmental pneumatic appliance for use with pneumatic compressor	Insufficient evidence of effectiveness	~~May, 2019~~ November, 2022

Errata
November 2022

On November 7, the following correction was made:

1. Line 465 COLLAPSED LUNG was erroneously attached to Guideline Note 118 SEPTOPLASTY. This was corrected to Line 466 CHRONIC SINUSITIS.

On October 20, 2022, the following two corrections were made:

1. The line numbers for Guideline Note 227 GASTRIC ELECTRICAL STIMULATION were corrected:

GUIDELINE NOTE 227, GASTRIC ELECTRICAL STIMULATION
Lines 8, 27, 529

Gastric electrical stimulation (CPT 43657, 43648, 43881, 43882) is included on these lines only for pairing with diabetic gastroparesis (ICD-10-CM E10.43, E11.43) or idiopathic gastroparesis (ICD-10-CM K31.84) and only when ALL of the following criteria are met:

A) The patient has intractable nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology; AND
B) The patient is refractory or intolerant of prokinetic medications and antiemetic medications; AND
C) The patient is not on opioid medications; AND
C) The patient does not have abdominal pain as the predominant symptom.

2. The sentence structure for Guideline Note 144 PROTON PUMP INHIBITOR THERAPY FOR GASTROESOPHAGEAL REFLUX DISEASE (GERD) was clarified:

GUIDELINE NOTE 144, PROTON PUMP INHIBITOR THERAPY FOR GASTROESOPHAGEAL REFLUX DISEASE (GERD)
Lines 314, 380, 513

Short term treatment (up to 8 weeks) of GERD without Barrett's (ICD-10-CM K20.8, K20.9, K21.0, K21.9) with proton pump inhibitor therapy is included on Line 380. Long term treatment is included on Line 513.

Long term proton pump inhibitor therapy is included on Line 380 for Barrett's esophagus (ICD-10-CM K22.70) and on Line 314 for Barrett's esophagus with dysplasia (ICD-10-CM K22.71).

Color Key

Topics under development
Upcoming discussion topics
Reviewed but no changes planned
Already approved changes

Request source	Topic Description	Meeting Date	Planned Imp. Date	Summary of change (or recommended change, decision not to change)
Staff review	Broader Orthopedic review	11/17/2022		Resolved with other issues (deformities of foot, knee)
BHAP request	Personality disorders	11/17/2022		Reviewed with BHAP, no changes recommended
Dr. Hoffman	Congenital ear anomalies without hearing impairment	10/6/2022	1/1/2023	Added coverage of microtia with a new guideline.
Staff review	Somatic symptoms line (Extreme feelings and anxiety about physical symptoms)	10/6/2022	1/1/2023	Housekeeping changes only.
Staff review	Deformities of upper body and all limbs	10/6/2022	1/1/2023	Housekeeping changes only.
Staff review	Genitourinary with minimal or no treatment required (genital and urinary organs)	10/6/2022	1/1/2023	Minor changes made.
Staff review	Deformities of foot	10/6/2022		Housekeeping changes only.
Dr. Hoffman	Conduct disorder/impulse disorders (A type of behavior disorder)	8/11/2022	1/1/2022	BHAP recommended adding to funded region
Staff review	Behavioral health coding	8/11/2022	1/1/2022	Based on review of social emotional learning codes.
Staff review	Sleep disorders other than sleep apnea (including insomnia)	8/11/2022	1/1/2023	Consider adding insomnia above the funding line for cognitive behavioral therapy for insomnia (CBTi). Consider role of medication.
HSD nurse reviewer	Median and radial nerve lesions	8/11/2022	1/1/2022	Proposal to add to covered nerve lesion line with ulnar nerve lesions

Request source	Topic Description	Meeting Date	Planned Imp. Date	Summary of change (or recommended change, decision not to change)
Staff review	Benign neoplasm of the digestive system (Surgery for an abnormal growth found in the stomach or intestines)	5/19/2022		Added benign carcinoid tumors to funded region
HSD	Bilateral bone anchored hearing aids (BAHA) (A specific type of hearing aid for children)	5/19/2022	10/1/2022	Proposal to expand coverage from unilateral to bilateral
Staff review	Scrotal varices (An enlargement of the veins within the skin that holds the testicles (scrotum))	5/19/2022	10/1/2022	Already on line 327 as well as line 548 with no guideline. Propose to remove from line 548 and change name of line
Staff review	Other complications of a procedure	5/19/2022	10/1/2022	Propose to rename line "Minor" as diagnoses are minor
Staff review	Anemias due to kidney diseases (erythropoietin) (A drug to treat low blood count caused by kidney disease)	5/19/2022		Recommend clarifying coverage of erythropoietin for non-end stage kidney disease
Staff review	Esophageal ulcer	3/10/2022	10/1/2022	Added to funded region
Dr. Hoffman	Foreign body in digestive tract	3/10/2022	1/1/2022	Had already been addressed prior to the concern raised, but implementation was pending
Staff review	Generalized muscle weakness	3/10/2022	10/1/2022	Added to funded region
HSD Staff	Handicapping malocclusion	11/18/2021	1/1/2023	Working on implementation issues; addition to funded region planned for 1/1/2023
CCO	Dorsal rhizotomy	3/10/2022	10/1/2022	Added to funded region
Staff review	Corneal abcess	3/10/2022	10/1/2022	Added to funded region
Staff review	Lichen planus	3/12/2020	10/1/2022	Change name of line to reflect mild/moderate; severe forms on funded line as defined by Guideline Note 21
Staff review	Mastoiditis	3/12/2020	10/1/2022	Added to funded region
Dr. Hoffman	Nightmare disorder	11/18/2021	1/1/2022	Added to funded region
Dr. Hoffman	Oral candidiasis (thrush)	8/12/2021	10/1/2021	Added to funded region for feeding problems in newborns line

Request source	Topic Description	Meeting Date	Planned Imp. Date	Summary of change (or recommended change, decision not to change)
Dr. Hoffman	Phimosis (acquired penile complications, circumcision etc)	10/7/2021	1/1/2022	Clarified coverage criteria for acquired vs congenital anomalies of the penis. Added to funded region for acquired anomalies.
Staff review	Polydactyly	3/12/2020	10/1/2022	Clarified earlier decision to confirm in funded region
Public	Rhinoplasty/septoplasty/ deviated septum	8/12/2021	10/1/2022	Created new criteria for septoplasty, clarified conditions for coverage. Some new coverage and new limitations for services that would be cosmetic.
Advocates	Selective mutism	11/18/2021	1/1/2022	Moved to funded anxiety line
Staff review	Sjogren syndrome	3/10/2022	10/1/2022	Added to funded region
Staff review	Tendon and ligament injuries	3/10/2022	10/1/2022	Added to funded region for full tears
Staff review	Viral endocarditis, myocarditis, pericarditis, cardiomyopathy	3/10/2022	10/1/2022	Added to funded region
Staff review	Vitiligo	10/7/2021	1/1/2022	Added vitiligo as a funded condition. Affects children's social function
Staff review	Acquired torsion of penis	3/10/2022	10/1/2022	Added to funded region
Staff review	Agenesis of lung	3/10/2022	10/1/2022	Added to funded region for supportive care
EPSDT	Child growth and development	11/18/2021	1/1/2022	Added path to coverage for treatments supporting growth, development and participation in school for children
Staff review	Chronic pancreatitis		1/1/2022	Already merged for 2022 before this review
Staff review	Vitiligo of eyelid	3/10/2022	10/1/2022	Added to funded region
Staff review	Congenital anomalies of knee (Knee problems since birth)	10/6/2022	n/a	No change made.
Staff (Val King)	Temporomandibular Joint Syndrome (TMJ) (Pain and dysfunction in the jaw joint and muscles controlling jaw movement)	8/11/2022		Review evidence; no change recommended at this time

Request source	Topic Description	Meeting Date	Planned Imp. Date	Summary of change (or recommended change, decision not to change)
Staff review	Physical therapy for minor musculoskeletal conditions (Injuries and disorders that affect the human body's movement or muscles, tendons, ligaments, nerves, discs, blood vessels, etc.)			Limited benefit; would be very difficult to implement
Dr. Hoffman	Allergic rhinitis (Nasal allergies/Hay fever)			No change; little impact on health except when comorbidity or growth/development/school exceptions apply
Dr. Hoffman	Angiodema (Swelling (edema) of the lower layer of skin and tissue just under the skin)	11/18/2021	1/1/2022	Removed unfunded duplicate line (no substantive change, was already covered)
Dr. Hoffman	Benign bone neoplasm			No change made; serious benign neoplasms are on line 401; Guideline 137 clarifies which are covered.
Dr. Hoffman	Congenital anomalies of female genital tract excluding vagina			No change: Diagnoses on this line have no treatment. Other anomalies that require repair are on funded line(s)
Dr. Hoffman	Dermatophytoses (ringworm, etc.)			No change; primary care and preferred medications should be sufficient for these conditions
Dr. Hoffman	Diaper rash			No change: Primary care and preferred medications (nystatin) should be sufficient
Dr. Hoffman	Dysmenorrhea			No change; primary care and preferred medications (NSAIDS, birth control) should be sufficient for these conditions
Dr. Hoffman	Hodeolum/chalazeon			No change; primary care and preferred meds should be sufficient for these conditions. Rare exceptions can be considered through existing processes
Dr. Hoffman	Mild eczema			No change; primary care and preferred medications should be sufficient for these conditions
Dr. Hoffman	Mild psoriasis			No change; primary care and preferred medications should be sufficient for these conditions

Request source	Topic Description	Meeting Date	Planned Imp. Date	Summary of change (or recommended change, decision not to change)
Dr. Hoffman	Minor burns			No change: Primary care and preferred medications should be sufficient
Advocates	Pica (Persistent eating of non-food items (for example clay, wool, lead, wood) at an age when it is considered to be developmentally inappropriate)	3/10/2022	10/1/2022	No change: Removed ambiguity of coverage for pica in children (should have already been in funded region), renamed line to clarify that the unfunded line is "Pica in adults"
Dr. Hoffman	Symptomatic urticaria			No change; primary care and preferred medications should be sufficient for these conditions
Staff review	Angiosarcoma of liver; intrahepatic bile duct carcinoma			Liver angiosarcoma has a very poor prognosis with any treatment (6 months even with surgery). Per NIH, the only treatment of bile duct carcinoma is palliative care
Staff review	Central retinal artery occlusion			Reviewed; no effective treatment is available
Dr. Hoffman	Conversion disorders F44.4-7, include non-epilectic seizures			Cognitive behavioral therapy would be available with another underlying disorder such as depression. No other treatment for actual disorder indicated
Staff review	Cysts of Bartholin's gland and vulva			N75.1 (Abscess of Bartholin's gland) is included on line 205. Cysts typically have no symptoms and do not need treatment
Staff review	Enophthalmos			Treatment is directed at underlying diseases, which appear in funded region
Dr. Hoffman	Infectious mononucleosis			Primary care should be sufficient; there is no treatment for this condition
Staff review	Miscellaneous rare congenital anomalies			Individual consideration will be required
Staff review	Nasal polyps			and saline. Surgery indicated if causing chronic sinusitis due to blockage of sinus ostia (would be covered on chronic sinusitis line)
Staff review	Personality disorders			No effective treatment

Request source	Topic Description	Meeting Date	Planned Imp. Date	Summary of change (or recommended change, decision not to change)
Staff review	Secondary and ill-defined neoplasms			Treatment should be targeted to primary cancer, which would be covered.
Staff review	Thrombosed and complicated hemorrhoids			Generally treated with fiber and observation. Could be addressed based on individual review
Staff review	Tension headaches			Primary care and NSAIDs are effective treatments.

Dental Implant Removal

Plain Language Summary:
Background: The metal post that replaces the root portion of a missing tooth removal. The Oregon Health Authority Ombuds Office recommends "pain" to be a reason for removal.

Should OHP cover this treatment? Oral Health Advisory Panel members said "pain" is subjective and decided not to recommend including that in its recommendations. Based on this, staff does not recommend adding coverage for implant removal for patients experiencing implant-related pain. However, a new code needs to be added to the existing line and guideline to continue coverage based on the current rules.

Question: Should the dental implant removal guideline be broadened to include more indications?

Question source: OHA Ombuds office

Issue: The current dental implant removal guideline allows coverage only for "advanced peri-implantitis with bone loss and mobility, abscess or implant fracture." The Ombuds office recently had a case where there was severe pain and inability to chew, and the claim was denied as not meeting the guideline note criteria. The Ombuds office also notes that the advanced dental imaging needed to determine need for dental implant removal is not specifically called out in the guideline as covered. The Ombuds office requested that a possible expansion of indications for dental implant removal be considered by HERC, as well as possible coverage of advanced dental imaging in cases with possible dental implant complications.

The advanced imaging needed to evaluate a failed dental implant are only on line 256 DEFORMITIES OF HEAD governed by GUIDELINE NOTE 169, ORTHODONTICS AND CRANIOFACIAL SURGERY FOR CRANIOFACIAL ANOMALIES which specifies that "Advanced dental imaging is included on this line only when required for surgical planning for repair of craniofacial anomalies."

In addition to the above issue, a new 2023 CDT code also requires placement: CDT D6105 (removal of implant body not requiring bone removal nor flap elevation).

Current Prioritized List status:
GUIDELINE NOTE 123, DENTAL IMPLANT REMOVAL
Lines 344,619
Removal of dental implants (D6100) is included on Line 344 only when there is advanced peri-implantitis with bone loss and mobility, abscess or implant fracture. Otherwise, this procedure is included on Line 619.

CDT code	Code Description	Current Line(s)
D6100	Surgical removal of implant body	344 DENTAL CONDITIONS (E.G., SEVERE CARIES, INFECTION) 619 DENTAL CONDITIONS (E.G., MISSING TEETH)
D0364	Cone beam ct capture and interpretation with limited field of view - less than one whole jaw	256 DEFORMITIES OF HEAD

D0365	Cone beam ct capture and interpretation with field of view of one full dental arch - mandible	256
D0366	Cone beam ct capture and interpretation with field of view of one full dental arch - maxilla, with or without cranium	256
D0367	Cone beam ct capture and interpretation with field of view of both jaws, with or without cranium	256

OHAP discussion:
HERC staff brought forward a possible modification to GN123 for OHAP discussion:

GUIDELINE NOTE 123, DENTAL IMPLANT REMOVAL
Lines 344,619
Removal of dental implants (D6100, D6105) is included on Line 344 only when there is
1) advanced peri-implantitis with bone loss and mobility, abscess or implant fracture; OR
2) pain, inability to masticate or inhibition of oral function related to the dental implant.
Otherwise, this procedure is included on Line 619.

Advanced dental imaging is included on line 344 only when needed to evaluate pain or dysfunction associated with a dental implant site.

OHAP members unanimously felt like the proposed guideline changes were overly broad. Allen had reviewed private plans and found that most have no benefit at all for dental implants, including removal. Patients with private dental insurance had to pay out of pocket for dental implant removal for any reason. OHP already has broader coverage that most private dental plans by allowing coverage of removal with peri-implantitis, abscess or implant fracture.

OHAP members were very concerned about inclusion of pain as a criterion. Pain is very subjective. It is also difficult to determine the source of the pain in many cases. OHAP members did not see any indication for advanced dental imaging for implant removal. The group unanimously agreed that the addition of pain was very problematic and recommended no change to the guideline other than the addition of the new CDT code.

HERC staff recommendations:
1) Add CDT D6105 (removal of implant body not requiring bone removal nor flap elevation) to lines 344 DENTAL CONDITIONS (E.G., SEVERE CARIES, INFECTION) and 619 DENTAL CONDITIONS (E.G., MISSING TEETH)
2) Modify GN123 as shown below

GUIDELINE NOTE 123, DENTAL IMPLANT REMOVAL
Lines 344,619
Removal of dental implants (D6100, D6105) is included on Line 344 only when there is advanced peri-implantitis with bone loss and mobility, abscess or implant fracture. Otherwise, this procedure is included on Line 619.

2023 CPT Code Review
BHAP Issues

1) Code: **96202-96203**
    a. Code descriptions:
        i. **96202** Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); initial 60 minutes
        ii. **96203** each additional 15 minutes
    b. Information: Training of parents or caregivers to help learn behavior management skills to help the child/affected person learn new desirable behaviors/coping skills and help to reduce and eliminate undesirable behaviors (for example, self-injury)
    c. Similar codes:
        i. 90849 (Multiple-family group psychotherapy) is on all behavioral health lines
        ii. 97157 (Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes) is on lines 193 AUTISM SPECTRUM DISORDERS and 438 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER
    d. Evidence
        i. **Deb 2020**, systematic review and meta-analysis of parent training for children with autism spectrum disorder
            1. N=15 studies (17 papers)
            2. Fifteen papers showed a positive treatment effect when compared with the control group, although not always significant. Meta-analysis based on pooled data from only two studies in each respective intervention, showed small to moderate treatment effects for three interventions, DIR/Floortime, Pivotal Response and Parent focused training respectively.
            3. Conclusions: As in previous systematic reviews there was a mild to moderate treatment effects of three specific types of interventions respectively. However, it was difficult to draw any definitive conclusion about the effectiveness and generalizability of any intervention because of the wide variation in the interventions, control groups, outcome measures, small sample size, small number of studies in meta-analysis, overlap between the intervention and control procedures used in the included studies
        ii. **Woolfenden 2010**, Cochrane review of family therapy for conduct disorder
            1. N=8 trials (749 children and their families)
            2. At follow up, family and parenting interventions significantly reduced the time spent by juvenile delinquents in institutions (WMD 51.34 days, 95%CI 72.52 to 30.16). There was also a significant reduction in the risk of a juvenile delinquent being re-arrested (RR 0.66, 95%CI 0.44 to 0.98) and in their rate of subsequent arrests at 1-3 years (SMD -0.56, 95% CI -1.100 to - 0.03).

3. At present there is insufficient evidence that family and parenting interventions reduce the risk of being incarcerated (RR=0.50, 95% CI 0.20 to 1.21). No significant difference was found for psychosocial outcomes such as family functioning, and child/adolescent behavior.
4. Conclusion: The evidence suggests that family and parenting interventions for juvenile delinquents and their families have beneficial effects on reducing time spent in institutions

iii. **Lee 2012**, meta-analysis of behavioral parent training (BPT) for children with ADHD
1. N=40 studies
2. When compared with the waiting list control or other treatment, 28 studies found small to large positive effects (r range: .90 to .06) supporting the effects of BPT at post-treatment, whereas 12 studies found small negative effects of BPT (r range: -.01 to -.33). On average, a moderate effect (r = .34, k = 40) was found that supported BPT as an effective intervention in enhancing child and parent behavior as well as parental perception about parenting. In 17 studies, follow-up outcomes of BPT were measured at 3 months to 3 years after the intervention and found a small positive effect (r = .17, k = 17, range: .66 to -.40). BPT effects remained meaningful but declined at follow-up
3. Conclusion: Behavioral parent training is an effective intervention for children with attention deficit hyperactivity disorder

e. Expert recommendations
i. **CDC**: parent training for behavior management for ADHD
1. https://www.cdc.gov/ncbddd/adhd/behavior-therapy.html
a. Accessed September 30, 2022
2. Behavior therapy is an effective treatment for attention-deficit/hyperactivity disorder (ADHD) that can improve a child's behavior, self-control, and self-esteem. It is most effective in young children when it is delivered by parents… When parents become trained in behavior therapy, they learn skills and strategies to help their child with ADHD succeed at school, at home, and in relationships.

ii. **Pilling 2013**, summary of NICE guidance on management of conduct disorders in children
1. Offer a group parent training programme to the parents of those aged 3-11 years who have or are at high risk of oppositional defiant disorder or conduct disorder or are in contact with the criminal justice system because of antisocial behaviour. [Based on moderate to high quality evidence from randomised controlled trials]
2. Offer a group foster carer/guardian training programme to foster carers and guardians of those aged 3-11 years who have or are at high risk of oppositional defiant disorder or conduct disorder or are in contact with the criminal justice system because of antisocial behaviour. [Based on limited high quality evidence from randomised controlled trials and on the experience and opinion of the GDG]

f. BHAP discussion: The group generally supported pairing these codes with diagnoses that had evidence to support use, such as autism spectrum disorder, ADHD, and conduct disorder. Lindsay expressed concern about whether these groups are support groups or training groups. She felt that there needs to be clarity on the type of service, the license or training of the group leader, and the quality of the program before these should be covered. Lindsey noted that there is good evidence that any program that affects the family system can help children. Savicki recommended looking at asthma, eating disorders, and other conditions that are impacted by the family system.

   Yvonne Hubbard suggested looking at adjustment disorders for possible evidence review. Her program (Oregon Community Programs) works with families in the foster care system. Many of these children have gone through trauma and are having behaviors on the extreme end. Ms. Hubbard suggested including coverage for caregivers (biologic or foster parents) of children in the foster system with more extreme behaviors. These trainings are given by qualified mental health professional and are referred to as PMTO and PCIT training. Lindsey noted that young children in many cases cannot be given a specific diagnosis, which might complicate pairing for foster care issues related issues.

   Note: HERC staff conducted a literature review of caregiver training for eating disorders and found scanty evidence, but the protocol for an RCT was published in 2021. It appears that this is an active area of investigation. No literature was found on caregiver training for adjustment disorder. There was good evidence for use of these trainings for resource parents (previously called foster parents). However, this training is required by and provided by DHS as part of the resource parent certification. After consultation with the agency responsible for resource parent training, HERC staff have concluded that such training is not in the purview of OHP.

g. <u>HERC staff summary</u>: Parent/caregiver training appears to have limited evidence of effectiveness for children with autism spectrum disorders, ADHD and conduct disorder. The new CPT codes could be used for a broad range of diagnoses. Current multi-family group therapy CPT codes are only on the autism related lines. Group psychotherapy codes (with patient present) are on all behavioral health lines. Staff review of the literature did not find sufficient evidence to support use for eating disorders or adjustment disorders. Use with resource patents (formerly foster parents) is paid for out of non-OHP funding sources.

h. <u>BHAP/HERC staff recommendations</u>:
   i. Place CPT **96202-96203** on the following lines
      1. 121 ATTENTION DEFICIT/HYPERACTIVITY DISORDERS
      2. 193 AUTISM SPECTRUM DISORDERS
      3. 420 OPPOSITIONAL DEFIANT DISORDER; CONDUCT DISORDER AGE 18 OR UNDER
      4. 438 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER

2) Code: **98978**
    a. Code description: Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days
    b. Information:
        a. Previously coded with CPT 0702T (Remote therapeutic monitoring of a standardized online digital cognitive behavioral therapy program ordered by a physician or other qualified health care professional; supply and technical support, per 30 days) and 0703T (Management services by physician or other qualified health care professional, per calendar month).
        b. Digital health products are technologies, platforms, and systems that engage consumers for lifestyle, wellness, and health-related purposes. Digital therapeutic products differ from digital health products in that they are practitioner-prescribed software that delivers evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease. Digital therapeutic products have been proposed to supplement or replace individual or group therapy and/or to deliver cognitive-behavioral therapy for the treatment of substance use disorders.
    c. Similar codes:
        a. 98975-98981 (Remote therapeutic monitoring) are EXCLUDED
    d. BHAP discussion: HERC staff noted that these codes are limited to FDA approved devices. CMS is still working on determining what would be an approved device. BHAP agreed that these codes should be EXCLUDED until further input is received from MED and CMS.
    e. <u>HERC staff summary</u>: The Medicaid Evidence Based Decision program (MED) is performing a review of digital health products, which will include behavioral health and substance use treatment products. This review is expected to be complete within the next year. Current remote therapeutic monitoring CPT codes are EXCLUDED. Staff recommend putting the new CBT remote monitoring code on EXCLUDED until the MED review is completed.
    f. <u>BHAP/HERC staff recommendation</u>:
        a. Place CPT **98978** on the EXCLUDED file
            i. Similar to current remote therapeutic monitoring codes
            ii. Await the final MED report and readdress placement at that time

2023 Behavioral Health HCPCS Code Review

Issue: One new HCPCS code was identified related to Behavioral Health. This code was reviewed by BHAP via email discussion after the October BHAP meeting and the placement below approved.

BHAP/HERC staff recommendation:

HCPCS Code	Code Description	Similar Code(s)/Comment	Recommended Placement
H2038	Skills training and development, per diem	H2014 (Skills training and development, per 15 minutes) is on all behavioral health lines	All behavioral health lines

Perpetrator Services

This issue summary contains material and discussion about child abuse, partner abuse and other forms of abuse.
If you or someone you know needs help, call 800.799.SAFE (7233) to be connected with a trained staff member in your area.
The National Domestic Violence Hotline is a safe, confidential service. When you call the hotline, only the first six numbers of the phone number are used to route the call, and your complete phone number is never stored in our system. Most states do have laws that require local staff to contact authorities in certain situations, like if there is a child or vulnerable adult who is in danger.

Plain Language Summary:
Background: In October, HERC approved coverage for mental health services for some perpetrators of abuse. Based on additional review and feedback, adding these codes could allow for coverage of ineffective or harmful treatments. More work is required to determine optimal coverage for these kinds of services.

Should OHP cover services for this condition? Staff recommends reversing the decision because some of the services that could be provided under it may be harmful. Staff also plans continued work to improve coverage of services which may prevent abuse.

Question: Should the October 2022 decision to cover diagnoses for perpetrators of abuse be reversed (at least temporarily)?

Question source: BHAP, CCO medical directors

Issue: At the October 2022 meeting, VBBS/HERC added three ICD-10-CM codes for perpetrators of abuse to the covered line for abuse and neglect (line 120 ABUSE AND NEGLECT) as a consent agenda item. These codes were previously on the INFORMATIONAL file. This change was made at the request of the Oregon Youth Authority to allow continued treatment of youth once they leave custody. Specifically, OYA is interested in coverage of perpetrators of sex related abuse (molestation, assault, etc.).

CCO medical directors at the QHOC and BHAP members at their October meeting both expressed concerns about this coverage change. BHAP noted that the evidence is poor that treatment was effective for these patients. QHOC members expressed concern that this treatment is frequently court-ordered and therefore outside the scope of what a CCO can reimburse. BHAP members and QHOC members requested that HERC reverse the decision to cover these codes until HERC staff conduct an evidence review and address who is responsible for payment for such services and under what circumstances. In at least some circumstances, Oregon statute does not allow Medicaid to pay for sex abuse treatment, but Medicaid could pay for treatments for other conditions these individuals may have if they are medically necessary and appropriate.

From the BHAP minutes:

> HERC staff will conduct an evidence review of the effectiveness of treatment on perpetrators of abuse. Staff will work with other sections of OHA to address who (corrections, legal, Medicaid) is responsible for payment for such services. This evidence review, as well as BHAP concerns regarding opening these diagnosis codes will be brought to the November VBBS/HERC meetings for further discussion and determine if the October HERC decision should be readdressed.

Further discussion with providers of counseling for perpetrators of abuse as well as OYA found that in some circumstances, perpetrators or their guardians reach out for treatment outside of the legal system. This type of counseling may be medically necessary, in which case it may be covered by OHP. "Sex offender treatment" specifically cannot be reimbursed by OHP under ORS, no can OHP cover treatment that is court ordered. However, frequently these patients have other conditions such as PTSD or ADHD that OHP does cover for counseling. The providers requested that ICD-10-CM Z69.021 (Encounter for mental health services for perpetrator of non-parental child abuse) be covered in some limited manner. This group of providers was exclusively involved with juveniles; however, they acknowledged that this code could also be used by providers treating adults or people who have committed physical abuse. The ICD-10-CM definition of Z69.021 could include non-parental child neglect as well as physical, emotional or sexual child abuse.

ICD-10-CM Codes
Z69.011 Encounter for mental health services for perpetrator of parental child abuse
Z69.021: Encounter for mental health services for perpetrator of non-parental child abuse
Z69.12: Encounter for mental health services for perpetrator of spousal or partner abuse
Z69.82: Encounter for mental health services for perpetrator of other abuse

Past VBBS/HERC review history:
The "Z" codes were reviewed as a consent item in October 2016. Among the changes suggested in that review was adding ICD-10-CM Z69.011 (Encounter for mental health services for perpetrator of parental child abuse) to what is now line 120 ABUSE AND NEGLECT and removing this code from the Informational File. There was no evidence review or discussion of this change, or indication regarding why this change was recommended.

Z69.021, Z69.12 and Z69.82 were included in the October 2016 review and kept on the Informational File.

Evidence on treatment for intimate partner violence

1) **Rand 2022**, Intimate Partner Abuse Solution Programs
    a. Approaches include the Duluth Model of power and control, cognitive behavioral therapy, Circles of Peace Program
    b. Research on effectiveness of programs
        i. Studies conducted to date often have limitations in their methodologies or the generalizability of findings, precluding any broad conclusions about whether IPAS programs work
        ii. Several meta-analyses since 2019 examining the efficacy of IPAS programs overall concluded that, although IPAS programs appear to have a significant positive effect on IPV recidivism when measured by official reports of rearrest, they have no effect when recidivism is reported by the survivor
        iii. The overarching observation made in research reviews is that the more rigorous the methods of evaluation studies, the less encouraging their findings

iv. Efforts to assess and compare IPAS efficacy are complicated not only by the exigencies of a real-world setting but also by variation in program length and components (even among interventions that carry the same label), differences in implementation quality, and measurement issues. Limited funding and relatively short timelines for research pose additional challenges.

2) **Smedslund 2011**, Cochrane review of CBT for men who physical abuse their female partner
   a. N=6 trials (2343 participants)
   b. A meta-analysis of four trials comparing CBT with a no-intervention control (1771 participants) reported that the relative risk of violence was 0.86 (favoring the intervention group) with a 95% confidence interval (CI) of 0.54 to 1.38. This is a small effect size, and the width of the CI suggests no clear evidence for an effect
   c. Conclusion: There are still too few randomi~~z~~zed controlled trials to draw conclusions about the effectiveness of cognitive behavio~~u~~r therapy for male perpetrators of domestic violence
3) **Arce 2020**, meta-analytical review of interventions for batterers
   a. N=25 studies (20,860 participants)
   b. The results of a global meta-analysis showed a positive, significant, and of a medium magnitude effect size for batterer interventions, but not generalizable. Nevertheless, the results exhibited a significantly higher rate of recidivism measured in couple reports (CRs) than in official records (ORs)
   c. The meta-analysis on the studies measuring intervention efficacy on the recidivism rate in CRs, with a sample of 1,351 batterers and 16 effect sizes, revealed that interventions had no effect on recidivism, with a null (δ = 0.005) mean true effect size (U1 = 0.007, i.e., the independence of the distributions of treated and non-treated batterers was only 0.7%), and could be negative by up to -0.10 or, in other words, the intervention could have a negative effect increasing recidivism rate by up to 4.99% (r = -.0499).
   d. The meta-analysis on studies estimating intervention efficacy on recidivism in ORs, with a sample of 19,509 batterers and 46 effect sizes, showed a positive, significant (confidence interval for *d* does not include zero), small-medium (δ = 0.45) and non-generalizable (credibility interval for δ includes zero) mean true effect size in the intervention, with possible negative effects of up to 4.99% (80% LCV converted to r = -.0499)
   e. As for the intervention model, positive and significant effects were observed under the Duluth Model and cognitive-behavioral treatment programs (CBTPs), but a higher effect size was obtained with CBTPs in comparison to the Duluth Model (under this model, interventions may have negative effects, i.e., an increase in recidivism rate).
   f. In conclusion, there is a corpus of literature on the efficacy of interventions, showing significant effects in reducing recidivism in official records. In other words, intervened batterers were less likely to be accused/sentenced again in (ORs) for the same offence. Notwithstanding, not all of the interventions were effective in ORs. Thus, short interventions were completely ineffective and could have negative effects of up to 40%, and certain interventions based on the Duluth Model may have negative effects of up to 10%. In contrast, long interventions based on CBTPs or OTIs (the results may not be generalized to other techniques than those revised) were on average effective and without negative effects on recidivism in ORs

Evidence on treatment of perpetrators of child abuse

1) **CDC 2020**, technical package for policies and programmatic activities for preventing child abuse and neglect
    a. Behavioral parent training programs such as Parent-Child Interaction Therapy (PCIT), The Incredible Years, and SafeCare demonstrate success in preventing recidivism for abuse in families with substantiated cases of child abuse and neglect, and in reducing child abuse and neglect risk factors in high-risk families (e.g., those who use harsh/ punitive parenting practices). A study conducted with parents reported to CPS found fewer re-reports of physical abuse and/or neglect at a 36-month follow-up for parents who completed SafeCare (15% recidivism) than families who completed services as usual (46% recidivism). Physically abusive parents in the child welfare system who participated in PCIT had significantly fewer re-reports of physical abuse than parents who participated in services as usual (19% vs 49%). In a study of families with chronic and severe neglect and/or physical abuse histories, PCIT plus a motivational enhancement was effective in reducing future child welfare reports, with a stronger effect observed when children were returned to the home sooner rather than later. The Incredible Years is effective in reducing harsh parenting and conduct problems and increasing positive discipline and nurturing parenting. In a study of primarily neglectful biological and foster parents, positive parenting skills increased for parents who participated in The Incredible Years program (when compared to controls), and the improvements were greatest when parents attended six or more sessions.

Evidence and background on treatment techniques for~~of~~ youth with problem sexual behavior

1) **California Evidence-Based Clearinghouse for Child Welfare**
    a. **https://www.cebc4cw.org/program/multisystemic-therapy-for-youth-with-problem-sexual-behaviors/**
    b. Gives multisystemic therapy for youth with problem sexual behaviors (MST-PSB) a "1" rating for well supported by research for treatment sexual behaviors and abusive behaviors in youth between 10 and 17.5 years of age
    c. Multisystemic Therapy for Youth with Problem Sexual Behaviors (MST-PSB) is a clinical adaptation of Multisystemic Therapy (MST) that has been specifically designed and developed to treat youth (and their families) for problematic sexual behavior. Building upon the research and dissemination foundation of standard MST, the MST-PSB model represents a practice uniquely developed to address the multiple determinants underlying problematic juvenile sexual behavior. MST-PSB is delivered in the community, occurs with a high level of intensity and frequency, incorporates treatment interventions from *MST*, and places a high premium on approaching each client and family as unique entities. Treatment incorporates intensive family therapy, parent training, cognitive-behavioral therapy, skills building, school and other community system interventions, and clarification work. Ensuring client, victim, and community safety is a paramount mission of the model.
2) **Borduin 2021**, long term effects of multisystemic therapy for problem sexual behaviors: a 24.9 year follow up to an RCT
    a. N=48 individuals
        i. randomized to MST-PSB or to usual community services (UCS)

   ii. Inclusion in the original study required that youths (a) had been arrested for a serious sexual offense (i.e., rape/sexual assault or molestation of younger children) with a subsequent court order for outpatient sexual offender counseling, (b) were currently living with at least one parent figure, and (c) showed no evidence of psychosis or serious intellectual disability
- b. Arrest, incarceration, and civil suit data were obtained in middle adulthood when participants averaged 39.4 years of age.
- c. Intent-to-treat analyses showed that MST-PSB participants had 85% fewer sexual offenses and 70% fewer nonsexual offenses than did UCS participants. In addition, MST-PSB participants were sentenced to 46% fewer days of incarceration and had 62% fewer family-related civil suits
- d. Conclusion: The current study is the longest and most comprehensive follow-up to date of an MST-PSB clinical trial. Over a period extending 24.9 years after the end of treatment, the results demonstrated that MST-PSB participants were less likely to be arrested for any felony offense than were UCS participants (37.5% vs. 79.2%).

3) **Langstrom 2013**, systematic review of medical and psychological interventions for preventing child sexual abuse
   - a. Limited evidence (one randomized controlled trial with moderate study quality) suggested that multisystemic therapy could be effective in preventing sexual reoffending among moderate risk adolescent sex offenders (relative risk 0.18, 95% confidence interval 0.04 to 0.73)
      i. Borduin above (multiple publications)
   - b. The scientific evidence was insufficient (one observational study with moderate quality34) to determine if cognitive behavioral therapy is effective at preventing sexual reoffending among moderate risk adolescent sex offenders
   - c. No evidence was available to determine the effect of cognitive behavioural therapy on sexual reoffending among adolescent sex offenders with low or high risk of reoffending
   - d. evidence was lacking to determine the effectiveness of methods aimed at preventing sexual offending in adolescents who have not sexually abused a child but are at risk of doing so.

Evidence on treatment of adults with problem sexual behavior

1) **Dennis 2012**, Cochrane review of psychological interventions for adults who have sexually offended or who are at risk
   - a. N=10 studies (944 adult men)
      i. Anderson-Varney 1991; Brown 1996; Hopkins 1991; Marques 1994; McAnaney 1981; McConaghy 1985; McConaghy 1988; Romero 1983; Rooth 1974; Ryan 1997;
   - b. Five trials involved primarily cognitive behavioral interventions (CBT) (n = 664). Of these, four compared CBT with no treatment or wait list control, and one compared CBT with standard care. Long-term outcome data are reported for groups in which the mean years 'at risk' in the community are similar (8.3 years for treatment (n = 259) compared to 8.4 in the control group (n = 225)). There was no difference between these groups in terms of the risk of reoffending as measured by reconviction for sexual offences (risk ratio (RR) 1.10; 95% CI 0.78 to 1.56).

   c. One study compared psychodynamic intervention with probation. Results for this study (n = 231) indicate a slight trend in favour of the control group (probation) over the intervention (group therapy) in terms of sexual offending as measured by rearrest (RR 1.87; 95% CI 0.78 to 4.47) at 10-year follow-up
   d. Authors' conclusions: The inescapable conclusion of this review is the need for further randomized controlled trials. While we recognize that randomization is considered by some to be unethical or politically unacceptable (both of which are based on the faulty premise that the experimental treatment is superior to the control - this being the point of the trial to begin with), without such evidence, the area will fail to progress. Not only could this result in the continued use of ineffective (and potentially harmful) interventions, but it also means that society is lured into a false sense of security in the belief that once the individual has been treated, their risk of reoffending is reduced. Current available evidence does not support this belief.

2) **Langstrom 2013**, systematic review of medical and psychological interventions for preventing child sexual abuse
   a. N=8 studies with low to moderate risk of bias
   b. For adults, evidence from five trials was insufficient regarding both benefits and risks with psychological treatment and pharmacotherapy
   c. For adolescents, limited evidence from one trial suggested that multisystemic therapy prevented reoffence (relative risk 0.18, 95% confidence interval 0.04 to 0.73)
   d. Finally, we found no eligible research on preventive methods for adults and adolescents who had not sexually abused children but were at higher risk of doing so (such as those with pedophilic sexual preference)
   e. Conclusion There are major weaknesses in the scientific evidence, particularly regarding adult men

Perpetrator Services

HERC staff summary: Existing literature on the effectiveness of programs to treat the perpetrators of intimate partner abuse find that such programs are generally ineffective and possibly harmful. These programs appear to reduce re-arrests, but actually increase violence against the victim(s).

The CDC recommends several evidence based behavioral parent training programs for treatment of families to reduce child physical abuse and neglect and reduce recidivism. Currently, the diagnosis code for mental health services for perpetrators of parental child abuse is on a covered line. This code contains the sub-diagnosis "encounter for mental health services for perpetrator of parental child sexual abuse" as well as psychological abuse and neglect.

Based on 1 RCT (N=48 adolescents), there is limited evidence that treatment of youth with problem sexual behaviors with multisystemic therapy is effective at reducing unwanted behaviors and recidivism. Such treatment is recommended by providers and by OYA. There evidence does not show effectiveness for the psychological treatment of adults with problem sexual behaviors. BHAP recommended against coverage of treatment of unwanted sexual behaviors due to lack of evidence that these programs are effective.

HERC staff recommendations:

1) Reverse the October 2022 decision to add the following ICD-10-CM codes to line 120 ABUSE AND NEGLECT and continue their placement on the INFORMATIONAL file
    a. Z69.12: Encounter for mental health services for perpetrator of spousal or partner abuse
    b. Z69.82: Encounter for mental health services for perpetrator of other abuse
2) Reverse the October 2022 decision to add ICD-10-CM Z69.021 (Encounter for mental health services for perpetrator of non-parental child abuse) to line 120 ABUSE AND NEGLECT
    a. Add Z69.021 to the DIAGNOSTIC WORKUP File
    b. Will allow initial evaluation for other, covered diagnoses such as PTSD or ADHD
    c. Temporarily addresses OYA and provider concerns until further clarification and research can be done as below
3) Keep ICD-10-CM Z69.011 (Encounter for mental health services for perpetrator of parental child abuse) on line 120 ABUSE AND NEGLECT for CDC recommended treatment programs
4) HERC staff will work with other state agencies, other parts of OHA, and outside stakeholders to determine the best prioritization of these diagnoses, and clarify billing rules/statutes and responsibilities
5) HERC staff will bring this topic back to BHAP at an upcoming meeting in 2023 for further input and discussion

Intentional Self-Harm

If you or someone you know is struggling or in crisis, help is available.
Call or text 988 or go to 988lifeline.org
The 988 Suicide & Crisis Lifeline (formerly known as the National Suicide Prevention Lifeline) offers 24/7 call text and chat access to trained crisis counselors who can help people experiencing suicidal substance use and/or mental health crisis or any other kind of emotional distress. People can also dial 988 if they are worried about a loved one who may need crisis support.

Plain Language Summary:
Background: These are codes that describe ways people harm themselves. Are these codes better served on behavior health or poisoning lines?

Should OHP cover this treatment? Based on input from the Behavioral Health Advisory panel, staff recommends no change in the covered status of these codes.

Question: Should the ICD-10 codes related to "intentional self-harm" be moved from the Diagnostic List or poisoning lines and placed on a behavioral health line?

Question source: OHA metrics group, HERC staff

Issue: There are a variety of diagnosis codes that include the phrase "intentional self-harm." Most of these codes appear on line 102 POISONING BY INGESTION, INJECTION, MEDICINAL AND NON-MEDICINAL AGENTS. These codes start with "poisoning" or "toxic effect" and are the "T" family of ICD-10-CM codes (for example, T36.0X2A Poisoning by penicillins, intentional self-harm, initial encounter and T51.0X2A Toxic effect of ethanol, intentional self-harm, initial encounter). There are other "intentional self harm" codes in the "X" family of ICD-10-CM codes that are on the 7 MAJOR DEPRESSION, RECURRENT; MAJOR DEPRESSION, SINGLE EPISODE, SEVERE? (for example, X81.0XXA Intentional self-harm by jumping or lying in front of motor vehicle, initial encounter).

Additionally, the ICD-10-CM code T14.91 (Suicide attempt) appears on the Diagnostic Workup File.

The OHA Behavioral Health team added these "T" and "X" intentional self-harm codes to the Social Emotional Reach Metric list, based on their expert perspective as potential ways young children could present for behavioral health services or supports. The "T" codes will be covered based on their placement on line 102, but not for behavioral health interventions. However, the underlying condition such as major depression would pair with behavioral health interventions on other lines. "X" codes are external causes of morbidity, so shouldn't be the condition being treated (the resulting injury or illness should be the billing diagnosis) and therefore are informational in HERC system.

BHAP input
BHAP felt that the current placement of the "intentional self-harm" T and X diagnosis codes as well as ICD-10-CM T14.91 were appropriate and did not require any changes. There was concern about coverage of low level self harm that did not reach the level of needing urgent/emergent behavioral health care. OHA metrics group had specifically asked about use of these codes in young children who could not be given another diagnosis. BHAP and HERC staff noted that young children do not have

"intent" and therefore these codes are inappropriate in this group. Young children would be given the "accidental" or "intentionally harmed by another" version of these codes.

BHAP/HERC staff recommendation:

1) Make no change in the placement of ICD-10-CM T14.91 (Suicide attempt) and the T/X codes for "intentional self harm"
    a. ICD-10-CM T14.91: DIAGNOSTIC WORKUP FILE
    b. "Intentional self harm" codes: line 102 POISONING BY INGESTION, INJECTION, MEDICINAL AND NON-MEDICINAL AGENTS

1) Issue: the NCCN guideline references need to be updated in Diagnostic Guideline D25 and Guideline Note 3. GAP approved these changes without discussion at their October 2022 meeting.

HERC staff recommendations:

1) Update Diagnostic Guideline D25 as shown below
2) Update Guideline Note 3 as shown below

DIAGNOSTIC GUIDELINE D25, HEREDITARY CANCER GENETIC TESTING

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

A) Lynch syndrome (hereditary colorectal, endometrial and other cancers associated with Lynch syndrome) services (CPT 81288, 81292-81300, 81317-81319, 81435, 81436) and familial adenomatous polyposis (FAP) services (CPT 81201-81203) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology (Genetic/Familial High-Risk Assessment: Colorectal V1.2022 (6/8/22) ~~V1.2021 (5/11/21)~~ www.nccn.org).

B) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81212, 81215-81217) for patients without a personal history of breast, ovarian and other associated cancers should be provided to high-risk patients as defined by the US Preventive Services Task Force or according to the NCCN Clinical Practice Guidelines in Oncology (Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic V1.2023 (9/7/22) ~~V1.2022 (8/11/21)~~ www.nccn.org).

C) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81212, 81215-81217)) for women with a personal history of breast, ovarian, or other associated cancers and for men with breast or other associated cancers should be provided according to the NCCN Clinical Practice Guidelines in Oncology (Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic V1.2023 (9/7/22) ~~V1.2022 (8/11/21)~~ www.nccn.org).

D) PTEN (Cowden syndrome) services (CPT 81321-81323) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology (Genetic/Familial High-Risk Assessment: Ovarian and Pancreatic. V1.2023 (9/7/22) ~~V1.2022 (8/11/21)~~ or Genetic/Familial High-Risk Assessment: Colorectal V1.2022 (6/8/22) www.nccn.org).

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

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

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

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

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

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

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

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

Line 191

Bilateral prophylactic breast removal and/or salpingo-oophorectomy are included on Line 191 for women without a personal history of invasive breast cancer who meet the criteria in the NCCN Clinical Practice Guidelines in Oncology (Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic V1.2023 (9/7/22) ~~V1.2022 (8/11/21)~~ www.nccn.org). Prior to surgery, women without a personal history of breast cancer must have a genetics consultation as defined in section B of the DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE.

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

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

Code	Code Description	Similar code	Recommended placement
81404	Molecular pathology procedure, Level 5 (eg, analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis) ACADS (acyl-CoA dehydrogenase, C-2 to C-3 short chain) (eg, short chain acyl-CoA dehydrogenase deficiency), targeted sequence analysis (eg, exons 5 and 6) AQP2 (aquaporin 2 [collecting duct]) (eg, nephrogenic diabetes insipidus), full gene sequence ARX (aristaless related homeobox) (eg, X-linked lissencephaly with ambiguous genitalia, X-linked mental retardation), full gene sequence AVPR2 (arginine vasopressin receptor 2) (eg, nephrogenic diabetes insipidus), full gene sequence BBS10 (Bardet-Biedl syndrome 10) (eg, Bardet-Biedl syndrome), full gene sequence BTD (biotinidase) (eg, biotinidase deficiency), full gene sequence C10orf2 (chromosome 10 open reading frame 2) (eg, mitochondrial DNA depletion syndrome), full gene sequence CAV3 (caveolin 3) (eg, CAV3-related distal myopathy, limb-girdle muscular dystrophy type 1C), full gene sequence CD40LG (CD40 ligand) (eg, X-linked hyper IgM syndrome), full gene sequence CDKN2A (cyclin-dependent kinase inhibitor 2A) (eg, CDKN2A-related cutaneous malignant melanoma, familial atypical mole-malignant melanoma syndrome), full gene sequence CLRN1 (clarin 1) (eg, Usher syndrome, type 3), full gene sequence COX6B1 (cytochrome c oxidase subunit VIb polypeptide 1) (eg, mitochondrial respiratory chain complex IV deficiency), full gene sequence CPT2 (carnitine palmitoyltransferase 2) (eg, carnitine palmitoyltransferase II deficiency), full gene sequence CRX (cone-rod homeobox) (eg, cone-rod dystrophy 2, Leber congenital amaurosis), full gene sequence CYP1B1 (cytochrome P450, family 1, subfamily B, polypeptide 1) (eg, primary congenital glaucoma), full gene sequence EGR2 (early growth response 2) (eg, Charcot-Marie-Tooth), full gene sequence EMD (emerin) (eg, Emery-Dreifuss muscular dystrophy), duplication/deletion analysis EPM2A (epilepsy, progressive myoclonus type 2A, Lafora disease [laforin]) (eg, progressive myoclonus epilepsy), full gene sequence FGF23 (fibroblast growth factor 23) (eg, hypophosphatemic rickets), full gene sequence FGFR2 (fibroblast growth factor receptor 2) (eg, craniosynostosis, Apert syndrome, Crouzon syndrome), targeted sequence analysis (eg, exons 8, 10) FGFR3 (fibroblast growth factor receptor 3) (eg, achondroplasia, hypochondroplasia), targeted sequence analysis (eg, exons 8, 11, 12, 13) FHL1 (four and a half LIM domains 1) (eg, Emery-Dreifuss muscular dystrophy), full gene sequence FKRP (fukutin	Other molecular pathology procedure codes (e.g. 81407, 81403) are DIAGNOSTIC PROCEDURES	DIAGNOSTIC PROCEDURES

Code	Code Description	Similar code	Recommended placement
81405	Molecular pathology procedure, Level 6 (eg, analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons, regionally targeted cytogenomic array analysis) ABCD1 (ATP-binding cassette, sub-family D [ALD], member 1) (eg, adrenoleukodystrophy), full gene sequence ACADS (acyl-CoA dehydrogenase, C-2 to C-3 short chain) (eg, short chain acyl-CoA dehydrogenase deficiency), full gene sequence ACTA2 (actin, alpha 2, smooth muscle, aorta) (eg, thoracic aortic aneurysms and aortic dissections), full gene sequence ACTC1 (actin, alpha, cardiac muscle 1) (eg, familial hypertrophic cardiomyopathy), full gene sequence ANKRD1 (ankyrin repeat domain 1) (eg, dilated cardiomyopathy), full gene sequence APTX (aprataxin) (eg, ataxia with oculomotor apraxia 1), full gene sequence ARSA (arylsulfatase A) (eg, arylsulfatase A deficiency), full gene sequence BCKDHA (branched chain keto acid dehydrogenase E1, alpha polypeptide) (eg, maple syrup urine disease, type 1A), full gene sequence BCS1L (BCS1-like [S. cerevisiae]) (eg, Leigh syndrome, mitochondrial complex III deficiency, GRACILE syndrome), full gene sequence BMPR2 (bone morphogenetic protein receptor, type II [serine/threonine kinase]) (eg, heritable pulmonary arterial hypertension), duplication/deletion analysis CASQ2 (calsequestrin 2 [cardiac muscle]) (eg, catecholaminergic polymorphic ventricular tachycardia), full gene sequence CASR (calcium-sensing receptor) (eg, hypocalcemia), full gene sequence CDKL5 (cyclin-dependent kinase-like 5) (eg, early infantile epileptic encephalopathy), duplication/deletion analysis CHRNA4 (cholinergic receptor, nicotinic, alpha 4) (eg, nocturnal frontal lobe epilepsy), full gene sequence CHRNB2 (cholinergic receptor, nicotinic, beta 2 [neuronal]) (eg, nocturnal frontal lobe epilepsy), full gene sequence COX10 (COX10 homolog, cytochrome c oxidase assembly protein) (eg, mitochondrial respiratory chain complex IV deficiency), full gene sequence COX15 (COX15 homolog, cytochrome c oxidase assembly protein) (eg, mitochondrial respiratory chain complex IV deficiency), full gene sequence CPOX (coproporphyrinogen oxidase) (eg, hereditary coproporphyria), full gene sequence CTRC (chymotrypsin C) (eg, hereditary pancreatitis), full gene sequence CYP11B1 (cytochrome P450, family 11, subfamily B, polypeptide 1) (eg, congenital adrenal hyperplasia), full gene sequence CYP17A1 (cytochrome P450, family 17, subfamily A, polypeptide 1) (eg, congenital adrenal hyperplasia), full gene sequence CYP21A2 (cytochrome P450, family 21, subfamily A, polypeptide2) (eg,	Other molecular pathology procedure codes (e.g. 81407, 81403) are DIAGNOSTIC PROCEDURES	DIAGNOSTIC PROCEDURES

Code	Code Description	Similar code	Recommended placement
81406	Molecular pathology procedure, Level 7 (eg, analysis of 11-25 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 26-50 exons) ACADVL (acyl-CoA dehydrogenase, very long chain) (eg, very long chain acyl-coenzyme A dehydrogenase deficiency), full gene sequence ACTN4 (actinin, alpha 4) (eg, focal segmental glomerulosclerosis), full gene sequence AFG3L2 (AFG3 ATPase family gene 3-like 2 [S. cerevisiae]) (eg, spinocerebellar ataxia), full gene sequence AIRE (autoimmune regulator) (eg, autoimmune polyendocrinopathy syndrome type 1), full gene sequence ALDH7A1 (aldehyde dehydrogenase 7 family, member A1) (eg, pyridoxine-dependent epilepsy), full gene sequence ANO5 (anoctamin 5) (eg, limb-girdle muscular dystrophy), full gene sequence ANOS1 (anosmin-1) (eg, Kallmann syndrome 1), full gene sequence APP (amyloid beta [A4] precursor protein) (eg, Alzheimer disease), full gene sequence ASS1 (argininosuccinate synthase 1) (eg, citrullinemia type I), full gene sequence ATL1 (atlastin GTPase 1) (eg, spastic paraplegia), full gene sequence ATP1A2 (ATPase, Na+/K+ transporting, alpha 2 polypeptide) (eg, familial hemiplegic migraine), full gene sequence ATP7B (ATPase, Cu++ transporting, beta polypeptide) (eg, Wilson disease), full gene sequence BBS1 (Bardet-Biedl syndrome 1) (eg, Bardet-Biedl syndrome), full gene sequence BBS2 (Bardet-Biedl syndrome 2) (eg, Bardet-Biedl syndrome), full gene sequence BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, maple syrup urine disease, type 1B), full gene sequence BEST1 (bestrophin 1) (eg, vitelliform macular dystrophy), full gene sequence BMPR2 (bone morphogenetic protein receptor, type II [serine/threonine kinase]) (eg, heritable pulmonary arterial hypertension), full gene sequence BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, Noonan syndrome), full gene sequence BSCL2 (Berardinelli-Seip congenital lipodystrophy 2 [seipin]) (eg, Berardinelli-Seip congenital lipodystrophy), full gene sequence BTK (Bruton agammaglobulinemia tyrosine kinase) (eg, X-linked agammaglobulinemia), full gene sequence CACNB2 (calcium channel, voltage-dependent, beta 2 subunit) (eg, Brugada syndrome), full gene sequence CAPN3 (calpain 3) (eg, limb-girdle muscular dystrophy [LGMD] type 2A, calpainopathy), full gene sequence CBS (cystathionine-beta-synthase) (eg, homocystinuria, cystathionine beta-synthase deficiency), full gene sequence CDH1 (cadherin 1, type 1, E-cadherin [epithelial]) (eg, hereditary diffuse gastric cancer), full gene sequence CDKL5 (cyclin-dependent kinase-like 5) (eg, early infantile epileptic encephalopathy), full gene	Other molecular pathology procedure codes (e.g. 81407, 81403) are DIAGNOSTIC PROCEDURES	DIAGNOSTIC PROCEDURES
81418	Drug metabolism (eg, pharmacogenomics) genomic sequence analysis panel, must include testing of at least 6 genes, including CYP2C19, CYP2D6, and CYP2D6 duplication/deletion analysis	See issues document	DIAGNOSTIC PROCEDURES

Code	Code Description	Similar code	Recommended placement
81441	Inherited bone marrow failure syndromes (IBMFS) (eg, Fanconi anemia, dyskeratosis congenita, Diamond-Blackfan anemia, Shwachman-Diamond syndrome, GATA2 deficiency syndrome, congenital amegakaryocytic thrombocytopenia) sequence analysis panel, must include sequencing of at least 30 genes, including BRCA2, BRIP1, DKC1, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, GATA1, GATA2, MPL, NHP2, NOP10, PALB2, RAD51C, RPL11, RPL35A, RPL5, RPS10, RPS19, RPS24, RPS26, RPS7, SBDS, TERT, and TINF2	See issues document	DIAGNOSTIC PROCEDURES
81449	Targeted genomic sequence analysis panel, solid organ neoplasm, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, MET, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed; RNA analysis	See issues document	DIAGNOSTIC PROCEDURES
81451	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NOTCH1, NPM1, NRAS), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis	See issues document	DIAGNOSTIC PROCEDURES
81456	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm or disorder, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MET, MLL, NOTCH1, NPM1, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis	See issues document	DIAGNOSTIC PROCEDURES
84433	Thiopurine S-methyltransferase (TPMT)	See individual issue	DIAGNOSTIC PROCEDURES

2023 CPT Codes
Genetic Testing Related Codes

1) Code **81418**
    a. Code description: Drug metabolism (eg, pharmacogenomics) genomic sequence analysis panel, must include testing of at least 6 genes, including CYP2C19, CYP2D6, and CYP2D6 duplication/deletion analysis
    b. Information: Cytochrome P450 2D6 (*CYP2D6*) is a critical pharmacogene involved in the metabolism of ~20% of commonly used drugs across a broad spectrum of medical disciplines including psychiatry, pain management, oncology and cardiology. Nevertheless, *CYP2D6* is highly polymorphic with single-nucleotide polymorphisms, small insertions/deletions and larger structural variants including multiplications, deletions, tandem arrangements, and hybridizations with non-functional *CYP2D7* pseudogenes. The frequency of these variants differs across populations, and they significantly influence the drug-metabolizing enzymatic function of CYP2D6. Importantly, altered CYP2D6 function has been associated with both adverse drug reactions and reduced drug efficacy
    c. Similar codes:
        i. The following drug metabolism codes are on the DIAGNOSTIC PROCEDURES file:
            1. 81225 CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)
            2. 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)
            3. 81227 CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)
        ii. The current non-prenatal genetic testing guideline lists the following criteria for the above tests:
            1. 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).
            2. See entire guideline note in Appendix A
    d. GAP discussion: GAP members felt that the staff recommendation was appropriate. Public testimony was heard from Devki Nagar, from Myriad Genetics. Myriad requested consideration of CPIC guidelines in addition to FDA guidelines. Nagar noted that Medicare is allowing FDA or CPIC guidelines to be followed for determination of coverage for this test. Staff was directed to look into CPIC guidelines further.

       CPIC guidelines are available at: https://cpicpgx.org/guidelines/. CPIC guidelines include recommendations for genetic testing of P450 enzyme mutations prior to use of various proton pump inhibitors, clopidogrel, voriconazole, phenytoin, warfarin, atomoxetine,

ondansetron, tropisetron, tamoxifen, SSRIs, tricyclic antidepressants, opioids, and tacrolimus. In general, the reviews appeared to be current (within the past 5 yrs), evidence based, and funded by impartial bodies (for example, the NIH). Some authors had conflicts of interest. Staff conclusion was that these reviews are evidence based, but the recommendations went far beyond current standard of care. Staff recommendation is to continue to use FDA guidelines and monitor CPIC and other evidence-based sources going forward.

e. **GAP/HERC staff recommendations**:
   i. Place **81418** on the DIAGNOSTIC PROCEDURES file
   ii. Modify the entry in DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE to read as below [see Appendix A for entire guideline with edit]:

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

2) Code **81441**
   a. Code description: Inherited bone marrow failure syndromes (IBMFS) (eg, Fanconi anemia, dyskeratosis congenita, Diamond-Blackfan anemia, Shwachman-Diamond syndrome, GATA2 deficiency syndrome, congenital amegakaryocytic thrombocytopenia) sequence analysis panel, must include sequencing of at least 30 genes, including BRCA2, BRIP1, DKC1, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, GATA1, GATA2, MPL, NHP2, NOP10, PALB2, RAD51C, RPL11, RPL35A, RPL5, RPS10, RPS19, RPS24, RPS26, RPS7, SBDS, TERT, and TINF2
   b. Information:
      i. Patients with inherited bone marrow failure syndrome (IBMFS) can develop peripheral blood cytopenia, which can ultimately progress to myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML).
      ii. Maintaining a high suspicion for rare IBMFSs is critical when evaluating patients of all ages with unusual cytopenia, especially in patients ≤40 years of age. Thorough physical examination and family history are important. An accurate diagnosis of IBMFS including laboratory workup, a surveillance schedule for malignancy, and potential therapeutic options according to disease severity, is critical for proper management. Additionally, cascade testing of at-risk relatives is required.
   c. Similar codes: Previously coded with 81443 (Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA,

GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)) which is on the DIAGNOSTIC PROCEDURES file

d. GAP discussion: GAP members agreed with staff recommendation.
e. **HERC staff recommendation**:
    i. Place **81441** on the DIAGNOSTIC PROCEDURES file

2023 CPT Codes
Genetic Testing Related Codes

Appendix A

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), AND
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: For infants with a positive newborn screen for cystic fibrosis or who are symptomatic for cystic fibrosis, or for clients that have previously been diagnosed with cystic fibrosis but have not had genetic testing, CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered. If two mutations are not identified, CFTR full gene sequencing (CPT 81223) is covered. If two mutations are still not identified, duplication/deletion testing (CPT 81222) is covered. These tests may be ordered as reflex testing on the same specimen.

c) CPT 81224, CFTR (cystic fibrosis transmembrane conductance regulator) (eg. cystic fibrosis) gene analysis; introm 8 poly-T analysis (eg. male infertility): Covered only after genetic counseling.

d) CPT 81225-81227, 81230-81231, 81418 (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 thromoboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.

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 thromoboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.

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

Next Generation Multi-Gene Sequencing/Targeted Genomic Sequencing Panels

Plain Language Summary:
Background: There are new genetic tests to guide treatment for certain cancers that include testing for multiple changes in the cancer DNA at one time.

Should OHP cover this test? Staff recommends coverage of these tests, and having a workgroup meet to provide advice on any guidelines for such testing.

Question: Should next generation multi-gene sequencing be covered for certain cancers?

Question source: New 2023 CPT codes, HERC staff, FoundationOne

Issue: Some types of cancers routinely have biomarker genetic testing done on tumor tissue to determine if there is an actionable mutation, to target drug therapy, or to determine prognosis. Initially, much of this testing was for single gene targets. Recent technical advances, in particular "next generation" or "massively parallel" sequencing (NGS), have enabled the simultaneous assessment of multiple genetic markers in a single assay run.

For some cancers, specific genetic tests are standard-of-care determinants for FDA-approved targeted therapies and are incorporated into professional practice guidelines from the National Comprehensive Cancer Network (NCCN). For other cancers, genetic tests are used to exclude the use of a targeted therapy and shift the focus of treatment instead towards other modalities. In still other cancers, genetic tests are used to indicate suitability for treatment with an investigational agent, as an alternative to an ineffective traditional therapy that is expected to have marginal, if any, benefit. Finally, genetic testing of cancer samples can be used to establish a definitive diagnosis or for stratification into risk-based treatment groups.

For patients, physicians, and laboratories, the advantages of the NGS panel tests are (1) more efficient use of limited samples, (2) more rapid time to a completed set of results, (3) more efficient resource utilization compared to performing multiple individual tests, (4) better ability to rapidly incorporate new genes into a panel in order to support clinical decision making since evidence in the field is rapidly evolving, and (5) identification of unexpected clinically actionable mutations that are not customarily associated with the tissue type of the tumor. A growing body of evidence supports the use of expanded panel testing in selected tumor types. The evidence shows that for selected tumors, expanded panel testing reveals “driver mutations”, (mutations that activate signaling pathways which cause uncontrolled tumor cell growth) for which there are known and/or investigational drugs that will improve outcomes in patients with these tumors in comparison to conventional cytotoxic therapy. HOWEVER, such testing many not be useful in some cancer types or in cancers in which such testing will not drive treatment decisions.

Targeted genomic sequencing can be focused on tumor DNA, tumor RNA, or both. Targeted RNA-sequencing (RNA-Seq) is a highly accurate method for selecting and sequencing specific transcripts of interest. It offers both quantitative and qualitative information.

Next Generation Multi-Gene Sequencing/Targeted Genomic Sequencing Panels

Previous HERC review
Targeted genetic sequencing of tumor DNA and tumor DNA and RNA together were added to the DIAGNOSTIC PROCEDURES file in 2014 as new 2015 CPT codes with minimal review. The entire HERC review on these codes was to indicate that as the component genes were covered; therefore the panel should be covered.

There are three new 2023 CPT codes related to targeted genetic sequencing of tumor RNA alone.

Current Prioritized List status:

The following codes are on the DIAGNOSTIC PROCEDURES file with no entry in the non-prenatal genetic testing guideline:

1) 81445 Targeted genomic sequence analysis panel, solid organ neoplasm, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, MET, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed; DNA analysis or combined DNA and RNA analysis
2) 81450 Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NOTCH1, NPM1, NRAS), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; DNA analysis or combined DNA and RNA analysis
3) 81455 Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm or disorder, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MET, MLL, NOTCH1, NPM1, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; DNA analysis or combined DNA and RNA analysis

New 2023 CPT code descriptions

1) 81449 Targeted genomic sequence analysis panel, solid organ neoplasm, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, MET, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed; RNA analysis
2) 81451 Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NOTCH1, NPM1, NRAS), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis
3) 81456 Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm or disorder, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MET, MLL, NOTCH1, NPM1, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis

In addition to the above CPT codes, there are a large number of CPT codes that refer to a specific proprietary test (usually designated with 0XXXU).

There are also specific CPT codes for single gene tests or for gene panel testing for a specific type of cancer, which are included in Guideline note 148.

GUIDELINE NOTE 148, BIOMARKER TESTS OF CANCER TISSUE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Selected expert guidelines

ASCO 2020: Somatic genomic testing is patients with metastatic or advanced cancer

1) Genomic testing should be performed for patients with metastatic or advanced solid tumors with adequate performance status in the following two clinical scenarios:
   - **a.** When there are genomic biomarker–linked therapies approved by regulatory agencies for their cancer.
   - **b.** When considering a treatment for which there are specific genomic biomarker–based contraindications or exclusions (strength of recommendation: strong)

NCCN Breast Cancer Version 4.2022

1) Neurotrophic tropomyosin receptor kinase (NTRK) gene fusions are seen in of a few rare types of cancer, such as secretory carcinoma of the breast or salivary gland and infantile fibrosarcoma and also infrequently in some common cancers, such as melanoma, glioma and carcinomas of the thyroid, lung and colon. NTRK fusions are identified by fluorescence in situ hybridization (FISH), Next Generation Sequencing (NGS) or polymerase chain reaction (PCR). Larotrectinib and entrectinib are two NTRK-inhibitors that are U.S FDA approved for the treatment of solid tumors that have an NTRK gene fusion without a known acquired resistance mutation and have no satisfactory alternative treatments or that have progressed following treatment. If patient with recurrent/stage IV breast presents with a tumor with an NTRK fusion, treatment with a NTRK-inhibitor is an option if no satisfactory alternative treatments exists or that have progressed following treatment

NCCN Melanoma 3.2022

1) Other uncommon mutations detected by NGS panel
   a. Fusions in NTRK1, NTRK2, and NTRK3 occur uncommonly (<1%) across subtypes of melanoma
      i. Fusions in these genes correspond with a high response rate to the TRK inhibitors larotrectinib or entrectinib
   b. Fusions in ALK and ROS1, more common in lung cancer, occur uncommonly (<1%) across subtypes of melanoma
      i. Fusions in these genes may predispose to clinical activity from inhibitors of these genes (eg, crizotinib, entrectinib)

2) NGS, also known as high-throughput sequencing, describes a number of different sequencing technologies that allow sequencing of DNA and RNA much more quickly and cheaply than the previously used Sanger sequencing. Single-gene or small multigene panels are also used in some cases to test either one gene (BRAF) or a limited number of genes.
    a. Molecular testing on tumor tissue is preferred, but may be performed on peripheral blood (liquid biopsy) if tumor tissue is not available
    b. The panel does not recommend BRAF or NGS testing for resected stage I–II cutaneous melanoma unless it will inform clinical trial participation
3) Principles of molecular testing
    a. For initial presentation with stage IV disease or clinical recurrence, obtain tissue to ascertain alterations in BRAF, and in the appropriate clinical setting, KIT from either biopsy of the metastasis (preferred) or archival material if the patient is being considered for targeted therapy. Broader genomic profiling (eg, larger NGS panels, BRAF non-V600 mutations) is recommended if feasible, especially if the test results might guide future treatment decisions or eligibility for participation in a clinical trial.
    b. If BRAF single-gene testing was the initial test performed, and is negative, clinicians should strongly consider larger NGS panels to identify other potential genetic targets (eg, KIT, BRAF non-V600).

NCCN 1.2022 Colon Cancer

1) Work up for metastatic disease
    a. Determination of tumor gene status for RAS and BRAF mutations and HER2 amplifications (individually or as part of tissue- or blood-based next-generation sequencing [NGS] panel)
    b. determination of tumor gene status for KRAS/NRAS and BRAF mutations, as well as HER2 amplifications and MSI/MMR status (if not previously done), are recommended for patients with mCRC. Testing may be carried out for individual genes or as part of an NGS panel, although no specific methodology is recommended. NGS panels have the advantage of being able to pick up rare and actionable genetic alterations, such as neurotrophic tyrosine receptor kinase (NTRK) fusions
2) Principle of pathologic and molecular review
    a. All patients with metastatic colorectal cancer should have tumor genotyped for RAS (KRAS and NRAS) and BRAF mutations individually or as part of an NGS panel. Patients with any known KRAS mutation (exon 2, 3, 4) or NRAS mutation (exon 2, 3, 4) should not be treated with either cetuximab or panitumumab.53-55 BRAF V600E mutation makes response to panitumumab or cetuximab highly unlikely unless given with a BRAF inhibitor
    b. Testing for MSI may be accomplished by polymerase chain reaction (PCR) or a validated NGS panel, the latter especially in patients with metastatic disease who require genotyping of RAS and BRAF

NCCN 5.2022 Ovarian cancer

1) With the availability of next-generation sequencing technology, the panel discussed whether comprehensive tumor molecular analysis should be recommended for all patients. Some panel members stated that comprehensive tumor testing may not be necessary for certain patients in the upfront setting, specifically those with a germline mutation in

BRCA1/2 or other homologous recombination/DNA repair pathway genes. However, some patients (such as those who lack a BRCA1/2 mutation or experience disease recurrence) may benefit from a more thorough tumor molecular analysis to inform additional targeted therapy options. The panel agreed that tumor testing may be beneficial at multiple points throughout the evolution of the disease. Therefore, the current guidelines recommend tumor molecular analysis both in the upfront setting and upon recurrence (OV-B 1 of 3). The goal of tumor testing in the upfront setting is to optimize identification of molecular alterations that can inform the use of interventions with demonstrated benefit in this setting, such as PARP inhibitors. Molecular alterations that should be probed for in this setting include BRCA1/2 status, loss of heterozygosity, or homologous recombination status, in the absence of a germline BRCA mutation. Other tumor tissue molecular markers may inform selection of treatment for persistent or recurrent disease but testing for these is not needed until the disease has proven to be refractory or at time of relapse. The panel recommends that tumor molecular analysis in the recurrence setting should include, at a minimum, tests to identify potential benefit from targeted therapeutics that have tumor-specific or tumor-agnostic benefit. These include (but are not limited to): BRCA1/2, HR status, microsatellite instability (MSI), mismatch repair (MMR), tumor mutational burden (TMB), BRAF, and NTRK, if prior testing did not include these markers. The panel emphasizes that more comprehensive tumor analysis may be particularly important for less common histologies with limited approved treatment options. Prior to selection of systemic therapy for refractory or recurrent disease, validated tumor molecular testing should be performed in a Clinical Laboratory Improvement Amendments (CLIA)-approved facility using the most recent available tumor tissue.

Selected payer policies

1) **Evicore 2021**: Somatic mutation testing-solid tumors
    a. The member has a tumor type that will benefit from information provided by the requested tumor marker test based on at least one of the following:
        i. All criteria are met from a test-specific guideline if one is available, or
        ii. An oncology therapy FDA label requires results from the tumor marker test to effectively or safely use the therapy for the member's cancer type (See Common cancer types and associated tumor markers table below for examples of currently recognized companion diagnostics), or
        iii. NCCN guidelines include the tumor marker test in the management algorithm for that particular cancer type and all other requirements are met (specific pathology findings, staging, etc.); however, the tumor marker must be explicitly included in the guidelines and not simply included in a footnote as an intervention that may be considered (See Common cancer types and associated tumor markers table below for examples of currently recommended gene tests)
    b. Note If five or more individually billed tumor marker tests are under review together (a "panel") and the member either has non-small cell lung cancer, metastatic colorectal cancer, or stage IV cutaneous melanoma OR meets criteria for 5 or more individual tumor markers, the panel will be approved. However, the laboratory will be redirected to use a panel CPT code for billing purposes (e.g. 81445 or 81455)
    c. When a multi-gene panel is being requested and will be billed with a single panel CPT code (e.g. 81445 or 81455), the panel will be considered medically necessary when the following criteria are met:
        i. The requested testing is a companion diagnostic per the FDA label for the member's cancer type and specific treatments being considered (e.g. FoundationOne CDx testing in an individual with ovarian cancer for treatment with olaparib), OR
        ii. The member has a diagnosis of one of the following cancers:
            1. Metastatic colorectal cancer
            2. Stage IV cutaneous melanoma
            3. Non-small cell lung cancer, OR
        iii. The member has a diagnosis of one of the following cancers, when the panel includes at least five of the genes associated with that cancer type listed in the below table Common cancer types and associated tumor markers:
            1. Gastrointestinal Stromal Tumor (GIST)
            2. Infiltrative glioma
            3. Locally advanced, metastatic, or recurrent pancreatic cancer
            4. Malignant peripheral nerve sheath tumor
            5. Regional or metastatic prostate cancer
            6. Metastatic urothelial bladder cancer that has progressed following at least one line of prior platinum-containing chemotherapy
            7. Metastatic or unresectable uveal melanoma that has progressed following all available treatments, OR
        iv. The member does not have one of the cancers listed in the section above, but at least 5 tumor markers included in the panel individually meet criteria for the member's tumor type based on one of the following:
            1. All criteria are met from a test-specific guideline if one is available, or

2. An oncology therapy FDA label requires results from the tumor marker test to effectively or safely use the therapy for the member's cancer type (See Common cancer types and associated tumor markers table below for examples of currently recognized companion diagnostics for available therapies.), or
3. NCCN guidelines include the tumor marker test in the management algorithm for that particular cancer type and all other requirements are met (specific pathology findings, staging, etc.); however, the tumor marker must be explicitly included in the guidelines and not simply included in a footnote as an intervention that may be considered.

2) **Wellmark BCBS 2021** Circulating tumor DNA and circulating tumor cells for cancer management (liquid biopsies)
   a. Has an extensive table with type of cancer and when the test is covered (diagnostic, stage of cancer, recurrent cancer, metastatic cancer, for monitoring, etc.)

GAP discussion: Members noted that there are a high volume of requests for this testing. HERC staff had drafted a guideline to help determine when these tests should be covered. However, GAP members felt that these tests are standard of care. Furthermore, the review required by the proposed guideline would be very time consuming if the reviewer had to constantly refer to the NCCN guidelines. GAP members recommended coverage of all 6 codes as diagnostic without a guideline.

HERC staff summary

The field of cancer biomarker testing is expanding at an extremely rapid pace. Single gene testing is rapidly being replaced in many instances by large gene panel testing. The ability to monitor and research each test and each indication is daunting. Such biomarker testing is required prior to treatment with certain agents by the FDA, and may be part of cancer treatment algorithms, such as the NCCN algorithms.

The Evidence-based Guidelines Subcommittee is planning on conducting a re-review of their cancer biomarkers coverage guidance. To inform this review, or possibly to better facilitate HERC changes, HERC staff are convening a work group of cancer genetic counselors, oncologists, and cancer pathologists. This work group will start meeting this winter.

In the interim, HERC staff recommends placing the new RNA panel testing on the DIAGNOSTIC PROCEDURES file to match the placement of the DNA and DNA+RNA panel tests. The placement of all 6 codes can be readdressed after the EbGS review. GAP members agreed with this recommendation.

GAP/HERC staff recommendation:

1) Place the new CPT codes 81449, 81451, and 81456 on the DIAGNOSTIC PROCEDURES file
    a. 81449 Targeted genomic sequence analysis panel, solid organ neoplasm, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, MET, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed; RNA analysis
    b. 81451 Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NOTCH1, NPM1, NRAS), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis
    c. 81456 Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm or disorder, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MET, MLL, NOTCH1, NPM1, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis

Decipher Prostate

Plain Language Summary:
Background: This is a test for prostate cancer patients who are considering radiation therapy. It is currently a non-covered test based on a 2017 evidence report.

Should OHP cover this test? Staff recommends covering this test now as the National Comprehensive Cancer Network (NCCN) gives Decipher a "1" rating for evidence supporting its use for helping make treatment decisions.

Question: Should Decipher Prostate genetic testing be covered?

Question source: Carl Stevens, MD CCO medical director; GAP

Issue: Decipher Prostate (CPT 81542) was reviewed in the 2017 HTAS Coverage Guidance on Gene Expression Profiling for Prostate Cancer and found to have little evidence to support its use. This test was included in GN148 BIOMARKER TESTS OF CANCER TISSUE as non-covered and listed in GN173 as non-covered. Dr. Stevens noted at the 2022 GAP meeting that Decipher Prostate is now recommended by NCCN for use in prostate cancer patients for consideration of radiation therapy.

HERC/subcommittee review history
The 2017 Biomarker for Prostate Cancer coverage guidance evidence review included only one cohort study (Gore et al 2017). NCCN relied on the results of two large prospective cohort studies (Marascio et al 2020 and Vince et al 2020) to inform their recommendations on Decipher.

Biomarkers for prostate cancer was reviewed in March, 2021 by VBBS. At that time, an AHRQ 2020 review was found that reported "We found no evidence that met our predefined inclusion criteria for the newer prognostic (proprietary) biomarkers such as Decipher, Oncotype Dx and Prolaris as it relates to comparative effectiveness modification." A 2018 review by Washington HTA included 8 studies at high risk for bias. This review concluded: "There is a mix of low-quality, very low-quality, and no evidence to support the other included tests for prostate cancer, colon cancer, and multiple myeloma. Multiple ongoing clinical trials on most of the tests will be reporting results in the next few years and will hopefully improve the evidence base for decision making regarding the clinical usefulness and economic effects of these tests." In the 2021 VBBS review, NCCN was noted to have only footnotes regarding biomarker assays in their prostate cancer treatment guideline.

Current Prioritized List status

GUIDELINE NOTE 148, BIOMARKER TESTS OF CANCER TISSUE
Lines 157,184,191,229,262,271,329
The use of tissue of origin testing (e.g. CPT 81504) is included on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

For early stage breast cancer, the following breast cancer genome profile tests are included on Line 191 when the listed criteria are met. One test per primary breast cancer is covered when the patient is

willing to use the test results in a shared decision-making process regarding adjuvant chemotherapy. Lymph nodes with micrometastases less than 2 mm in size are considered node negative.

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

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

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

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

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

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

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

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

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

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

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

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
Prostate Cancer Gene Expression tests billed with nonspecific codes (e.g. 81479, 81599, 84999)	• Oncotype DX Genomic Prostate Score • Decipher RP for prostate cancer	Unproven Intervention	March, 2021 Coverage guidance
81541	Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping)	Insufficient evidence of effectiveness	March, 2021
81542	Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as metastasis risk score	Insufficient evidence of effectiveness	March, 2021

Expert guidelines

1) **NCCN 1.2023** treatment guideline for prostate cancer
    a. Several tissue-based molecular assays have been developed in an effort to improve decision-making in newly diagnosed patients considering active surveillance and in treated patients considering adjuvant therapy or treatment for recurrence. Uncertainty about the risk of disease progression can be reduced if such molecular assays can provide accurate and reproducible prognostic or predictive information beyond NCCN risk group assignment and currently available life expectancy tables and nomograms. Retrospective case cohort studies have shown that these assays provide prognostic information independent of NCCN or CAPRA risk groups, which include likelihood of death with conservative management, likelihood of biochemical recurrence after radical prostatectomy or EBRT, likelihood of adverse pathologic features after radical prostatectomy, and likelihood of developing metastasis after operation, definitive EBRT, or post-recurrence EBRT
    b. Decipher: Given a level of evidence of 1 for prognostic testing
    c. Patients with NCCN low, favorable intermediate, unfavorable intermediate, or high-risk disease and life expectancy ≥10 y may consider the use of the following tumor-based molecular assays: Decipher, Oncotype DX Prostate, and Prolaris.
        i. Note: Oncotype Dx and Prolaris testing are also non-covered
        ii. Note: NCCN gives Oncotype Dx and Prolaris a level of evidence of 3 for prognostic testing
    d. For patients with PSA persistence/recurrence and a life expectancy > 5 yrs, NCCN recommends risk stratification with a PSADT
        i. Foot note: "PSADT can be calculated to inform nomogram use and counseling and/or Decipher molecular assay (category 2B) can be considered to inform counseling."
    e. Post-Prostatectomy Radiation Therapy
        i. The panel recommends use of nomograms and consideration of age and comorbidities, clinical and pathologic information, PSA levels, PSADT, and Decipher molecular assay to individualize treatment discussion. Patients with high Decipher genomic classifier scores (GC >0.6) should be strongly considered for EBRT and addition of ADT when the opportunity for early EBRT has been missed.
            1. EBRT with 2 years of 150 mg/day of bicalutamide demonstrated improved overall and metastasis-free survival on a prospective randomized trial (RTOG 9601) versus radiation alone in the salvage setting. A secondary analysis of RTOG 9601 found that patients with PSA ≤0.6 ng/mL had no overall survival improvement with the addition of the antiandrogen to EBRT. In addition, results of a retrospective analysis of RP specimens from patients in RTOG 9601 suggest that those with low PSA and a low Decipher score derived less benefit (development of distant metastases, overall survival) from bicalutamide than those with a high Decipher score.
            2. EBRT with 6 months of ADT (luteinizing hormone-releasing hormone [LHRH] agonist) improved biochemical or clinical progression at 5 years on a prospective randomized trial (GETUG-16) versus radiation alone in patients with rising PSA levels between 0.2 and 2.0 ng/mL after RP.

f. The Decipher molecular assay is recommended to inform adjuvant treatment if adverse features are found post-radical prostatectomy, and can be considered as part of counseling for risk stratification in patients with PSA resistance/recurrence after radical prostatectomy (category 2B).
g. Decisions about when to initiate post-radical prostatectomy radiation and whether to include ADT are complex. The Panel recommends use of nomograms and consideration of age and comorbidities, clinical and pathologic information, PSA levels, PSADT, and Decipher molecular assay to individualize treatment discussion.
h. the panel believes that patients with low or favorable intermediate disease and life expectancy greater than or equal to 10 years may consider the use of Decipher, Oncotype DX Prostate, or Prolaris during initial risk stratification.

HERC staff summary

The area of biomarkers for prostate cancer is rapidly changing. Since the last review 18 months ago, NCCN has come out with significantly updated recommendations regarding biomarker testing, based on two large prospective cohort studies on Decipher. NCCN gives Decipher a "1" rating for evidence supporting its use for prognosis, while the panel gives OncotypeDx Prostate and Prolaris "3" evidence ratings. NCCN notes that Decipher can be useful in decision making regarding adjuvant radiation or other treatment.

HERC staff recommendations:

1) Add CPT 81542 (Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as metastasis risk score) to the DIAGNOSTIC PROCEDURES file and remove from line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
    a. Do not change non-coverage of OncotypeDx Prostate and Prolaris given the low evidence rating in NCCN
2) Modify GN148 as shown below
3) Modify GN173 as shown below
4) Add a note to the coverage guidance "Gene Expression Profiling for Prostate Cancer" indicating this review supersedes the portion of the coverage guidance addressing Decipher.

GUIDELINE NOTE 148, BIOMARKER TESTS OF CANCER TISSUE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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:

Decipher Prostate

Procedure Code	Intervention Description	Rationale	Last Review
Prostate Cancer Gene Expression tests billed with nonspecific codes (e.g. 81479, 81599, 84999)	• Oncotype DX Genomic Prostate Score • ~~Decipher RP for prostate cancer~~	Unproven Intervention	~~**March, 2021**~~ November 2022 Coverage guidance
81541	Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping)	Insufficient evidence of effectiveness	~~**March, 2021**~~ November 2022
~~81542~~	~~Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as metastasis risk score~~	~~Insufficient evidence of effectiveness~~	~~**March, 2021**~~

Code	Code Description	Similar code	Recommended placement
15853	Removal of sutures or staples not requiring anesthesia (List separately in addition to E/M code)	Similar codes 15850 and 15851 (Removal of sutures under anesthesia (other than local), same/other surgeon) are Ancillary	ANCILLARY PROCEDURES
15854	Removal of sutures and staples not requiring anesthesia (List separately in addition to E/M code)	See 15853	ANCILLARY PROCEDURES
33900	Percutaneous pulmonary artery revascularization by stent placement, initial; normal native connections, unilateral	Stenting is a standard treatment for pulmonary artery stenosis (PAS) from congenital or acquired causes. Congenital conditions with PAS are on line 104 and aquired conditions are on line 357.	104 TETRALOGY OF FALLOT (TOF); CONGENITAL VENOUS ABNORMALITIES 357 CONDITIONS OF PULMONARY ARTERY
33901	Percutaneous pulmonary artery revascularization by stent placement, initial; normal native connections, bilateral	See 33900	104 TETRALOGY OF FALLOT (TOF); CONGENITAL VENOUS ABNORMALITIES 357 CONDITIONS OF PULMONARY ARTERY
33902	Percutaneous pulmonary artery revascularization by stent placement, initial; abnormal connections, unilateral	See 33900	104 TETRALOGY OF FALLOT (TOF); CONGENITAL VENOUS ABNORMALITIES 357 CONDITIONS OF PULMONARY ARTERY
33903	Percutaneous pulmonary artery revascularization by stent placement, initial; abnormal connections, bilateral	See 33900	104 TETRALOGY OF FALLOT (TOF); CONGENITAL VENOUS ABNORMALITIES 357 CONDITIONS OF PULMONARY ARTERY
33904	Percutaneous pulmonary artery revascularization by stent placement, each additional vessel or separate lesion, normal or abnormal connections (List separately in addition to code for primary procedure)	See 33900	104 TETRALOGY OF FALLOT (TOF); CONGENITAL VENOUS ABNORMALITIES 357 CONDITIONS OF PULMONARY ARTERY

Code	Code Description	Similar code	Recommended placement
36836	Percutaneous arteriovenous fistula creation, upper extremity, single access of both the peripheral artery and peripheral vein, including fistula maturation procedures (eg, transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation	Done for creation of dialysis access Similar codes (e.g. 36825 Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); autogenous graft) are on line 339	339 CHRONIC KIDNEY DISEASE
36837	Percutaneous arteriovenous fistula creation, upper extremity, separate access sites of the peripheral artery and peripheral vein, including fistula maturation procedures (eg, transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation	See 36836	339 CHRONIC KIDNEY DISEASE
43291	Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)	Removal may be necessary due to a complication, infection, perforation, etc.	424 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
49591	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible	Replaces CPT 49652 (Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); reducible) as well as the individual open repair codes which were on lines 168, 524. There is a guideline regarding hernia repair	168 COMPLICATED HERNIAS; PERSISTENT HYDROCELE 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN DIAPHRAGMATIC HERNIA)

Code	Code Description	Similar code	Recommended placement
49592	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated	Replaces CPT 49653 (Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); incarcerated or strangulated) as well as the individual open repair codes which were on lines 168, 524. There is a guideline regarding hernia repair	168 COMPLICATED HERNIAS; PERSISTENT HYDROCELE 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN DIAPHRAGMATIC HERNIA)
49593	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible	See 49591	168 COMPLICATED HERNIAS; PERSISTENT HYDROCELE 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN DIAPHRAGMATIC HERNIA)
49594	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated	See 49592	168 COMPLICATED HERNIAS; PERSISTENT HYDROCELE 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN DIAPHRAGMATIC HERNIA)
49595	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible	See 49591	168 COMPLICATED HERNIAS; PERSISTENT HYDROCELE 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN DIAPHRAGMATIC HERNIA)

Code	Code Description	Similar code	Recommended placement
49596	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated	See 49592	168 COMPLICATED HERNIAS; PERSISTENT HYDROCELE 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN DIAPHRAGMATIC HERNIA)
49613	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible	See 49591	168 COMPLICATED HERNIAS; PERSISTENT HYDROCELE 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN DIAPHRAGMATIC HERNIA)
49614	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, incarcerated or strangulated	See 49592	168 COMPLICATED HERNIAS; PERSISTENT HYDROCELE 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN DIAPHRAGMATIC HERNIA)
49615	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible	See 49591	168 COMPLICATED HERNIAS; PERSISTENT HYDROCELE 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN DIAPHRAGMATIC HERNIA)
49616	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated	See 49592	168 COMPLICATED HERNIAS; PERSISTENT HYDROCELE 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN DIAPHRAGMATIC HERNIA)

Code	Code Description	Similar code	Recommended placement
49617	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible	See 49591	168 COMPLICATED HERNIAS; PERSISTENT HYDROCELE 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN DIAPHRAGMATIC HERNIA)
49618	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated	See 49592	168 COMPLICATED HERNIAS; PERSISTENT HYDROCELE 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN DIAPHRAGMATIC HERNIA)
49621	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including implantation of mesh or other prosthesis, when performed; reducible	Previously coded with recurrent incisional hernia (CPT 49654-49657 Laparoscopy, surgical, repair, incisional hernia, recurrent/non-recurrent) which were on lines 168, 524	168 COMPLICATED HERNIAS; PERSISTENT HYDROCELE 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN DIAPHRAGMATIC HERNIA)
49622	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including implantation of mesh or other prosthesis, when performed; incarcerated or strangulated	See 49621	168 COMPLICATED HERNIAS; PERSISTENT HYDROCELE 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN DIAPHRAGMATIC HERNIA)
49623	Removal of total or near total non-infected mesh or other prosthesis at the time of initial or recurrent anterior abdominal hernia repair or parastomal hernia repair, any approach (ie, open, laparoscopic, robotic) (List separately in addition to code for primary procedure)	See 49591	168 COMPLICATED HERNIAS; PERSISTENT HYDROCELE 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN DIAPHRAGMATIC HERNIA)

Code	Code Description	Similar code	Recommended placement
55867	Laparoscopy, surgical prostatectomy, simple subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy), includes robotic assistance, when performed	55802 (Prostatectomy, perineal, subtotal) is on lines 327, 515, 585	327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION 515 CHRONIC PROSTATITIS, OTHER DISORDERS OF PROSTATE 585 BENIGN NEOPLASM OF MALE GENITAL ORGANS: TESTIS, PROSTATE, EPIDIDYMIS
69728	Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex	Similar codes 69726 and 69727 are on lines 285,311,446	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 311 HEARING LOSS - AGE 5 OR UNDER 446 HEARING LOSS - OVER AGE OF FIVE
69729	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside of the mastoid and resulting in removal of greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex	Similar codes 69714 and 69716 are on lines 311, 446	311 HEARING LOSS - AGE 5 OR UNDER 446 HEARING LOSS - OVER AGE OF FIVE
69730	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex	Similar code 69717 is on lines 311, 446	311 HEARING LOSS - AGE 5 OR UNDER 446 HEARING LOSS - OVER AGE OF FIVE

Code	Code Description	Similar code	Recommended placement
76883	Ultrasound, nerve(s) and accompanying structures throughout their entire anatomic course in one extremity, comprehensive, including real-time cine imaging with image documentation, per extremity	Similar code 76882 (Ultrasound, limited, joint or other nonvascular extremity structure(s) (eg, joint space, peri-articular tendon[s], muscle[s], nerve[s], other soft-tissue structure[s], or soft-tissue mass[es]), real-time with image documentation) is on DIAGNOSTIC PROCEDURES	DIAGNOSTIC PROCEDURES
87468	Infectious agent detection by nucleic acid (DNA or RNA); Anaplasma phagocytophilum, amplified probe technique	Causes anaplasmosis, a tick bourne disease	DIAGNOSTIC PROCEDURES
87469	Infectious agent detection by nucleic acid (DNA or RNA); Babesia microti, amplified probe technique	Causes babesosis, a tick bourne disease	DIAGNOSTIC PROCEDURES
87478	Infectious agent detection by nucleic acid (DNA or RNA); Borrelia miyamotoi, amplified probe technique	Causes tickbourne relapsing fever	DIAGNOSTIC PROCEDURES
87484	Infectious agent detection by nucleic acid (DNA or RNA); Ehrlichia chaffeensis, amplified probe technique	Causes ehrlichiosis, a tick bourne disease	DIAGNOSTIC PROCEDURES
93569	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary arterial angiography, unilateral (List separately in addition to code for primary procedure)	Similar codes 93563-93567 (Injection procedure during cardiac catheterization) are DIAGNOSTIC PROCEDURES	DIAGNOSTIC PROCEDURES
93573	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary arterial angiography, bilateral (List separately in addition to code for primary procedure)	Similar codes 93563-93567 (Injection procedure during cardiac catheterization) are DIAGNOSTIC PROCEDURES	DIAGNOSTIC PROCEDURES

Code	Code Description	Similar code	Recommended placement
93574	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary venous angiography of each distinct pulmonary vein during cardiac catheterization (List separately in addition to code for primary procedure)	Similar codes 93563-93567 (Injection procedure during cardiac catheterization) are DIAGNOSTIC PROCEDURES	DIAGNOSTIC PROCEDURES
93575	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary angiography of major aortopulmonary collateral arteries (MAPCAs) arising off the aorta or its systemic branches, during cardiac catheterization for congenital heart defects, each distinct vessel (List separately in addition to code for primary procedure)	Similar codes 93563-93567 (Injection procedure during cardiac catheterization) are DIAGNOSTIC PROCEDURES	DIAGNOSTIC PROCEDURES
99418	Prolonged inpatient or observation evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time (List separately in addition to the code of the inpatient and observation Evaluation and Management service)		All lines with inpatient E&M codes

Code	Code Description	Similar code	Recommended placement
15778	Implantation of absorbable mesh or other prosthesis for delayed closure of defect(s) (ie, external genitalia, perineum, abdominal wall) due to soft tissue infection or trauma	See issues	502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)	See issues	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
30469	Repair of nasal valve collapse with low energy, temperature-controlled (ie, radiofrequency) subcutaneous/submucosal remodeling	See issues	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
43290	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon	See issues	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
87467	Hepatitis B surface antigen (HBsAg), quantitative	See issues	198 CHRONIC HEPATITIS; VIRAL HEPATITIS
90678	Respiratory syncytial virus vaccine, preF, subunit, bivalent, for intramuscular use	See issues	EXCLUDED
92066	Orthoptic training; under supervision of a physician or other qualified health care professional	See issues	393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN
95919	Quantitative pupillometry with physician or other qualified health care professional interpretation and report, unilateral or bilateral	See issues	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

2023 CPT Code Review
Issues

1) Code: **15778**
    a. Code description: Implantation of absorbable mesh or other prosthesis for delayed closure of defect(s) (ie, external genitalia, perineum, abdominal wall) due to soft tissue infection or trauma
    b. Information: Biosynthetic prosthetics are those designed to allow for tissue ingrowth and wound healing before completely dissolving in a prescribed time period. Absorbable meshes made of Vicryl (Ethicon) or Dexon (Medtronic) were initially developed for hernia repair in infected fields; however, their use is limited by a prohibitive rate of hernia recurrence if used as a bridging repair. Examples of biologics include the human acellular dermal matrices AlloDerm (Allergan), AlloMax (Bard), and FlexHD (Ethicon).
    c. Similar codes:
        i. 15777 Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk)
            1. Line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS
    d. Current Prioritized List status: Relevant wound or surgical site dehiscence diagnosis codes are on lines 47, 131, 159, 205, 235, 285, and 385. Line 379 CHRONIC ULCER OF SKIN; VARICOSE VEINS WITH MAJOR COMPLICATIONS already has skin substitute codes attached with a guideline
        i. 47 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS
        ii. 131 CRUSH INJURIES OTHER THAN DIGITS; COMPARTMENT SYNDROME
        iii. 159 TOXIC EPIDERMAL NECROLYSIS AND STAPHYLOCOCCAL SCALDED SKIN SYNDROME; STEVENS-JOHNSON SYNDROME; ERYTHEMA MULTIFORME MAJOR; ECZEMA HERPETICUM
        iv. 205 SUPERFICIAL ABSCESSES AND CELLULITIS
        v. 207 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT
        vi. 235 LIMB THREATENING VASCULAR DISEASE, INFECTIONS, AND VASCULAR COMPLICATIONS
        vii. 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
        viii. 385 SUPERFICIAL INJURIES WITH INFECTION
    e. Evidence:
        i. **Rosen 2022**, RCT comparing biologic vs synthetic mesh for repair of contaminated ventral hernias [CONSORT trial]
            1. N=253 patients with contaminated wound
                a. N=126 with synthetic mesh
                b. N=127 with biologic mesh
            2. Synthetic mesh significantly reduced the risk of hernia recurrence (site adjustment: HR 0.31; CI, 0.23-0.42, P ≤ .001) and (surgeon adjustment: HR, 0.31; 95% CI, 0.13-0.75; P = .009)

3. Comparable risks of surgical site occurrences requiring procedural intervention were found at each time point through the 2-year study period (biologic vs synthetic at 30 days, 27.6% vs 24.6%; P = .70; 6 months, 7.1% vs 4.8%; P = .61; 12 months, 1.6% vs 2.4%; P = .68; 24 months, 0.8% vs 1.6%; P = .62)
4. Overall, there were comparable rates of surgical site infection; however, the biologic mesh group tended to have a higher risk of deep surgical site infection than the synthetic group (14 [11%] vs 5 [4%], respectively; P = .06).
5. There were significantly more adverse events in the biologic vs the synthetic mesh group (84 [66.1%] vs 65 [51.6%], respectively; P = .03). Patients receiving synthetic mesh had a 14.5% (95% CI, 1.7-27.3) absolute risk reduction of having an adverse event compared with the biologic mesh group. Most adverse events were either wound morbidity or ileus
6. the 30-day adverse events in the biologic group tended to be more severe than the synthetic group (20.9 [95% CI, 0.0-28.2] vs 8.7 [95% CI, 0.0-22.6], respectively; P = .05)
7. There were no significant differences between the groups regarding QOL
8. Conclusion: In this randomized clinical trial, synthetic mesh added a substantial benefit over biologic mesh during single-stage ventral hernia repair in a clean-contaminated or contaminated surgical field in terms of reducing hernia recurrence risk at 2-year follow-up. Safety profiles were similar between the meshes at up to 2 years; however, there was a significant difference in the prespecified secondary end point of cost between the groups, with biologic mesh costing roughly 200 times as much as synthetic mesh and being the sole driver doubling the total 30-day median hospital costs.

ii. **Lak 2018**, mesh selection in abdominal wall reconstruction

1. Absorbable meshes made of Vicryl (Ethicon) or Dexon (Medtronic) were initially developed for hernia repair in infected fields; however, their use is limited by a prohibitive rate of hernia recurrence if used as a bridging repair. Biosynthetic prosthetics are those designed to allow for tissue ingrowth and wound healing before completely dissolving in a prescribed time period. Biologic prosthetics have been commonly derived from human, porcine, or bovine tissues and are decellularized in efforts to create a collagen scaffold to support native tissue ingrowth. Examples of biologics include the human acellular dermal matrices AlloDerm (Allergan), AlloMax (Bard), and FlexHD (Ethicon).
2. Management of contaminated wounds is challenging as placement of a permanent material into the field increases the risk of postoperative infection, bowel adhesions, mesh extrusion, mesh erosion, fistula formation, seroma development, and pain. The most efficacious

management strategy of a ventral hernia in a contaminated clinical situation has been debated and includes methods of staging the repair, primary facial closure alone, or use of a permanent, absorbable synthetic or biologic mesh

3. **It is important to note that there is no current indication for any reinforcement material (mesh) for use in a contaminated field. Therefore, any use of such material would be considered off-label.**
4. Two prospective cohort studies of biologic mesh use in repair of infected or contaminated ventral hernias were summarized (Repair of Infected or Contaminated ventral incisional Hernias (RICH) and the Complex Open Bioabsorbable Reconstruction of the Abdominal Wall (COBRA) studies)
    a. RICH examined Allergan, COBRA examined Bio-A (Gore)
    b. RICH: demonstrated a surgical-site occurrence rate of 66% and a surgical-site infection rate of 30%. By 24-month follow-up, the hernia recurrence was 28%.
    c. COBRA: In a 24-month follow-up, the surgical-site occurrence rate was 28%, and surgical-site infection rate was 18%. The overall recurrence rate was 17%.

iii. **Petro 2019**, review of long-acting resorbable meshes in abdominal wall reconstruction
    1. Biologic mesh—decellularized human or animal collagen that serves as a scaffold for tissue ingrowth—is typically regarded as a "safe" alternative in contaminated settings, but at $25–30/ cm2 adds a significant expense to the patient's care in exchange for widely variable recurrence rates

f. HERC staff summary:
    i. Use of absorbable mesh or biologic prosthesis appears to be a controversial topic in surgery. The evidence identified comes from contaminated surgical wounds rather than wounds from trauma or infection. The evidence indicates that absorbable mesh/biologic prostheses have higher rates of complications and hernia formation compared to non-absorbable mesh, and a trend toward higher infection rates. Other treatments are available, including wound vacuum therapy, traditional wound care, and non-absorbable mesh repair. However, staff literature review did not find comparison of more traditional wound care with closure with either absorbable or non-absorbable mesh, making the efficacy of absorbable mesh vs standard care not determinable. Of note, use of any type of mesh or prosthesis in an infected site is an off-label use of these products. Also of note, absorbable mesh/biologic prostheses have a much higher cost than non-absorbable mesh.

g. **HERC staff recommendation**:
    i. Place 15778 on the line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS
        1. 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
15778	Implantation of absorbable mesh or other prosthesis for delayed closure of defect(s) (ie, external genitalia, perineum, abdominal wall) due to soft tissue infection or trauma	More cost-effective treatments with lower complications rates are available	November 2022

2) Code **22860**
   a. Code description: Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar
   b. Similar codes: Similar code 22857 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar) is on lines 346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS and 530 530 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS.
   c. Information: artificial discs are covered based on GN101 ARTIFICIAL DISC REPLACEMENT. This guideline restricts coverage to a single level lumbar artificial disc replacement: "Replacement of a single disc for degenerative disc disease at one level confirmed by patient history and imaging." Coverage of artificial discs was last reviewed in January 2016.
   d. Evidence
      i. **NICE 2020**, evidence review for low back pain and sciatica
         1. N=5 RCTs, comparing artificial disc to other treatment (fusion or multidisciplinary rehabilitation)
            a. Unclear from study descriptions if any patients had multi-level artificial disc replacement
         2. Evidence from 1 study comparing disc replacement to anterior lumbar interbody fusion suggested clinical benefit of disc replacement for quality of life (SF-36 mental component) both at short and long term, but this was not demonstrated for the SF-36 physical component summary score (low to very low quality; n=577). Clinical benefit of disc replacement compared to posterior lumbar interbody fusion for quality of life (EQ-5D) at 1 year was also observed; however, this was not demonstrated at 2 years (1 study, low to very low quality; n=152). Evidence from the 2 studies also demonstrated no clinical difference

between disc replacement and spinal fusion for pain (back and leg pain VAS) or function (ODI) at both short and long term (low to very low quality; n=577, n=152).

3. In terms of adverse events, evidence from a single study showed greater numbers of adverse events for disc replacement compared to spinal fusion below 4 months (low to very low quality; n=577)
4. There was no clinical difference between the 2 procedures for the reoperation outcome at 2 years (2 studies; low to very low quality; n=577, n=152) and at 5 years (1 study; low to very low quality; n=152), while there was evidence of clinical benefit favoring disc replacement for device-related reoperations at 5 years (1 RCT; low to very low quality; n=152)
5. Summary: The guideline development group (GDG) noted that there were some signs of benefit from disc replacement compared to other interventions, but this evidence was very limited and not consistent across outcomes. Furthermore the GDG felt the risk of harms associated with disc replacement outweighed the potential benefits. The GDG were aware of the lack of long-term follow-up data for disc replacement surgery. The GDG expressed their concerns about this, particularly as disc replacement is often performed in younger age-groups in consideration of its claimed motion preservation benefits. However, it was highlighted that there is currently limited evidence of disc replacement benefits regarding motion and adjacent level degeneration compared to other surgical procedures, and the reported risks of disc replacement would often prevail over the benefits. As a result, the GDG agreed that the limited evidence of effectiveness alongside the above concerns meant it was appropriate to recommend against the use of disc replacement in people with low back pain with/without sciatica.

ii. **Scott-Young 2019**, patient reported outcomes after multilevel lumbar disc arthroplasty
    1. N=122 patients with two level (120 patients) or three level (2 patient) artificial disc arthroplasty
        a. Surgery 1999-2009
        b. 24 month follow-up
    2. VAS outcomes for both back and leg pain: At all stages of follow-up, a statistically significant difference from baseline can be seen ($P < 0.001$). By 12 months, the median VAS-B had improved by 88.75% to a score of 9/100
    3. Conclusion: Multilevel lumbar disc arthroplasty surgery appears to be a suitable option for individuals with multilevel symptomatic DDD refractory to conservative management, when appropriate diagnosis, patient selection, surgical technique, and rehabilitation methods are followed.
    4. Level of evidence: 4

e. Other payer policies
   i. NICE 2020: Do not offer disc replacement in people with low back pain.
   ii. CMS 2007: The Centers for Medicare and Medicaid Services (CMS) has determined that LADR is not reasonable and necessary for the Medicare population over sixty years of age. Therefore, Section 150.10 of the Medicare National Coverage Determination (NCD) Manual is amended to reflect the change from non-coverage for LADR with a specific implant to non-coverage for the LADR procedure for the Medicare population over sixty years of age. For Medicare beneficiaries sixty years of age and under, there is no national coverage determination, leaving such determinations to be made on a local basis.
   iii. United Healthcare 2022: only covers single level lumbar artificial disc
   iv. Aetna 2022: considers lumbar artificial discs experimental

f. HERC staff summary: since the last review in 2016, minimal new literature was identified that examined the outcomes of multiple level lumbar artificial disc placement. A recent NICE review concluded that there was insufficient evidence for even single level disc replacement. Other payers either recommend against any coverage (NICE) or only cover single level disc replacement. Multi-level replacement appears to continue to be experimental. https://www.nice.org.uk/guidance/ng59/resources/low-back-pain-and-sciatica-in-over-16s-assessment-and-management-pdf-1837521693637

g. **HERC staff recommendation**:
   i. Place CPT 22860 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
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar	Insufficient evidence of effectiveness	November 2022

3) Code **30469**
   a. Code description: Repair of nasal valve collapse with low energy, temperature-controlled (ie, radiofrequency) subcutaneous/submucosal remodeling

b. Information: The Aerin™ VivAer® procedure is a non-invasive, office-based procedure that employs low-dose radiofrequency (RF) energy to modify soft tissues of the nose with the intent of improving airflow for patients with nasal valve collapse.
c. Similar codes: Similar code 30468 (Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)) is on lines 466, 506, and 577
    i. 466 CHRONIC SINUSITIS
    ii. 506 NASAL POLYPS, OTHER DISORDERS OF NASAL CAVITY AND SINUSES
    iii. 577 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT
d. Evidence
    i. **Silvers 2021,** RCT of radiofrequency treatment vs sham for nasal valve obstruction
        1. All authors had funding from Aerin Medical
        2. N=119 patients
            a. N=77 patients in the radiofrequency arm, N=41 in the sham procedure arm
        3. Follow up 3 months
        4. At baseline, patients had a mean NOSE-scale score of 76.7 (95% confidence interval [CI], 73.8 to 79.5) and 78.8 (95% CI, 74.2 to 83.3) (p = 0.424) in the active treatment and sham-control arms, respectively. At 3 months, the responder rate was significantly higher in the active treatment arm (88.3% [95% CI, 79.2%-93.7%] vs 42.5% [95% CI, 28.5%-57.8%]; p < 0.001). The active treatment arm had a significantly greater decrease in NOSE-scale score (mean, −42.3 [95% CI, −47.6 to −37.1] vs −16.8 [95% CI, −26.3 to −7.2]; p < 0.001). Three adverse events at least possibly related to the device and/or procedure were reported, and all resolved.
        5. There was no significant difference in pain score immediately post-procedure (active treatment median [n = 76]: 5 mm [IQR, 0-14.5 mm]; sham-control median: 2 mm [IQR, 0-10.5 mm]; p = 0.235)
    ii. Three prospective cohort studies were identified (Yao 2021, Brehmer 2019, Jacobowitz 2019) with N=122, N=31 and N=50 respectively
e. Expert guidelines: none identified
f. Other payer policies
    i. Anthem BCBS 2022: Low-dose radiofrequency intranasal tissue remodeling as a treatment of nasal airway obstruction is considered investigational and not medically necessary**.**
    ii. Centene 2022: It is the policy of health plans affiliated with Centene Corporation that safety and efficacy have not been established for the following procedures for repair of nasal vestibular stenosis: A. Radiofrequency ablation (VivAer®)
g. HERC staff summary:
    i. Radiofrequency treatment of nasal valves is a new procedure with a very limited evidence base. Its efficacy at treating nasal obstruction due to nasal valve collapse cannot be determined from the limited evidence available.

h. **HERC staff recommendation**:
   i. Place CPT 30469 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
30469	Repair of nasal valve collapse with low energy, temperature-controlled (ie, radiofrequency) subcutaneous/submucosal remodeling	Insufficient evidence of effectiveness	November 2022

4) Code: **43290**
   a. Code description: Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon
   b. From GUIDELINE NOTE 5, OBESITY AND OVERWEIGHT
      i. Pharmacological treatments and devices (e.g. gastric balloons, duodenal jejunal bypass liners, and vagus nerve blocking devices) for obesity are not intended to be included as services on this line or any other line on the Prioritized List.
   c. HERC staff recommendation:
      i. Place **43290** on lines 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
      ii. Modify GN 173 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
43290	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon	Insufficient evidence of effectiveness	November 2022

5) Code: **87467**
    a. Code description: Hepatitis B surface antigen (HBsAg), quantitative
    b. Information:
        i. From LabCorp: Quantitative HBV surface antigen (HBsAg) testing is intended for use in individuals with a confirmed diagnosis of Hepatitis B Virus infection based on positive HBsAg, Anti-HBs antibody and/or Anti-core antigen (anti-HBc) antibody test results. Quantitative HBsAg testing has utility in assessing HBV replication in the absence and presence of antiviral therapy, which may inform monitoring treatment response and relapse in the setting of initial and prolonged antiviral therapy, respectively. Quantitative HBsAg testing is not intended for the diagnosis of HBV infection. The relationship between HBsAg levels and ongoing HBV replication and/or persistent infection has not been fully defined. HBV DNA viral load measurements reflect the extent of ongoing HBV replication. HBsAg levels reflect the transcription and trranslational expression of HBV DNA. The clinical ramifications of detectable levels of HBsAg in the absence of detectable levels of HBV DNA are the subject of ongoing investigation.
    c. Other codes of interest:
        i. ICD-10-CM B18.X (Chronic viral hepatitis B) is online 198 CHRONIC HEPATITIS; VIRAL HEPATITIS
    d. Evidence
        i. **Vachon 2021**, novel biomarkers of hepatitis B virus and their use in chronic hepatitis B patient management
            1. There are two types of therapies available for the treatment of hepatitis B infection: NA and peg-IFN. NAs include lamivudine, telbivudine, tenofovir disoproxil fumarate, adefovir, and entecavir
            2. While qualitative detection of HBsAg may be used to screen for and diagnose HBV infection, quantitative HBsAg (qHBsAg) measurement may better inform clinicians regarding response to treatment, prediction of SVR, and disease progression, among other clinical situations
            3. Serum HBsAg levels have been shown to correlate with other markers of HBV infection. During antiviral treatment, HBsAg levels correlate with serum HBV DNA and serum HBV RNA, although a stronger correlation is observed in HBeAg-positive patients than those who are HBeAg negative
            4. Quantitative HBsAg has also been used to predict treatment response in HBeAg-positive and -negative patients treated with peg-IFN with or without NA
            5. HBsAg levels have also been investigated as a predictor of chronic disease progression to fibrosis and HCC

e. Expert guidelines
    i. **NICE 2017** management of hepatitis B
        1. Monitor HBV DNA and quantitative HBsAg levels and HBeAg status before starting peginterferon alfa-2a at 12, 24 and 48 weeks after starting treatment to determine treatment response
        2. Monitor HBV DNA and quantitative HBsAg levels and HBeAg status before starting entecavir or lamivudine, 12, 24 and 48 weeks after starting treatment and then every 6 months to determine treatment response and medicines adherence
        3. Monitor HBV DNA and quantitative HBsAg levels and HBeAg status before starting tenofovir disoproxil, 12, 24 and 48 weeks after starting treatment and then every 6 months to determine treatment response and medicines adherence
        4. Further research should be undertaken to evaluate the clinical and cost effectiveness of hepatitis B surface antigen (HBsAg) quantitative assays in determining treatment duration in hepatitis B antigen (HBeAg) negative disease
f. HERC staff summary: Diagnosis of hepatitis B is done with qualitative HBsAg levels. Quantitative testing is recommended during treatment with antiviral therapy.
g. **HERC staff recommendation**:
    i. Place CPT 87467 on line 198 CHRONIC HEPATITIS; VIRAL HEPATITIS
        1. Can be used in the management of treatment of chronic hepatitis B but not in diagnosis of this condition

6) CPT **90678**
    h. Code description: Respiratory syncytial virus vaccine, preF, subunit, bivalent, for intramuscular use
    i. Similar codes: none
    j. Issue: there is currently no FDA approved vaccine for respiratory syncytial virus (RSV). RSV is a contagious virus and a common cause of respiratory illness. RSV can be potentially life-threatening for young infants, the immunocompromised, and older adults. Pfizer announced in September 2022 that it is seeking FDA approval for its RSV vaccine, which is designed to protect adults 60 years of age and older. Pfizer has also studied its vaccine in pregnant women as a method to prevent severe RSV infection in their babies up to 6 months. This vaccine has not yet been reviewed by the FDA. Jansson and Moderna are also developing vaccines against RSV. Per the CDC, there is no vaccine for RSV currently available.
    k. ACIP October 2022 meeting:
        i. RSV Older Adults: The Committee heard presentations from both GSK (RSVpreF3 vaccine) and Pfizer (RSVpreF vaccine) on their phase 3 clinical trials for RSV vaccines for adults ≥60. Both clinical trials presented today were conducted during the COVID-19 pandemic; no RSV associated deaths in trials. Efficacy point estimates against the primary outcomes in both trials exceeded 60% (82.6% GSK

against lower respiratory tract disease; 66.7%-85.7% against lower respiratory tract illness), but efficacy cannot be compared across trials. Data from only the first year will be available for consideration of the first policy recommendations; there is no established immunologic correlate of protection for RSV. Cases of Guillain-Barre syndrome (GBS) were reported in both trials (1 in GSK, 2 in Pfizer) The Committee felt that both vaccine candidates should be studied further in frailer, older adults 70+ or 80+, and there were concerns about GBS associated with the GSK product. Neither of these vaccines are ACIP recommended in the U.S., but the RSV-Adults ACIP Work Group will continue to consider safety and efficacy data into 2023.

l. HERC staff recommendation
    i. Place CPT **90678** on the EXCLUDED file
        1. Currently no approved vaccine for use with this code
        2. If an RSV vaccine is approved, HSD can move this code to a funded list and then HERC can reassess placement

7) CPT **92066**

m. Code description: Orthoptic training; under supervision of a physician or other qualified health care professional
n. Similar code: Similar code 92065 (Orthoptic training; performed by a physician or other qualified health care professional) is on line 393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN
o. Prior review: Opthoptic training was reviewed in 2017. From the 2017 HERC staff summary: "There is little evidence to support the use of vision therapy for any indication. The best available evidence (small case series) is for intermittent esotropia and exotropia. Current OAR limits vision therapy to children up through age 20 for 6 sessions without a PA, and for unlimited sessions with a PA, using only the CPT code specific for Orthoptic and/or pleoptic training (i.e. CPT 92065)." Based on this review, a new coding specification was added to the Prioritized List, that later became GN215.
p. Current Prioritized List status
q. **HERC staff recommendations**:
    i. Place 92066 on line 393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN
        1. Note: There may be additional benefits for children with different diagnoses through the requirements of EPSDT benefits.
    ii. Modify GN215 as shown below

GUIDELINE NOTE 215, ORTHOPTIC AND/OR PLEOPTIC TRAINING

Line 393

CPT 92065**, 92066** (Orthoptic and/or pleoptic training) is included on Line 393 only for pairing with ICD-10-CM H50.31 (Intermittent monocular esotropia), H50.32 (Intermittent alternating esotropia), H50.33 (Intermittent monocular exotropia), and H50.34 (Intermittent alternating exotropia).

8) CPT **95919**

r. Code description: Quantitative pupillometry with physician or other qualified health care professional interpretation and report, unilateral or bilateral

s. Information: Pupillary examination has been used as a basic measure in critically ill patients and is important for the prognosis and management of disease. Traditionally, pupillary measurements have been carried out in a subjective manner – by means of a pen flash-light to evaluate for reactivity and a pupil gauge for pupil size. Pupillometry refers to an objective way of measuring the diameter of the pupil. The NeurOptics NPi-100 Pupillometer is a hand-held infrared device that allows for objective measurement of pupillary light reflex and pupil size. Moreover, the numeric scale of the Neurological Pupil index (NPi), allows for a more rigorous interpretation and classification of the pupillary response. The Pupillometer and its NPi scale reduce subjectivity from the measurement by comparing the pupillary light reflex against normative data in the NPi model and automatically deriving whether the pupillary reflex falls within the normal range or outside of the normal range and provide a reliable way to quantitatively classify the pupillary light response.

t. Evidence

i. **NICE 2020**, NPi-2000 for pupillary light reflex in critical care patients, innovation briefing

1. N=6 observations studies (1,217 patients)
2. The evidence for the technology is of low methodological quality, and most of the studies are small in terms of patient numbers
3. The studies show that NPi-200 can predict poor outcomes in critically ill people. Further evidence comparing NPi-200 with standard care, with a large sample size is needed.

u. Expert guidelines: none found

v. Other payer policies

i. Aetna 2021

1. Aetna considers the use of quantitative pupillometry/pupillography experimental and investigational for all indications

w. HERC staff summary: Quantitative pupillometry appears to be an experimental test, and is far expensive than the standard of care (hand held pen-light)

x. HERC staff recommendation:

i. Place **95919** on lines 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

ii. Modify GN 173 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
95919	Quantitative pupillometry with physician or other qualified health care professional interpretation and report, unilateral or bilateral	Insufficient evidence of effectiveness	November 2022

2023 HCPCS Code Review

1) Vaccine counseling codes (G0310-G0315)
    a. Codes
        i. **G0310** - Immunization counseling by a physician or other qualified health care professional when the vaccine(s) is not administered on the same date of service, 5-15 minutes. (This code is used for Medicaid billing purposes.)
        ii. **G0311** - Immunization counseling by a physician or other qualified health care professional when the vaccine(s) is not administered on the same date of service, 16-30 minutes. (This code is used for Medicaid billing purposes.)
        iii. **G0312** - Immunization counseling by a physician or other qualified health care professional when the vaccine(s) is not administered on the same date of service for ages under 21, 5-15 minutes. (This code is used for Medicaid billing purposes.)
        iv. **G0313** - Immunization counseling by a physician or other qualified health care professional when the vaccine(s) is not administered on the same date of service for ages under 21, 16-30 minutes. (This code is used for Medicaid billing purposes.)
        v. **G0314** - Immunization counseling by a physician or other qualified health care professional for COVID-19, ages under 21, 16-30 minutes. (This code is used for the Medicaid EPSDT benefit).
        vi. **G0315** - Immunization counseling by a physician or other qualified health care professional for COVID-19, ages under 21, 5-15 minutes. (This code is used for the Medicaid EPSDT benefit).
    b. Information: Six new HCPCS codes were released in early 2022 by CMS for use in counseling patients and guardians regarding vaccines when the vaccine is not administered (for example, if a parent declines the vaccine). Currently, vaccine counseling is only included as part of the CPT code for vaccine administration. CMS intends that these new HCPCS codes be used for stand-alone vaccine counseling and is requiring coverage of the under-21 codes as part of the EPSDT benefit. These codes will be very useful to providers who spend extensive time in vaccine counseling but the patient/guardian decides to decline the vaccine. The under-21 versions of these codes were intended to be opened early this year per CMS directive. HSD opened these codes when HERC staff became aware of them, with the vaccine program staff approval.
    c. **HERC staff recommendation**:
        i. Add HCPCS G0310-G0315 to the Ancillary Procedures File
            1. This will allow use at any type of visit and with any visit diagnosis when vaccine counseling is done by a provider

2) Home COVID testing (K1034)
    a. Code: **K1034** Provision of covid-19 test, nonprescription self-administered and self-collected use, fda approved, authorized or cleared, one test count
    b. Information: CMS released a new HCPCS code for home COVID-19 tests in spring 2022. HSD has already opened this code to allow the testing required by the American Rescue Plan legislation. HSD staff report that the HCPCS code is in the Durable Medical Equipment file (similar to the Ancillary file).
    c. **HERC staff recommendation**:
        i. Affirm the placement of K1034 on the Ancillary File

3) Doula services (T1032-T1033)
    a. Codes
        i. **T1032** Services performed by a doula birth worker, per 15 minutes
        ii. **T1033** per diem
    b. Information: Two new HCPCS codes were released in October 2022 by CMS for use by doulas. A Doula is a birth companion who provides personal, nonmedical support to women and families throughout a woman's pregnancy, childbirth, and post-partum experience. OHA is currently paying for doula services using a modifier added to the CPT codes for vaginal or other types of delivery. Doulas are certified under the traditional health worker certification process by OHA and then added to the state registry. The certification requirements can be found at https://www.oregon.gov/oha/OEI/Pages/THW_birthdoulas.aspx. Currently, the rate is $350 per delivery, which includes two visits before delivery, delivery care, and two visits after delivery. If the doula is present for only the delivery, the rate is $150. Of note, Oregon just received CMS approval to increase birth doula rates from $350 up to $1500.
    c. HERC staff consulted with HSD staff and with the staff who administer the doula program, and the new HCPCS codes were recommended for addition to line 1 PREGNANCY. The doula community has asked for this coverage and adding this code to line 1 would align with OHA's goal of expanding access to doula care.
    d. **HERC staff recommendation**:
        i. Add HCPCS T1032-T1033 to line 1 PREGNANCY

Hydrocele Repair in Adults

Plain Language Summary:
Background: Consideration for coverage for adults for swelling or fluid collection in the scrotum. Left unrepaired, this can result in a hernia.

Should OHP cover this treatment? Staff recommends extending coverage for repair to adults who have pain or functional limitations due to the fluid collection.

Question: Should there continue to be limitations on hydrocele repair to children through age 18?

Question source: Ombuds office

Issue: A hydrocele is a type of swelling in the scrotum that occurs when fluid collects in the thin sheath surrounding a testicle. Hydrocele is common in newborns and usually disappears without treatment by age 1. Older boys and adult men can develop a hydrocele due to inflammation or injury within the scrotum. Hydroceles can be asymptomatic or cause pain. A symptomatic hydrocele can be surgically removed. Non-repaired communicating hydroceles can lead to inguinal hernia formation.

Recently, the Ombuds office had a case involving a recent immigrant who had a hydrocele causing pain that had not been repaired in childhood. The guideline note limiting hydrocele repair led to a denial of repair for him.

The current guideline was adopted in 2007, when hernias of any type were not repaired in persons over the age of 18.

HERC staff have done a data review, and found multiple claims for hydrocele repair in adults, all of which were paid. There were 111 paid claims for patients over age 18 between 1/2018 and 1/2022.

All private payers cover repair of hydroceles regardless of age.

This topic was discussed at the October 2022 VBBS meeting. At that meeting, members requested consideration of criteria for coverage in adults similar to the criteria outlined in the hernia guideline, as hydroceles can develop into inguinal hernias. There was also a request to look at the evidence that hydrocele repair in adults is effective at relieving pain or other symptoms.

Current Prioritized List status
Line 168 COMPLICATED HERNIAS; PERSISTENT HYDROCELE
Treatment: REPAIR
ICD-10-CM
N43.0 Encysted hydrocele
N43.2 Other hydrocele
N43.3 Hydrocele, unspecified
P83.5 Congenital hydrocele

Line 545 HYDROCELE
Treatment: MEDICAL THERAPY, EXCISION
ICD-10-CM

N43.3 Hydrocele, unspecified
N43.4 Spermatocele of epididymis
N50.89 Other specified disorders of the male genital organs
P83.5 Congenital hydrocele

GUIDELINE NOTE 63, HYDROCELE REPAIR

Line 168

Excision of hydrocele is only covered for children age 18 and younger with hydroceles which persist after 18 months of age.

GUIDELINE NOTE 24, COMPLICATED HERNIAS

Lines 168,524

Complicated inguinal and femoral hernias in men are included on Line 168 if the hernia

A) Causes symptoms of intestinal obstruction and/or strangulation; OR
B) Is incarcerated (defined as non-reducible by physical manipulation); OR
C) Causes pain and functional limitations as assessed and documented by a medical professional; OR
D) Affects the patient's ability to obtain or maintain gainful employment.

Repair of inguinal and femoral hernias in women and in children age 18 or younger are included on Line 168 due to the different natural history of disease in these populations.

Ventral hernias are included on Line 524. Incarcerated ventral hernias (including incarcerated abdominal incisional and umbilical hernias) are included on Line 524, because the chronic incarceration of large ventral hernias does not place the patient at risk for impending strangulation. Ventral hernias are defined as anterior abdominal wall hernias and include primary ventral hernias (epigastric, umbilical, Spigelian), paratomal hernias and most incisional hernias (ventral incisional hernias). ICD-10-CM K42.0, K43.0, K43.3, K43.6 and K46.0 are included on Line 524 when used to designate incarcerated abdominal incisional and umbilical hernias without intestinal obstruction or gangrene

Evidence

1) **Rioja 2011**, review of hydrocele in adults https://docslib.org/doc/12605449/surgery-illustrated-surgical-atlas-adult-hydrocele-and-spermatocele-bjuibju-international-jorge-rioja-francisco-m
    a. In the adult, a hydrocele is an accumulation of excessive secretion of the vaginal mucosa; exudates collect in the non-communicative vaginal cavities. In the young adult, a communicative hydrocele must be excluded, as its treatment is similar to pediatric herniorrhaphy
    b. Surgical treatment is the gold standard for adult hydrocele.
    c. Surgical treatment is indicated when functional problems are present such as pain, discomfort or disability due to the size, but not for aesthetics only
2) **Lundstrom 2019**, epidemiology of hydrocele and spermatocele; incidence, treatment and complications

a. Cystic intra-scrotal changes such as hydroceles and spermatoceles are common in general urological practice. Small studies suggests that 10% of healthy volunteers have a small or moderate amount of extra-testicular fluid and 30% have cystic structures in the epididymis.

b. In tropical regions, mainly low income countries, it is estimated that 25,000,000 men suffer from hydrocele, due to the infection of Wuchericia bancroftii

c. Treatment includes both surgery and aspiration with or without sclerotherapy

d. hydroceles in childhood are common but have a completely different pathogenesis [than in adults]

e. In Sweden, between 2004 and 2015 the overall annual incidence of hydro and spermatoceles as main or secondary complaint for in and outpatient visits at hospital-based specialties were 98.5/100,000 men (59.9 for hydroceles and 38.5 for spermatoceles) with variation between years. Overall treatment incidence was 17.3/100,000/year corresponding to treatment of [approximately] 20% of all men diagnosed with a cystic lesion in the scrotum

f. The evidence for the indications of treatment is lacking. Also, comparative treatment studies are scarce. A recent meta-analysis on the subject found only a total of 275 patients in studies comparing surgery vs sclerotherapy. Data in the current study is not sufficient to compare cure rates between treatments

g. Conclusion: The incidence of healthcare visits for fluid collections in the scrotum is near 100/100,000 and subsequent treatment rates are low, indicating that most scrotal cysts are minimally symptomatic

Hydrocele Repair in Adults

HERC staff summary

Hydroceles are common in adult men and have a different etiology than hydroceles in children. Hydroceles are common in men from lower income countries due to infection of Wuchericia bancroftii. Repair is only recommended when functional problems are present such as pain, discomfort or disability due to the size, but not for aesthetics only.

HERC staff recommendations:

1) Change the name of line 545 to UNCOMPLICATED HYDROCELE, SPERMATOCELE
2) Modify GN 63 as shown below

GUIDELINE NOTE 63, HYDROCELE REPAIR

Line 168,545

Excision of hydrocele is only included on line 168 ~~covered~~ for children age 18 and younger with hydroceles which persist after 18 months of age. Treatment of hydrocele in men over age 18 is included on line 168 only when the hydrocele causes pain and functional limitations as assessed and documented by a medical professional.

For children under 18 months of age and men over age 18 who do not meet the above criteria, treatment of hydroceles is included on line 545.

Plain Language Summary:
Background: Human growth hormone (HGH) fuels childhood growth and helps maintain tissues and organs throughout life. It's produced by the gland located at the brain's base (pituitary). Currently, OHP limits use of HGH to children who are not yet done growing. There are other important uses which should be considered for other conditions.

Should OHP cover this treatment? Staff recommends extensive changes to the current guideline to allow limited coverage of HGH for adults and allow individualized review for HGH needs for children.

Question: Should the growth hormone guideline be deleted or extensively modified?

Question source: advocates, OHA leadership, HERC staff, P&T staff

Issue: Over the past year, several concerns have arisen regarding Guideline Note 74 GROWTH HORMONE TREATMENT.

This medication has several different formulations which have indications applying to different pediatric populations, including endocrine disorders, developmental disorders and short stature. For adults they are indicated only for growth hormone deficiency, HIV wasting or cachexia and short bowel syndrome. The medication is sometimes also used off label as anti-aging therapy and for athletic performance or for bodybuilding. This latter use is illegal in the United States.

Diagnosis code ICD-10-CM E23.0 (hypopituitarism) can be used either for a serious conditions resulting in lack of growth hormone from pituitary disease or absence or a pituitary gland, in association with several developmental syndromes or in an attempt to obtain coverage for human growth hormone used for anti-aging therapy, athletic performance or body building.

Currently, GN74 restricts growth hormone (HGH) use to children "until adult height as determined by bone age is achieved." It also specifies the conditions under which E23.0 is above or below the funding line. As a result, use in adults with FDA approved HGH indications such as pituitary malformation, post-surgical pan hypopituitary dysfunction, or HIV cachexia is not covered under OHP, and some other potentially funded indications related to pediatric-onset endocrine or developmental syndromes are not covered after adult bone age is achieved.

In addition, during OHA's waiver renewal process, an issue was raised about coverage of HGH in an adolescent with closed growth plates who had Prader-Willi syndrome, a genetic multisystem disorder characterized during infancy by lethargy, hypotonia, a weak suck and feeding difficulties with poor weight gain and growth and other hormone deficiency. Treatment of Prader-Willi syndrome in children, as well as persons who have obtained adult height, is an FDA approved indication for certain formulations of HGH.

Currently, congenital pediatric short stature is expressly not covered as the ICD-10-CM code for this condition (E34.3 family) is on line 652 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY. However, this is another FDA approved indication for certain formulations of HGH.

Current Prioritized List status

GUIDELINE NOTE 74, GROWTH HORMONE TREATMENT

Lines 40,386,470,652

Treatment with growth hormone should continue only until adult height as determined by bone age is achieved. ICD-10-CM E23.0 (Hypopituitarism) is included on Lines 40 and 386 for conditions other than adult human growth hormone deficiency. ICD-10-CM E23.0 is included on Line 652 only for adult human growth hormone deficiency.

The current lines referenced in GN74 are 40 PANHYPOPITUITARISM, IATROGENIC AND OTHER PITUITARY DISORDERS, 386 PITUITARY DWARFISM, 470 GONADAL DYSFUNCTION, MENOPAUSAL MANAGEMENT and 652 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

Expert guideline (Adults)

1) **Yuen 2019,** AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY GUIDELINES FOR MANAGEMENT OF GROWTH HORMONE DEFICIENCY IN ADULTS
    a. Adult GHD is a well-defined clinical entity characterized by decreased lean body mass and increased fat mass, dyslipidemia, cardiac dysfunction, decreased fibrinolysis and premature atherosclerosis, decreased muscle strength and exercise capacity, decreased bone mineral density (BMD), increased insulin resistance, and impaired QoL
    b. It is recommended that adults with childhood onset growth hormone deficiency caused by structural pituitary or brain tumors be followed up closely during transition as these patients tend to have lower bone mineral density, impaired bone microarchitecture, and more adverse body composition abnormalities and cardiovascular risk markers than those with adult onset growth hormone deficiency (Grade A; BEL 1).
    c. In the U.S., off-label distribution or marketing of GH for the enhancement of athletic performance or to treat aging or aging-related conditions is illegal and punishable by imprisonment. Under no circumstances should rhGH be prescribed for sports or for "anti-aging" purposes (Grade A; BEL 1).

Other payer policies

1) Premara BCBS 2022
- **a.** Growth hormone* may be considered medically necessary in the treatment of adults who meet ALL criteria for the conditions listed below:
    - **i.** AIDS wasting syndrome
    - **ii.** Severe growth hormone deficiency
        - **1.** Adult growth deficiency must be confirmed by a negative response to a growth hormone stimulation test (eg, serum GH levels of <5 ng/ml on stimulation testing with either of the following: glucagon or insulin).
        OR

2. Growth hormone deficiency may be assumed without a stimulation test if patient has had the pituitary removed or destroyed or has had panhypopituitarism since birth.
   AND
3. Growth hormone therapy is prescribed by or in consultation with an endocrinologist

iii. Short bowel syndrome

b. Growth hormone is considered not medically necessary in the treatment of idiopathic short stature without growth hormone deficiency.

2) Cigna 2022

a. Growth Hormone Deficiency in an Adult or Transition Adolescent. Approve for 1 year if the individual meets the following criteria (A, B, C, and D):

A) The endocrinologist must certify that somatropin is not being prescribed for anti-aging therapy or to enhance athletic ability or for body building; AND

B) Individual must have a diagnosis of growth hormone deficiency that is one of the following (i or ii): [documentation required for all elements]

i. Childhood onset; OR

ii. Adult onset that results from one of the following: growth hormone deficiency alone or multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, pituitary surgery, cranial radiation therapy, tumor treatment, traumatic brain injury, or subarachnoid hemorrhage; AND

C) Individual meets one of the following criteria (i, ii, or iii):

i. Individual (adult or transition adolescent) has known mutations, embryopathic lesions, congenital or genetic defects, or structural hypothalamic-pituitary defects; [documentation required] OR

ii. Individual meets the following criteria (a, b, and c):

a) Individual (adult onset or transition adolescent) has three or more of the following pituitary hormone deficiencies: Adrenocorticotropic hormone, thyroid-stimulation hormone, gonadotropin deficiency (luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency), and prolactin [documentation required]; AND

b) The age and gender adjusted serum insulin-like growth factor-1 is below the lower limit of the normal reference range for the reporting laboratory [documentation required]; AND

Other causes of low serum insulin-like growth factor-1 have been excluded (e.g., malnutrition, prolonged fasting, poorly controlled diabetes mellitus, hypothyroidism, hepatic insufficiency, oral estrogen therapy); OR

Individual meets one of the following (a or b):

a) Adult. Individual has had a negative response to one of the following standard growth hormone stimulation tests (1, 2, 3, 4, 5, or 6) [documentation required for all elements]: Note: If the individual has had a previous trial of an arginine alone test with a peak response of ≤ 0.4 mcg/L, this would meet the criteria for a negative response to a growth hormone stimulation test.

(1) Insulin tolerance test (obtaining at least 3 growth hormone levels in at least a 60 minute timeframe [not including a level at timeframe zero], with adequate hypoglycemia being achieved) with peak response ≤ 5.0 mcg/L; OR
(2) Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with peak response ≤ 3.0 mcg/L AND the individual's body mass index (BMI) is < 25 kg/m2; OR
(3) Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response ≤ 3.0 mcg/L AND the individual's BMI is ≥ 25 kg/m2 and ≤ 30 kg/m2 with, according to the prescriber, a high pretest probability of growth hormone deficiency; OR
(4) Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response ≤ 1.0 mcg/L AND the individual's BMI is ≥ 25 kg/m2 and ≤ 30 kg/m2 with, according to the prescriber, a low pretest probability of growth hormone deficiency; OR
(5) Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with peak response ≤ 1.0 mcg/L AND the individual's BMI is > 30 kg/m2; OR
(6) Macrilen (macimorelin oral solution) test (obtaining at least 4 growth hormone levels in at least a 90 minute timeframe [not including a level at timeframe zero]) with peak responses < 2.8 ng/mL (2.8 mcg/L) AND the individual's BMI is ≤ 40 kg/m2. Note: The following formula can be used to calculate BMI: BMI equals body weight in kg divided by height meters squared (m2) [i.e., BMI = kg/m2]; OR

HERC staff summary:
Human growth hormone treatment is indicated in adults with childhood onset growth hormone deficiency caused by structural pituitary damage, brain tumors or clinically significant pituitary dysfunction when medically appropriate based on expert guidelines. Federal law requires the Oregon Health Plan to cover medically necessary medications for funded conditions according to FDA indications. For people under age 21, the Early and Periodic Screening, Diagnosis and Treatment Program as well as recent changes to HERC's Statement of Intent 4 requiring coverage of services which would benefit a child in terms of growth, development and ability to attend school, even if they appear in the unfunded region.

HERC staff recommends modifying the current guideline to clearly exclude use of these agents for anti-aging therapy, to enhance athletic ability or for body building, but to allow limited appropriate use in adults as well as children when prescribed according to FDA indications for funded conditions. In addition, the guideline would require consultation with an endocrinologist, as well as lab or historical evidence of lack of growth hormone.

HERC staff recommendations:
1) Remove GN74 from line 470 GONADAL DYSFUNCTION, MENOPAUSAL MANAGEMENT
2) Modify GN74 as shown below
    a. Alternative: delete guideline

GUIDELINE NOTE 74, GROWTH HORMONE TREATMENT

Lines 40,386,~~470,~~652

~~Treatment with growth hormone should continue only until adult height as determined by bone age is achieved. ICD-10-CM E23.0 (Hypopituitarism) is included on Lines 40 and 386 for conditions other than adult human growth hormone deficiency. ICD-10-CM E23.0 is included on Line 652 only for adult human growth hormone deficiency.~~

Treatment with growth hormone for ICD-10-CM E23.0 (Hypopituitarism) is included on Lines 40 and 386 for adults when

1 Prescribed by or in consultation with an endocrinologist; AND
2 Either
    i. Growth hormone deficiency is confirmed by a negative response to a growth hormone stimulation test (eg, serum GH levels of <5 ng/ml on stimulation testing with either of the following: glucagon or insulin); OR
    ii. patient has had the pituitary removed or destroyed or has had panhypopituitarism since birth; AND
3 The prescriber certifies that the growth hormone is not being prescribed for anti-aging therapy or to enhance athletic ability or body building

ICD-10-CM E23.0 is included on Line 652 only for adult human growth hormone deficiency that does not meet the above criteria.

Treatment of children and adolescents with growth hormone (for any indication) must be evaluated for medical appropriateness and medical necessity on a case-by-case basis. Therapy must be initiated by and continued in consultation with a pediatric endocrinologist.

FDA approved indications for various HGH agents

GENOTROPIN (somatropin) for injection, for subcutaneous use

Pediatric: Treatment of children with growth failure due to growth hormone deficiency, Prader-Willi syndrome, Small for Gestational Age, Turner syndrome, and Idiopathic Short Stature.

Adult: Treatment of adults with either adult onset or childhood onset GHD

HUMATROPE (somatropin) for injection, for subcutaneous use

Pediatric: Growth failure due to inadequate secretion of endogenous growth hormone; short stature associated with Turner syndrome; Idiopathic Short Stature, height standard deviation score <-2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range; short stature or growth failure in short stature homeobox-containing gene deficiency; short stature born small for gestational age with no catch-up growth by 2 years to 4 years of age.

Adult: Replacement of endogenous growth hormone in adults with growth hormone deficiency.

NORDITROPIN (somatropin) injection, for subcutaneous use

Pediatric: Treatment of pediatric patients with growth failure due to inadequate secretion of endogenous growth hormone, short stature associated with Noonan syndrome, short stature associated with Turner syndrome, short stature born small for gestational age with no catch-up growth by age 2 to 4 years, Idiopathic Short Stature, and growth failure due to Prader-Willi Syndrome.

Adult: Replacement of endogenous growth hormone in adults with growth hormone deficiency.

NUTROPIN (somatropin) injection, for subcutaneous use

Pediatric: Treatment of children with growth failure due to growth hormone deficiency, idiopathic short stature, Turner syndrome, and chronic kidney disease up to the time of renal transplantation.

Adult: Treatment of adults with either childhood-onset or adult-onset growth hormone deficiency.

OMNITROPE (somatropin) injection, for subcutaneous use

Pediatric: Treatment of children with growth failure due to growth hormone deficiency, Prader-Willi Syndrome, Small for Gestational Age, Turner syndrome, and Idiopathic Short Stature.

Adult: Treatment of adults with either adult onset or childhood onset growth hormone deficiency.

SAIZEN (somatropin) for injection, for subcutaneous use

Pediatric: Treatment of children with growth failure due to growth hormone deficiency.

Adult: Treatment of adults with either adult onset or childhood onset growth hormone deficiency.

SEROSTIM (somatropin) for injection, for subcutaneous use

Pediatric and Adult: Treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance.

SKYTROFA (lonapegsomatropin-tcgd) for injection, for subcutaneous use

Pediatric: treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone.

Adult: N/A

ZOMACTON (somatropin) for injection, for subcutaneous use

Pediatric: Treatment of pediatric patients with growth failure due to inadequate secretion of endogenous growth hormone, short stature associated with Turner syndrome, idiopathic short stature, short stature or growth failure in short stature homeobox-containing gene deficiency, and short stature born small for gestational age with no catch-up growth by 2 years to 4 years.

Adult: Replacement of endogenous growth hormone in adults with growth hormone deficiency.

ZORBTIVE (somatropin) for injection, for subcutaneous use

Pediatric: N/A

Adult: Treatment of short bowel syndrome in adult patients receiving specialized nutritional support.

Eosinophilic Esophagitis

Plain Language Summary:
Background: Should a chronic inflammatory disorder that can make swallowing difficult and be painful be treated with a medicine used to treat certain disorders of the stomach and intestines, such as heartburn and ulcers (proton pump inhibitor (PPI) therapy)?

Should OHP cover this treatment? Staff recommends covering this treatment because studies show it is effective and has lower side effects then other treatments.

Question: Should eosinophilic esophagitis be moved to a line attached to the proton pump inhibitor therapy (PPI) guideline?

Question source: P&T staff

Issue: Eosinophilic esophagitis is a chronic inflammatory disorder characterized by symptoms of esophageal dysfunction and eosinophil-predominant inflammation. The symptoms of eosinophilic esophagitis resemble those of other esophagitis conditions, such as GERD. These include stomach/chest pain, dysphagia (difficulty swallowing), vomiting, poor appetite, and globus (a feeling of food being stuck in the throat). The eosinophil accumulation may be caused by immune hypersensitivity to particular foods, as well as a variety of genetic mutations found to increase predisposition to this condition. Eosinophilic esophagitis has historically been characterized by lack of response to anti-GERD therapy such as proton pump inhibitors (PPIs). Recently, it has been appreciated that some patients with pronounced esophageal eosinophilia can have complete responses to proton pump inhibitor (PPI) therapy, but the PPI appears to exert its effects by direct action rather than blockade of stomach acid alone. Standard treatment includes diet modification so that allergenic food is removed, most commonly milk, egg, soy, wheat, nuts and fish. Steroid medications are often used to control inflammation if dietary changes alone are not sufficient. In 2022, dupilumab (Dupixant) was approved by the U.S. Food and Drug Administration (FDA) to treat adults and children 12 years and older with eosinophilic esophagitis. This is the first FDA approved treatment for eosinophilic esophagitis.

P&T recently reviewed dupilumab for eosinophilic esophagitis. This review found that "Dupilumab was studied in one trial that lasted 24 weeks, in adults and children older than age 12. Patients who took dupilumab in the trial had better improvement in tissue taken from the esophagus when viewed under a microscope. More importantly, patients tended to feel better on dupilumab because they could swallow food better." P&T's recommendations were to revise PA criteria for dupilumab to allow coverage for treatment of eosinophilic esophagitis with dupilumab in patients aged 12 years of age and older who weigh at least 40 kg. The PA criteria for PPIs was then modified to allow PPI therapy for eosinophilic esophagitis for 1 year per PA cycle. This criteria was added per the American Gastroenterology Association guidance on treatment of eosinophilic esophagitis.

HERC/HSD history
Eosinophilic esophagitis was last reviewed in January, 2016 as part of a larger review of Barrett's esophagus and esophageal dysphagia. Until that time, eosinophilic esophagitis was on the upper and lower GERD lines. At the January 2016 meeting, the HERC added eosinophilic esophagitis to what is now line 378 ESOPHAGEAL STRICTURE; ACHALASIA to pair with esophageal dilation, and removed from the upper and lower GERD lines. From the meeting materials:

During the current review of this topic, HERC staff noted that eosinophilic esophagitis was included on the upper and lower GERD lines. However, review of the treatment of this condition finds that it is treated with allergy medications and dietary changes; it is resistant to PPI therapy in most cases as it is caused by some type of underlying allergic condition. This condition mainly becomes an issue when it causes narrowing of the esophagus; esophageal dilation is the mainstay of treatment for this. The esophageal dilation CPT codes are not included on the upper, covered GERD line.

Adopted changes:

1) Add K20.0 (Eosinophilic esophagitis) to line 383 ESOPHAGEAL STRICTURE; ACHALASIA and remove from lines 385 ESOPHAGITIS; ESOPHAGEAL AND INTRAESOPHAGEAL HERNIAS and 516 ESOPHAGITIS AND GERD; ESOPHAGEAL SPASM; ASYMPTOMATIC DIAPHRAGMATIC HERNIA
    a. Main therapy is medical (allergy medications, diet therapy) and esophageal dilation. Dilation CPT codes are available on line 383 but not lines 385 or 516

Current Prioritized List status

ICD-10-CM K20.0 (Eosinophilic esophagitis) is on line 378 ESOPHAGEAL STRICTURE; ACHALASIA

Most other esophagitis diagnosis codes are on lines 380 ESOPHAGITIS; GERD and 513 ESOPHAGITIS AND GERD; ESOPHAGEAL SPASM; ASYMPTOMATIC DIAPHRAGMATIC HERNIA, with placements and treatments governed by GN144.

DIAGNOSTIC GUIDELINE D12, UPPER ENDOSCOPY FOR GERD OR DYSPEPSIA SYMPTOMS
Upper endoscopy for uninvestigated dyspepsia or GERD symptoms is covered for:

Patients less than 50 years of age with persistent symptoms following advice on lifestyle modifications and completion of an appropriate course of twice daily PPI therapy or an H. pylori test and treat protocol.
Patients 50 years of age and older
Patients with “alarm symptoms” including, but not limited to, iron deficiency anemia or weight loss

Upper endoscopy is not covered for patients with previous upper endoscopy with non-malignant findings (other than Barrett’s esophagus) in the absence of significant new symptoms.

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 144, PROTON PUMP INHIBITOR THERAPY FOR GASTROESOPHAGEAL REFLUX DISEASE (GERD)

Lines 314,380,513

Short term treatment (up to 8 weeks) of GERD without Barrett's (ICD-10-CM K20.8, K20.9, K21.0, K21.9) with proton pump inhibitor therapy is included on Line 380. Long term treatment is included on Line 513.

Long term proton pump inhibitor therapy is included on Line 380 for Barrett's esophagus (ICD-10-CM K22.70) and on Line 314 for Barrett's esophagus with dysplasia (ICD-10-CM K22.71).

Evidence

1) **Lucendo 2016**, systematic review and meta-analysis of PPIs for treatment of eosinophilic esophagitis
    - **a.** N=33 studies (11 prospective cohort) with N=619 patients
        - **i.** N=13 retrospective cohort studies
        - **ii.** N=11 prospective cohort studies
        - **iii.** N=9 case series (1 to 66 patients)
    - **b.** An overall favorable clinical response after PPI treatment given at any dose was reported for 60.8% (95% CI, 48.38%–72.2%; I 2 ¼ 80.2%) of patients, with a similar benefit for children and adults (64.9% vs 56.2%). The overall effectiveness for inducing histologic remission of EoE (defined as the reduction of peak eosinophil counts to < 15 eosinophils/hpf) for any PPI administered at any dosage was 50.5% (95% CI, 42.2%–58.7%; I 2 ¼ 67.5%)
    - **c.** In conclusion, the present study proves that PPI therapy is an effective treatment that induces histologic and clinical remission in half of patients with symptomatic esophageal eosinophilia suggestive of EoE. Our results support the concept of PPIs as the first-line therapy in both children and adults for this subset of patients. Other effective alternatives, such as dietary or topical steroid therapy, likely might be set aside as second-line treatment, owing to long-term safety concerns (topical steroid therapy) and impairment of quality of life and nutritional inadequacy (dietary interventions).

Expert guidelines

1) **American Gastroenterological Association Guideline/Allergy Immunology Practice Parameters 2020**, clinical guidelines for the management of eosinophilic esophagitis (EoE)
    a. In patients with symptomatic esophageal eosinophilia, the AGA/JTF suggests using proton pump inhibition over no treatment. (Conditional recommendation, very low-quality evidence)
        i. Twenty-three observational studies that evaluated the histologic response to proton pump inhibitors (PPIs) reported an overall, unweighted histologic response rate of 42%. PPIs failed to induce histologic remission in approximately two-thirds of treated patients, compared with >85% of patients treated with placebo (RR, 0.66; 95% confidence interval [CI], 0.61e0.72).
        ii. It should be emphasized that direct comparison of the efficacy of PPI and other medical or dietary EoE therapies is limited because, up to this time, most trials in EoE have excluded patients with esophageal eosinophilia that responded to a PPI (formerly denoted as PPI-responsive esophageal eosinophilia).
    b. In patients with EoE, the AGA/JTF recommends topical glucocorticosteroids over no treatment. (Strong recommendation, moderate quality evidence)
    c. In patients with EoE, the AGA/JTF recommends topical glucocorticosteroids over no treatment. (Strong recommendation, moderate quality evidence)

Eosinophilic Esophagitis

HERC staff summary

Long term PPI therapy is effective in treatment approximately half of patients with eosinophilic esophagitis (EoE), based on observational studies. Long term therapy with PPIs is recommended by expert groups as a first line therapy for treating EoE. Other therapies for EoE include dietary restriction, which can impact quality of life and nutrition, and topical steroid therapy, which has a greater risk of side effects compared to PPI therapy. A newer therapy, dupilumab, was recently FDA approved for treatment of EoE. Of note, EoE patients need esophageal dilatation and upper endoscopy at higher frequency that patients with GERD; however, the esophageal stricture line has diagnosis codes for esophageal stricture which allows dilation if present.

HERC staff recommendations:

1) Add ICD-10-CM K20.0 (Eosinophilic esophagitis) to line 380 ESOPHAGITIS; GERD
    a. Remove K20.0 from line 378 ESOPHAGEAL STRICTURE; ACHALASIA
2) Modify GN144 as shown below
    a. Add eosinophilic esophagitis as a diagnosis eligible for long term PPI therapy
    b. Clarify the wording around coverage of GERD without Barrett's

GUIDELINE NOTE 144, PROTON PUMP INHIBITOR THERAPY FOR GASTROESOPHAGEAL REFLUX DISEASE (GERD)

Lines 314,380,513

Short term treatment (up to 8 weeks) of GERD without Barrett's (ICD-10-CM K20.8, K20.9, K21.0, K21.9) with proton pump inhibitor therapy is included on Line 380. Long term treatment of GERD without Barrett's with proton pump inhibitor therapy is included on Line 513.

Long term proton pump inhibitor therapy is included on Line 380 for Barrett's esophagus (ICD-10-CM K22.70) and eosinophilic esophagitis (ICD-10-CM K20.0) and on Line 314 for Barrett's esophagus with dysplasia (ICD-10-CM K22.71).

Botulinum Toxin for Strabismus

Plain Language Summary:
Background: Should Botox be used in eye conditions that cause the eye to turn either inward or outward?

Should OHP cover this treatment? Staff recommends not cover this treatment because there is insufficient evidence that it works.

Question: Should the guideline regarding botulinum toxin injection be clarified regarding the intent for coverage for strabismus, esotropia and related conditions?

Question source: Medical Management Committee case review

Issue: Strabismus is a deviation of the ocular alignment where one eye turns, which may be intermittent or constant. Strabismus can be further divided into esotropia (in-turning deviation), exotropia (out-turning deviation) or, less commonly, hypertropia (upturning deviation), hypotropia (downturning deviation) and cyclotropia (rotatory deviation). Strabismus can be caused by a variety of insults such as abnormal anatomical development of extraocular muscles or the orbit, impaired neurological input to extraocular muscles, uncorrected refractive error or hereditary factors. Sequelae to strabismus can include blurring of vision, diplopia (double vision), impaired depth (3-D) perception, and in younger children, amblyopia. Amblyopia is impaired vision in the deviating eye due to the lack of correct stimulation of that eye and results in permanent loss of vision if left untreated at a young age.

There are various treatments available for strabismus. Conservative options include prisms to realign the visual axes and orthoptic exercises to promote and establish binocular control of ocular alignment where both eyes can subsequently work as a pair. Invasive treatment options include surgery and botulinum toxin to individual extraocular muscles.

HSC/HERC history: botulinum toxin injection (67345)
2012 Ophthalmology review: did not look specifically at Botox
August 2014 botulinum toxin review: "In the treatment of strabismus, there is very low quality evidence, based on a systematic review with limited data that BoNT may be as effective as surgery for retreatment of acquired or infantile esotropia, but does not appear effective for acute 6th nerve palsy or adult horizontal strabismus." As a result of that review, CPT 67345 (Chemodenervation of extraocular muscle) was removed from line 397/372 AMBLYOPIA, as botulinum toxin is not FDA approved for amblyopia. A new coding specification was added to the two strabismus lines, which later was incorporated into the botulinum toxin guideline: "Chemodenervation with botulinum toxin injection (CPT 67345) is included on this line for the treatment of strabismus due to other neurological disorders (ICD-9 378.73 /ICD-10 H50.89)."
May 2018 P&T review: included only the 2017 Cochrane review of botulinum toxin for strabismus

Current Prioritized List status
CPT 67345 (351,393) is on lines 351 STRABISMUS DUE TO NEUROLOGIC DISORDER and 393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN

- ICD-10-CM H49.8 family (paralytic strabismus) and various ophthalmologic nerve palsies are on line 351
- ICD-10-CM H50.0 family (esotroptia) is on line 393
- ICD-10-CM H50.1 family (exotropia) is on line 393
- ICD-10-CM H50.3 family (esotroptia) is on line 393
- ICD-10-CM H50.60 (Mechanical strabismus, unspecified) and H50.69 (Other mechanical strabismus) are on line 393
- ICD-10-CM H50.89 (Other specified strabismus) is on line 393. Sub-diagnoses include strabismus in neuromuscular disorder

GUIDELINE NOTE 219, CHEMODENERVATION

Lines 292,327,351,362,378,393,410,500,517,526

Inclusion of chemodenervation on the Prioritized List has the following limitations for the lines specified below:

Line 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS

Chemodenervation with botulinum toxin injection (CPT 64642-64647) is included on this line for treatment of upper and lower limb spasticity (ICD-10-CM codes G24.02, G24.1, G35, G36.0, I69.03- I69.06 and categories G71, and G80-G83)

Line 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION

Chemodenervation of the bladder (CPT 52287) is included on this line only for treatment of idiopathic detrusor over-activity or neurogenic detrusor over-activity (ICD-10-CM N32.81) in patients who have not responded to or been unable to tolerate at least two urinary incontinence antimuscarinic therapies (e.g. fesoterodine, oxybutynin, solifenacin, darifenacin, tolterodine, trospium). Treatment is limited to 90 days, with additional treatment only if the patient shows documented positive response. Positive response to therapy is defined as a reduction of urinary frequency of 8 episodes per day or urinary incontinence of 2 episodes per day compared to baseline frequency.

Line 351 STRABISMUS DUE TO NEUROLOGIC DISORDER

Chemodenervation with botulinum toxin injection (CPT 67345) is included on this line for the treatment of strabismus due to other neurological disorders (ICD-10-CM H50.89).

Line 362 DYSTONIA (UNCONTROLLABLE); LARYNGEAL SPASM

Chemodenervation with botulinum toxin injection (CPT 64612, 64616) is included on this line only for treatment of blepharospasm (ICD-10-CM G24.5), spasmodic torticollis (ICD-10-CM G24.3), and other fragments of torsion dystonia (ICD-10-CM G24.9).

Line 378 ESOPHAGEAL STRICTURE; ACHALASIA

Chemodenervation with botulinum toxin injection (CPT 43201) is included on this line for treatment of achalasia (ICD-10 K22.0).

Line 393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN

Chemodenervation with botulinum toxin injection (CPT 67345) is included on this line for the treatment of strabismus due to other neurological disorders (ICD-10-CM H50.89).

Line 410 MIGRAINE HEADACHES

Chemodenervation for treatment of chronic migraine (CPT 64615) is included on this line for prophylactic treatment of adults who meet all of the following criteria:

A) have chronic migraine defined as headaches on at least 15 days per month of which at least 8 days are with migraine

B) has not responded to or have contraindications to at least three prior pharmacological prophylaxis therapies (e.g. beta-blocker, anticonvulsant or tricyclic antidepressant)

C) their condition has been appropriately managed for medication overuse

D) treatment is administered in consultation with a neurologist or headache specialist.

Treatment is limited to two injections given 3 months apart. Additional treatment requires documented positive response to therapy. Positive response to therapy is defined as a reduction of at least 7 headache days per month compared to baseline headache frequency.

Line 500 SIALOLITHIASIS, MUCOCELE, DISTURBANCE OF SALIVARY SECRETION, OTHER AND UNSPECIFIED DISEASES OF SALIVARY GLANDS

Chemodenervation with botulinum toxin injection (CPT 64611) is included on this line for the treatment of excessive salivation.

Line 517 DISORDERS OF SWEAT GLANDS

Chemodenervation with botulinum toxin injection (CPT 64650, 64653) is included on this line for the treatment of axillary hyperhidrosis and palmar hyperhidrosis (ICD-10-CM L74.52, R61).

Line 526 CHRONIC ANAL FISSURE

Chemodenervation with botulinum toxin injection (CPT 46505) is included on this line for the treatment of anal fissures.

Evidence

1) **Rowe 2017,** Cochrane review of botulinum toxin for the treatment of strabismus
    a. N=6 RCTs
    b. 2 trials (102 people) compared botulinum toxin with surgery in people with acquired or infantile esotropia.
        i. low-certainty evidence that children who received botulinum toxin may have a similar or slightly reduced chance of achieving ocular alignment (pooled risk ratio (RR) 0.91, 95% confidence interval (CI) 0.71 to 1.16), binocular single vision (RR 0.88, 95% CI 0.63 to 1.23), sensory fusion (RR 0.88, 95% CI 0.63 to 1.23) and stereopsis (RR 0.86, 95% CI 0.59 to 1.25) compared with children who received surgery.
    c. 1 trial of 30 adults comparing botulinum toxin with surgery in patients with horizontal strabismus found a reduced change of ocular alignment with botulinum toxin (RR 0.38, 95% CI 0.17 to 0.85; low-certainty evidence).
    d. 1 trial of people with acute onset sixth nerve palsy found that people treated with botulinum toxin may have a similar or slightly improved chance of ocular alignment in people compared with observation (RR 1.19, 95% CI 0.96 to 1.48; 47 participants, low-certainty evidence).
    e. 1 trial of adjuvant botulinum toxin in strabismus surgery found that it may increase the chances of ocular alignment compared with strabismus surgery alone (RR 1.83, 95% CI 0.41 to 8.11; 23 participants, very low-certainty evidence).
    f. Reported complications in people given botulinum toxin in the included trials included ptosis (range 9% to 41.66%) and vertical deviation (range 8.3% to 18.51%).
    g. Authors' conclusions: Most published literature on the use of botulinum toxin in the treatment of strabismus consists of retrospective studies, cohort studies or case reviews. Although these provide useful descriptive information, clarification is required as to the effective use of botulinum toxin as an independent treatment modality. Six RCTs on the therapeutic use of botulinum toxin in strabismus, graded as low and very low certainty evidence, have shown varying responses. These include a lack of evidence for effect of botulinum toxin on reducing visual symptoms in acute sixth nerve palsy, poor response in people with horizontal strabismus without binocular vision, similar or slightly reduced achievement of successful ocular alignment in children with esotropia and potential increased achievement of successful ocular alignment where surgery and botulinum toxin are combined. Further high quality trials using robust methodologies are required to botulinum toxin to alternative surgical interventions in strabismus cases with and without potential for binocular vision.

Expert guidelines

1) **American Academy of Ophthalmology 2017**, preferred practice pattern for esotropia and exotropia
    a. Treatment for esotropia includes the following:
        i. Correction of refractive errors
        ii. Bifocal eyeglasses
        iii. Prism therapy
        iv. Amblyopia treatment
        v. Extraocular muscle surgery
            1. Botulinum toxin injection

a. Favorable prognostic indicators include good vision in each eye, absence of restricted eye movement, a small to moderate angle of esotropia, and the potential for binocular vision. Such treatment may be an alternative to conventional extraocular muscle surgery in selected patients, but its value in managing infantile esotropia has not been definitively established.

2. Other pharmacologic agents

b. Treatment for exotropia includes
   i. Correction of refractive errors
   ii. Stimulating accommodative convergence (overcorrection of myopia or undercorrection of hyperopia)
   iii. Patching (antisuppression) therapy
   iv. Amblyopia treatment
   v. Prism therapy
   vi. Convergence exercises for convergence insufficiency exotropia
   vii. Extraocular muscle surgery
   viii. Botulinum toxin injection
      1. There is insufficient evidence to make treatment recommendations for botulinum toxin treatment for exotropia

Other payer policies

1) Aetna 2022

a. OnabotulinumtoxinA (Botox Brand of Botulinum Toxin Type A): Aetna considers onabotulinumtoxinA (Botox) medically necessary for any of the following conditions:
   i. A. Strabismus (including gaze palsies accompanying diseases, such as neuromyelitis optica and Schilder's disease), for deviations less than 50 prism diopters.
   ii. Note: Strabismus repair is considered cosmetic in adults with uncorrected congenital strabismus and no binocular fusion.

2) Cigna 2021

a. Botox is indicated for the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and older

Botulinum Toxin for Strabismus

HERC staff summary

There is limited evidence for the treatment of strabismus with botulinum toxin. The American Academy of Ophthalmology has not found evidence for the use of botulinum toxin for treatment of exotropia and states that the value of botulinum toxin for the management of esotropia is not well established.

The current botulinum toxin guideline is consistent with the evidence and private payer policies; however, several housekeeping items need to be addressed.

HERC staff summary

1) Delete ICD-10-CM H50.89 (Other specified strabismus) from line 393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN
2) Add ICD-10-CM H50.89 (Other specified strabismus) to line 351 STRABISMUS DUE TO NEUROLOGIC DISORDER
    a. Sub-diagnoses include strabismus in neuromuscular disorder
3) Delete CPT 67345 Chemodenervation of extraocular muscle (currently on lines 351 and 393) from line 393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN
4) Modify GN 219 as shown below
    a. Does not contain the specified ICD-10-CM code

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Line 526 CHRONIC ANAL FISSURE

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Acupuncture 2022 Review

Plain Language Summary:
Background: A procedure that inserts thin needles into the skin. Should OHP add more coverage for acupuncture for:

- -Language problems following a stroke (post-stroke aphasia)
- -Chronic pain in the muscles and trigger points (tender lumps under the skin), most commonly in the upper back, shoulder and neck (myofascial pain)
- -A condition caused by the lack of blood that carries oxygen and nutrients to a part of the brain. It causes problems with reasoning, planning, judgment and memory (vascular dementia)
- - A disorder that affects muscle and soft tissue characterized by chronic muscle pain, tenderness, fatigue and sleep disturbances (fibromyalgia)
- -How soon a person can breastfeed their child after childbirth (rates of lactation within 24 hours after delivery)
- -Hay fever (allergic rhinitis)
- -A chronic, painful bladder condition where increased urinary urgency and frequency is seen (interstitial cystitis)

Should OHP cover this treatment? Staff recommends discussing treatment for fibromyalgia (line 531) because studies show a small, short term benefit. Other conditions did not have sufficient evidence that acupuncture is helpful.

Questions:

1) Should additional conditions be paired with acupuncture on the Prioritized List?
2) Should the diagnosis code for post-stroke depression be clarified in the acupuncture guideline?

Question sources:

1) Laura Ocker, LAc; Ali Jones
2) Holly Jo Hodges, CCO medical director

Issue: A new review of systematic reviews (Lu et al, 2022) found high or moderate certainty evidence that acupuncture is effective for treatment of post-stroke aphasia, myofascial pain, vascular dementia, fibromyalgia, rates of lactation within 24 hours after delivery, and allergic rhinitis.

Additionally, Ali Jones (member of the public) submitted a request to review acupuncture as a possible treatment for interstitial cystitis through the coverage guidance nomination process.

Acupuncture is currently paired with a variety of indications, governed by Guideline Note 92 ACUPUNCTURE.

Dr. Hodges is requesting that the diagnosis code for post stroke depression be clarified. Per the MODA behavioral health director, the best codes for use with this diagnosis are ICD-10-CM F06.31 (Mood disorder due to known physiological condition with depressive features) and F06.32 (Mood disorder due to known physiological condition with major depressive-like episode).

Current Prioritized List guideline

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,4,5,64,65,92,111,112,114,125,129,133,135,157,158,191,199-201,208,210,214,215,229,234, 237,238,258,259,262,271,276,286,287,294,314-316,329,342,361,396,397,402,410,419,435,464,541, 559

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

Line 1 PREGNANCY

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

Hyperemesis gravidarum

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

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

Breech presentation

ICD-10-CM: O32.1

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

Back and pelvic pain of pregnancy

ICD-10-CM: O99.89

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

Line 4 SUBSTANCE USE DISORDER, Line 62 SUBSTANCE-INDUCED MOOD, ANXIETY, DELUSIONAL AND OBSESSIVE-COMPULSIVE DISORDERS, Line 65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL

Acupuncture is included on these lines only when used as part of a program that offers patients a variety of evidence-based interventions including behavioral interventions, social support, and Medication Assisted Treatment (MAT), as appropriate.

Line 5 TOBACCO DEPENDENCE

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

Lines 92, 111, 112, 114, 125, 129, 133, 135, 157, 158, 191, 199, 200, 208, 210, 214, 215, 229, 234, 237, 238, 258, 259, 261, 262, 271, 276, 286, 287, 294, 314, 315, 316, 329, 342, 372, 396, 397, 419, 435 and 559

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

Line 201 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS

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

Line 361 SCOLIOSIS

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

Line 402 CONDITIONS OF THE BACK AND SPINE

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

Line 410 MIGRAINE HEADACHES

Acupuncture pairs on Line 410 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), for up to 12 sessions per year.

Line 464 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 464 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions per year.

*Line 541 TENSION HEADACHES

Acupuncture is included on Line 541 for treatment of tension headaches (ICD-10-CM G44.2), for up to 12 sessions per year.

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

*Below the current funding line.

Evidence

Post stroke aphasia

1) **Lu 2022**
    a. Zhang 2019 was the only systematic review of meta-analysis included in the analysis of post-stoke aphasia
        i. Included 8 RCTs, 243 patients in acupuncture group and 238 in control group
        ii. Acupuncture plus rehabilitation therapy vs rehabilitation therapy alone
        iii. Standard mean difference 1.01 (0.81, 1.2)
            1. There is no information presented on what scale or what outcome this measures
        iv. Moderate certainty of evidence of effectiveness
        v. No details given on length of follow up, quality of included studies or other specifics
2) **Zhang 2019** Acupuncture is effective in improving functional communication in post-stroke aphasia : A systematic review and meta-analysis of randomized controlled trials
    a. Not available in Medline
3) **Huang 2020** An overview of systematic reviews and meta-analyses on acupuncture for post-stroke aphasia
    a. Not available in Medline
4) **Deng 2022**: published protocol for a multi-center RCT to examine efficacy of acupuncture for post-stroke motor aphasia
    a. Acupuncture + language training vs sham acupuncture + language training
5) **Li 2021**: protocol for randomized, blinded, controlled multicenter trial to examine acupuncture for post-stroke aphasia

Myofascial pain/fibromyalgia

1) **Lu 2022**
    a. Yuan 2016 only systematic review included in analysis of myofascial pain
        i. Included 13 RCTs, 222 patients in acupuncture group and 192 in control group
        ii. Acupuncture vs sham acupuncture
        iii. Standard mean difference -1 (-1.43, -0.57)
            1. No information given on what this scale represents
        iv. Moderate certainty of evidence of effectiveness, large therapeutic effect
        v. Follow up less than 1 week after acupuncture
        vi. No details given on quality of included studies or other specifics
    b. Kim Jiwon 2019 only systematic review included in analysis of fibromyalgia
        i. 11 RCTs, 242 patients in the acupuncture group, 317 in the control group
        ii. Acupuncture vs western medicine
        iii. Standard mean difference -0.49 (-0.79, -0.2)
            1. No information given on what this scale represents
        iv. Moderate certainty of evidence of effectiveness, moderate therapeutic effect
2) **Zhang 2019,** Systematic review and meta-analysis of acupuncture for fibromyalgia
    a. N=12 RCTs
        i. Acupuncture vs sham acupuncture
        ii. N=12 to 164 patients
    b. Meta-analysis showed that acupuncture was significantly better than sham acupuncture for relieving pain (VAS 0-10 cm scale) (MD =-1.04, 95% CI [-1.70, –0.38], P=0.002, I2

=78%) and improving the quality of life (FIQ 0-80 point scale) (MD =-13.39, 95% CI [-21.69, –5.10], P=0.002, I 2 =82%), with low- to moderate-quality evidence in the short term. At follow-up in the long term, the effect of acupuncture was also superior to that of sham acupuncture. No serious adverse events were found during acupuncture.

   i. Note: minimal clinically important difference on the VAS scale is 1.37 cm
   ii. Note: minimal clinically important difference on the FIQ scale is 14

c. Two studies reported on pain intensity. Pool results indicated that there were no statistically significant differences in pain reduction between real MA and sham MA (MD =-1.23, 95% CI [–4.74, 2.27], P=0.49, I 2 =0%) with low quality of evidence
d. Four studies evaluated quality of life by using the FIQ score. The pooled results indicated that real acupuncture was significantly better than sham acupuncture in improving quality of life after treatment (MD =-13.39, 95% CI [-21.69, –5.10], P=0.002, I 2 =82%; Figure 3C). The quality of evidence was evaluated as low (downgraded because of inconsistency and imprecision)
e. Conclusion: Acupuncture therapy is an effective and safe treatment for patients with FM, and this treatment can be recommended for the management of FM.

3) **Deare 2013**, Cochrane review of acupuncture for fibromyalgia
https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD007070.pub2/epdf/full

a. N=9 trials (395 participants)
b. Low quality evidence from one study (13 participants) showed electro-acupuncture (EA) improved symptoms with no adverse events at one month following treatment. Mean pain in the non-treatment control group was 70 points on a 100 point scale; EA reduced pain by a mean of 22 points (95% confidence interval (CI) 4 to 41), or 22% absolute improvement. Control group global well-being was 66.5 points on a 100 point scale; EA improved well-being by a mean of 15 points (95% CI 5 to 26 points). Control group stiffness was 4.8 points on a 0 to 10 point; EA reduced stiffness by a mean of 0.9 points (95% CI 0.1 to 2 points; absolute reduction 9%, 95% CI 4% to 16%). Fatigue was 4.5 points (10 point scale) without treatment; EA reduced fatigue by a mean of 1 point (95% CI 0.22 to 2 points), absolute reduction 11% (2% to 20%). There was no difference in sleep quality (MD 0.4 points, 95% CI -1 to 0.21 points, 10 point scale), and physical function was not reported.
c. Moderate quality evidence from six studies (286 participants) indicated that acupuncture (EA or MA) was no better than sham acupuncture, except for less stiffness at one month. Subgroup analysis of two studies (104 participants) indicated benefits of EA. Mean pain was 70 points on 0 to 100 point scale with sham treatment; EA reduced pain by 13% (5% to 22%); (SMD -0.63, 95% CI -1.02 to -0.23). Global well-being was 5.2 points on a 10 point scale with sham treatment; EA improved well-being: SMD 0.65, 95% CI 0.26 to 1.05; absolute improvement 11% (4% to 17%). EA improved sleep, from 3 points on a 0 to 10 point scale in the sham group: SMD 0.40 (95% CI 0.01 to 0.79); absolute improvement 8% (0.2% to 16%). Low-quality evidence from one study suggested that MA group resulted in poorer physical function: mean function in the sham group was 28 points (100 point scale); treatment worsened function by a mean of 6 points (95% CI -10.9 to -0.7). Low-quality evidence from three trials (289 participants) suggested no difference in adverse events between real (9%) and sham acupuncture (35%); RR 0.44 (95% CI 0.12 to 1.63).
d. Moderate quality evidence from one study (58 participants) found that compared with standard therapy alone (antidepressants and exercise), adjunct acupuncture therapy reduced pain at one month after treatment: mean pain was 8 points on a 0 to 10 point

scale in the standard therapy group; treatment reduced pain by 3 points (95% CI -3.9 to -2.1), an absolute reduction of 30% (21% to 39%).

e. Four studies reported no differences between acupuncture and control or other treatments described at six to seven months follow-up

f. Authors' conclusions There is low to moderate-level evidence that compared with no treatment and standard therapy, acupuncture improves pain and stiffness in people with fibromyalgia. There is moderate-level evidence that the effect of acupuncture does not differ from sham acupuncture in reducing pain or fatigue, or improving sleep or global well-being

Chronic pain

1) **NICE 2021** Evidence review of acupuncture for chronic pain
    a. Overall
        i. N=32 studies
            1. the majority of evidence was based on women with chronic neck pain or fibromyalgia
        ii. The majority of the evidence identified was of low to very low quality, with only a small amount of moderate quality evidence. The evidence was mainly downgraded due to risk of bias and imprecision. Risk of bias was often high due to attrition and selection bias. In the usual care comparisons there was a lack of blinding in the studies due to the nature of the intervention; this combined with the mostly subjective outcomes resulted in a high risk of performance bias.
        iii. Evidence of acupuncture versus sham acupuncture was based on 19 studies and showed a benefit of treatment in terms of pain and quality of life in the short term
        iv. Evidence of acupuncture versus usual care was based on 9 studies and showed a benefit of acupuncture (mainly for pain and quality of life), which was consistent to the sham comparison. There was evidence for all critical and important outcomes and the evidence quality was downgraded mainly due to risk of bias and imprecision, ranging from very low to moderate.
    b. Acupuncture vs sham acupuncture
        i. Pain reduction
            1. Very low quality evidence from 13 studies with 1230 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months. Low quality evidence from 2 studies with 159 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months.
            2. Low quality evidence from 4 studies with 376 participants showed no clinically important difference between acupuncture and sham acupuncture at >3 months. Moderate quality evidence from 2 studies with 159 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at >3 months. Low quality evidence from 1 study with 61 participants showed no clinically important difference between acupuncture and sham acupuncture at >3 months
        ii. Quality of life

1. Low to moderate quality evidence from 2 studies with 210 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months. Moderate quality evidence from 1 study with 158 participants showed sham acupuncture to have a clinically important improvement compared to acupuncture at ≤3 months. Very low quality evidence from 3 studies with 244 participants showed no clinically important difference between acupuncture and sham acupuncture at ≤3 months. Very low quality evidence from 2 studies with 168 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months. Very low to low quality evidence from 1 study with 178 participants showed a clinically important benefit, clinically important harm and no clinically important difference of acupuncture compared to sham acupuncture at ≤3 months (various quality of life subscales). Moderate quality evidence from 2 studies with 159 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months. Low quality evidence from 1 study with 72 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months. Very low quality evidence from 1 study with 76 participants showed a clinically important benefit of sham acupuncture compared to verum acupuncture at >3 months. Low quality evidence from 1 study with 96 participants showed no clinically important difference between acupuncture and sham acupuncture at >3 months. Low quality evidence from 1 study with 153 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at >3 months. Moderate quality evidence from 1 study with 159 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at >3 months

iii. Physical function
    1. Very low quality evidence from 1 study with 118 participants showed no clinically important difference between acupuncture and sham acupuncture at ≤3 months. Very low quality evidence from 1 study with 106 participants showed no clinically important difference between acupuncture and sham acupuncture at >3 months.

c. Acupuncture vs usual care
    i. Pain reduction
        1. Low quality evidence from 5 studies with 234 participants showed a clinically important benefit of acupuncture compared to usual care at ≤3 months. Low quality evidence from 2 studies with 384 participants showed no clinically important difference between acupuncture and usual care at ≤3 months. Moderate quality evidence from 1 study with 3162 participants showed a clinically important benefit of acupuncture compared to usual care at ≤3 months. Moderate quality evidence from 1 study with 344 participants showed no clinically important difference between acupuncture and usual care at >3 months.
    ii. Quality of life
        1. Moderate quality evidence from 1 study with 3213 participants showed a clinically important benefit of acupuncture compared to usual care at

≤3 months. Very low quality evidence from 1 study with 100 participants showed both a clinically important benefit and no clinically important difference between acupuncture and usual care at ≤3 months (various quality of life subscales). Low quality evidence from 1 study with 204 participants showed a clinically important benefit of acupuncture compared to usual care at >3 months.

iii. Physical function
    1. Very low quality evidence from 1 study with 45 participants showed no clinically important difference between acupuncture and usual care at ≤3 months. Very low quality evidence from 1 study with 100 participants showed a clinically important benefit of acupuncture compared to usual care at ≤3 months.

Vascular dementia

1) Lu 2022

a. Tong Li 2019 only systematic review included in analysis of vascular dementia
    i. Included 6 RCTs, 265 patients in acupuncture group and 265 in control group
    ii. Acupuncture vs western medicine
    iii. Standard mean difference 0.5 (0.29, 0.76)
    iv. Given moderate certainty of evidence of effectiveness, moderate therapeutic effect
    v. No details given on length of follow up, quality of included studies or other specifics

2) **Ma 2021**, review of systematic reviews of acupuncture for dementia

a. N=13 systematic reviews with meta-analyses
    i. 137 RCTs, 9012 patients
    ii. All conducted in China

b. The results suggested that acupuncture has beneficial effects on effectiveness, cognitive ability, and activities of daily living in the treatment of dementia for 4–24 weeks, although there was a high degree of heterogeneity. The quality of reports was rated “high” in one SR, “moderate” in five SRs, and “low” in seven SRs. The methodological quality of only one SR was “low,” and the rest were rated "very low." The quality of evidence was rated “high” in one SR, including the effectiveness rate, MMSE, ADAS-cog, HDS, MoCA and FAQ.

c. 9 SRs assessed the efficacy of acupuncture on the treatment of dementia (5094 patients, 79 RCTs). The pooled effects reported in these reviews were quite inconsistent. Two SRs had a high degree of heterogeneity, even after subgroup analysis. Four SRs showed no significant difference in acupuncture compared with western medicine.

d. Nine SRs assessed the cognitive performance of acupuncture in the treatment of dementia, with a total of 5210 patients and 75 RCTs enrolled. The pooled effects were not statistically significant in the subgroup analysis of four SRs. Three SRs showed moderate heterogeneity and two SRs showed high heterogeneity. Two SRs showed no statistical significance in acupuncture compared with western medicine.

e. Nine SRs assessed the quality of life of acupuncture in the treatment of dementia, with a total of 2302 patients and 34 RCTs enrolled. The pooled effects were not statistically significant in the subgroup analysis of four SRs. One SR showed moderate heterogeneity

and three SRs showed high heterogeneity. Three SRs showed no statistical significance in acupuncture compared with western medicine

f. Conclusion: Acupuncture showed potential therapeutic effects for patients with dementia, but the quality of the evidence was not high. Higher-quality RCTs are warranted to confirm the clinical effects of acupuncture in the treatment of dementia

3) **Su 2021** Systematic review and meta-analysis of acupuncture for vascular dementia
   a. N=48 RCTs (3,778 patients)
      i. Control groups included western medicine, usual care
   b. The pooled data demonstrated that acupuncture was more beneficial for a global cognitive function (measured by MMSE, HDS, MoCA, and ADAS-cog) [mean difference (MD) 1.86, 95% CI 1.19–2.54, $p < 0.01$] and activities of daily living (measured by ADL Scale and BI) (MD −3.08, 95% CI −4.81 to −1.35, $p < 0.01$) compared with western medicine (WM). The favorable results were also observed when acupuncture was combined with WM (MD 2.37, 95% CI 1.6–3.14, $p < 0.01$) or usual care (UC, MD 4.4, 95% CI 1.61–7.19, $p = 0.002$) in comparison with the corresponding control conditions. Meanwhile, the subgroup analysis did not indicate a statistical effect difference between manual acupuncture (MA) and electroacupuncture (EA) (inter-group I 2 < 50% and $p > 0.1$) when comparing acupuncture with WM. There were no significant differences in the occurrence of adverse events (AEs) between the acupuncture group and the control group ($p > 0.05$). Owing to the poor methodological quality and considerable heterogeneity among studies, the certainty of the evidence was low or very low.
   c. Conclusions: This review suggests that acupuncture as a monotherapy or an adjuvant therapy may play a positive role in improving the cognition and daily performance of VCI patients associated with few side effects

Breast feeding

1) Lu 2022
   a. Ying Tang 2017 only systematic review included in analysis of breastfeeding
      i. Included 5 RCTs, 279 patients in acupuncture group and 278 in control group
      ii. Acupuncture vs sham acupuncture
      iii. Relative risk 2.24 (1.58, 3.17)
      iv. Given moderate certainty of evidence of effectiveness, high therapeutic effect
      v. No details given on length of follow up, quality of included studies or other specifics
      vi. Original study not found in Medline search

2) **Bao 2022**, protocol published for systematic review and meta-analysis of acupuncture on breast feeding
3) No studies found in Medline when searching for acupuncture and lactation, breastfeeding

Allergic rhinitis

1) Lu 2022
   a. Jinzhang 2017 only systematic review included in analysis of breastfeeding
      i. Included 4 RCTs, 198 patients in acupuncture group and 194 in control group
      ii. Acupuncture vs sham acupuncture
      iii. Standard mean difference -0.47 (-0.67, -0.27)

   iv. Given moderate certainty of evidence of effectiveness, moderate therapeutic effect
   v. No details given on length of follow up, quality of included studies or other specifics

2) **He 2022**, systematic review and meta-analysis of acupuncture for allergic rhinitis
   a. N=30 trials (4413 patients)
      i. Sample sizes ranged from 24 to 981
      ii. The performance bias and attrition bias are serious in most studies that were included. Selection bias may also have affected the quality of the evidence.
   b. Acupuncture vs wait list
      i. N=3 studies
      ii. Data pooled from three studies also showed that acupuncture improved the life quality of patients, measured by Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) or Mini RQLQ (n=1112, SMD −0.95, 95% CI −1.17, −0.73)
   c. Acupuncture vs sham acupuncture
      i. N=4 trials
      ii. The post-intervention nasal symptoms score was lower in the acupuncture group than in the sham acupuncture group (RQLQ nasal symptom subscale: n=489, MD −0.60, 95% CI −1.16 to −0.04)
      iii. Evidence from three trials demonstrated that the acupuncture group had significantly improved life quality (RQLQ) compared to the sham acupuncture group (n=436, SMD −0.26 95% CI −0.44, −0.07)
   d. Acupuncture vs western medicine (cetirizine, loratadine, terfenadine, Tranilast capsules and desloratadine)
      i. N=17 trials
      ii. There was no difference for clinical response between these two groups (n=588, RR 1.10 95% CI 0.96, 1.26)
      iii. The difference in the quality of life between two groups was inconsistent
   e. Acupuncture in children
      i. Only two trials enrolled participants younger than 18 years old. Ng et al. found no difference between real acupuncture and sham acupuncture in the severity of nasal symptoms (n=72, MD −1.76, 95% CI −3.59 to 0.07)
      ii. Determined to have insufficient data
   f. Conclusion: Acupuncture may have an advantage over no intervention and sham acupuncture in improving nasal symptoms and quality of life for adults with AR. The effect of acupuncture and cetirizine or loratadine for AR may be similar. Additional trials are necessary to confirm these results.

Interstitial cystitis

1) **Verghese 2016**, systematic review of complementary therapies for bladder pain syndrome
   a. Acupuncture
      i. Cohort study (N=11 patients with bladder pain syndrome, 25 patients with overactive bladder) [Honjo et al]
         1. At the end of treatment there was a significant decrease in the 24-h frequency and VAS for pain ($p<0.001$). However, the results for the BPS and overactive bladder patients were presented together, preventing an assessment of symptoms in patients with BPS alone.

ii. Pilot study (N=7 patients) [Staack et al]
    1. acupuncture treatment with electric stimulation led to modest improvement in the urinary frequency, voiding difficulty and abdominal/genital pain
iii. Case series of 8 patients [Katayama et al]
    1. 38 % of women showed improvement in symptoms after 3 months

Other payer policies

1) Aetna 2022

a. Considers the following experimental (excerpts)
    i. Fibromyalgia
    ii. Myofascial pain
    iii. Vascular dementia

2) Cigna 2022

a. Covers acupuncture for chronic pain conditions
    i. Fibromyalgia or myofascial pain ICD-10-CM codes not included on covered list

HERC staff summary

Acupuncture appears to be a promising treatment modality for post-stroke aphasia and breastfeeding difficulties, but the quality of evidence is low and there appear to be ongoing RCTs in these areas. There is poor evidence based on low to very low quality studies to support the use of acupuncture for vascular dementia. Acupuncture was not superior to routine medical therapy in adults with allergic rhinitis; insufficient evidence was found to evaluate effectiveness as a treatment for allergic rhinitis in children. Very little evidence was found on acupuncture to treat interstitial cystitis.

There is moderate quality evidence that acupuncture improves pain and stiffness in fibromyalgia; however, this improvement has borderline clinical significance and is only short term. NICE found low to moderate quality evidence for effectiveness of acupuncture for the treatment of chronic pain (pain reduction and quality of life) in the short term (<3 months), with the majority of included studies in patients with fibromyalgia. However, the NICE review found no evidence of clinically important improvement with acupuncture over sham at more than 3 months.

HERC staff recommendation

1) Modify GN 92 as shown below
    a. Clarify that post-stroke depression refers to ICD-10-CM F06.31 (Mood disorder due to known physiological condition with depressive features) and F06.32 (Mood disorder due to known physiological condition with major depressive-like episode).
    b. Note: previously adopted change from October 2022 is shown under substance use disorder
2) Discuss adding acupuncture (CPT 97810-97814) to line 531 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS
    a. If acupuncture is added to this line, modify GN92 as shown below in purple

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,4,5,64,65,92,111,112,114,125,129,133,135,157,158,191,199-201,208,210,214,215,229,234, 237,238,258,259,262,271,276,286,287,294,314-316,329,342,361,396,397,402,410,419,435,464, ***531,****541,559*

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

Line 1 PREGNANCY

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

Hyperemesis gravidarum

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

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

Breech presentation

ICD-10-CM: O32.1

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

Back and pelvic pain of pregnancy

ICD-10-CM: O99.89

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

Line 4 SUBSTANCE USE DISORDER, Line 62 SUBSTANCE-INDUCED MOOD, ANXIETY, DELUSIONAL AND OBSESSIVE-COMPULSIVE DISORDERS, Line 65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL

Acupuncture is included on these lines only when used as part of a ~~program~~ documented broader treatment plan that offers patients a variety of evidence-based interventions including behavioral interventions, social support, and Medication Assisted Treatment (MAT), as appropriate.

Line 5 TOBACCO DEPENDENCE

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

Lines 92, 111, 112, 114, 125, 129, 133, 135, 157, 158, 191, 199, 200, 208, 210, 214, 215, 229, 234, 237, 238, 258, 259, 261, 262, 271, 276, 286, 287, 294, 314, 315, 316, 329, 342, 372, 396, 397, 419, 435 and 559

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

Line 201 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS

Acupuncture is paired with the treatment of post-stroke depression only (ICD-10-CM F06.31 or F06.32). Treatments may be billed to a maximum of 30 minutes face-to-face time and limited to 12 total sessions per year, with documentation of meaningful improvement; patients may have additional visits authorized beyond these limits if medically appropriate

Line 361 SCOLIOSIS

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

Line 402 CONDITIONS OF THE BACK AND SPINE

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

Line 410 MIGRAINE HEADACHES

Acupuncture pairs on Line 410 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), for up to 12 sessions per year.

Line 464 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 464 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions per year.

*Line 531 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS

Acupuncture is included on Line 531 for treatment of fibromyalgia (ICD-10-CM M79.7), for up to 12 sessions per year.

*Line 541 TENSION HEADACHES

Acupuncture is included on Line 541 for treatment of tension headaches (ICD-10-CM G44.2), for up to 12 sessions per year.

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

*Below the current funding line.

Intrauterine Devices as Treatment for Endometrial Cancer

Plain Language Summary:
Background: Should OHP cover an alternative treatment for cancer of the lining of the uterus?

Should OHP cover this treatment? Staff recommends covering this treatment for people who cannot have standard treatments (removal of the uterus and ovaries and/or radiation) or who want to be able to have a child in the future.

Question: Should IUD insertion procedure codes be added to the endometrial cancer line?

Question source: Medical Management Committee (MMC) of HSD

Issue: Progestin-containing intrauterine devices (IUDs) are included in the NCCN management of endometrial cancer for women who are not candidates for hysterectomy due to co-morbidities or desire for future fertility. Recently, MMC had a case in which a woman with significant co-morbidities was not able to have hysterectomy/oophorectomy nor pelvic radiation. IUD insertion was approved by exception. As this treatment is recommended in certain circumstances by NCCN, HERC staff recommend pairing IUD insertion with endometrial cancer so that these procedures can be approved without going through the exception process.

Evidence:

1) **Janda 2021**, FeMMe RCT of IUD for endometrial cancer
    a. N=154 patients
        i. Endometrial hyperplasia with atypia (EHA) for FIGO grade 1 endometrial adenocarcinoma (EAC)
        ii. BMI>30
        iii. Depth of myometrial invasion of <50% on MRI
        iv. CA125≤30 U/mL
        v. IUD with or without metformin (M) or weight loss (WL)
    b. After 6 months of treatment, the rate of pathologic complete response (pCR) was 61% (20/33, 95% CI: 42–77%) for OBS, 67% (22/33, 95% CI: 48–82%) for WL, and 57% (24/42, 95% CI: 41–72%) for M
    c. In summary, the feMMe trial demonstrates encouraging response rates for EHA and EAC to IUD therapy with or without metformin or weight loss

Expert guidelines

1) **NCCN 1.2022** Guideline for treatment of endometrial cancer
    a. Although the primary treatment of endometrial cancer is usually hysterectomy, continuous progestin-based therapy may be considered for highly selected patients with Grade 1, stage IA (noninvasive) disease who wish to preserve their fertility
    b. Continuous progestin-based therapy may include megestrol acetate, medroxyprogesterone, or an intrauterine device containing levonorgestrel. A durable complete response occurs in about 50% of patients
    c. For uterine-confined disease not suitable for primary surgery, EBRT and/or brachytherapy is the preferred treatment approach. Initial systemic therapy can also be considered for selected patients with uterine-confined tumors of endometrioid histology (eg, estrogen and progesterone receptor–positive [ER/PR-positive]). Patients

receiving hormonal therapy alone should be closely monitored by endometrial biopsy (eg, consider endometrial biopsies every 3–6 months). Progesterone-based therapy has been shown to provide some benefit with low toxicity in patients with low-grade tumors

HERC staff summary

The standard treatment for endometrial cancer is hysterectomy/oophorectomy with or without pelvic radiation. However, for women who are unable to undergo these therapies due to co-morbidities or due to a desire for fertility, progestin containing IUDs can be an alternative therapy.

HERC staff recommendation

1) Add 58300 (Insertion of intrauterine device (IUD)) to line 208 CANCER OF UTERUS

Cochlear Implant Guideline

Plain Language Summary:
Background: Should OHP cover a device that provides a sense of sound for people who are deaf or severely hard of hearing (cochlear implants) for one-sided hearing loss or just for two-sided, as is currently covered? Also, should the current hearing loss criteria needed to qualify for a cochlear implant be updated to allow people with lower levels of hearing loss receive one?

1) A Medicaid director asked for a review of cochlear implants since the Centers for Medicaid and Medicare Services (CMS) updated the guidelines to include people with lower levels of hearing loss.

2) An organization requested cochlear implant coverage for single-sided hearing loss.

Should OHP change its coverage policy? Staff recommends OHP change coverage policy to include patients with lower levels of hearing loss but not include cochlear implants for single-sided hearing loss.

Question: Should the criteria for eligibility for cochlear implants be updated?

Question sources:

1) Holly Jo Hodges, CCO medical director
2) Cochlear

Issues:

1) CMS recently updated their coverage criteria for cochlear implants, reducing the hearing loss level required for eligibility. Dr. Hodges has requested a review of the current cochlear implant requirements in the Prioritized List guideline to see if the guideline needs to be updated in light of the new CMS guidance.
2) Cochlear is requesting review of lack of coverage of cochlear implants for single-sided deafness/unilateral hearing loss. Per Cochlear: "On January 10, 2022, the Food and Drug Administration (FDA) approved (P970051/S205) the Cochlear™ Nucleus® for the treatment of unilateral hearing loss (UHL)/single-sided deafness (SSD)… We are requesting you revise your cochlear implant medical coverage policy to include coverage for individuals with UHL/SSD candidates for surgical implantation." The company is specifically requesting expansion of coverage to:
    a. Individuals 5 years or older who have one ear with a severe to profound sensorineural hearing loss and obtain limited benefit from an appropriately fitted unilateral hearing device and one ear with normal or near normal hearing.
        i. In the ear to be implanted, a severe to profound sensorineural hearing loss is defined as a PTA at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz of > 80 dB HL.
        ii. In the contralateral ear, normal or near normal hearing is defined as a PTA at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz ≤ 30 dB HL.
    b. Limited benefit from an appropriately fit unilateral hearing device is defined as a score of less than or equal to 5% on a Consonant-Nucleus-Consonant (CNC) word test. For individuals between 5 years and 18 years of age, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of 5% or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.

c. Failed trial of at least 2 weeks wearing appropriately fit Contralateral Routing of Signal (CROS) hearing aid or another suitable hearing device.

A cochlear implant is an implanted electronic hearing device, designed to produce useful hearing sensations to a person with severe to profound nerve deafness by electrically stimulating nerves inside the inner ear.

Previous HSC/HERC review history

January 2005

Cochlear Implant: Criteria posted on OSHU website are the same as Medicare's, with the exception that for adults, the criteria is for test scores of 40% or less on open set sentence recognition. Current Medicare criteria is for test scores of 30% or less, though there is proposal to expand coverage to 40% or less, and 60% or less if the patient is enrolled in a clinical trial. Action: Adopt OHSU guidelines for cochlear implants.
Note: at this time, there were two cochlear implant guidelines, one for age 5 and older, one for under age 5

May 2013

Added a definition for profound sensorineural hearing loss for children age 5 and under: (defined as 91dB hearing loss or greater at 500, 1000 and 2000 Hz), and for post-linguistic adults: (defined as 71dB (decibels) hearing loss or greater at 500 Hz (hertz), 1000 Hz and 2000 Hz) and for prelinguistic adults: (defined as 91dB (decibels) hearing loss or greater at 500 Hz (hertz), 1000 Hz and 2000 Hz)
Allowed coverage of bilateral cochlear implants for all ages

March 2015

The two cochlear implant lines (over age 5 and age 5 and younger) were merged and the accompanying guidelines were merged into a single guideline and modified. Profound sensorineural hearing loss was defined as 71 dB hearing loss, and a definition was added regarding what was meant be "limited useful benefit for appropriately fitted hearing aids:" defined as a speech discrimination score of <30% on age appropriate testing for children and as scores of 40% or less on sentence recognition test in the best-aided listening condition for adults.

Specific notation was added to the unilateral hearing loss line clarifying that cochlear implants were not included for treatment of unilateral hearing loss.

Current Prioritized List status

CPT 69930 (Cochlear device implantation, with or without mastoidectomy) is on line 326 SENSORINEURAL HEARING LOSS Treatment: COCHLEAR IMPLANT

ICD-10-CM H90.3 (Sensorineural hearing loss, bilateral), H90.4X (Sensorineural hearing loss, unilateral), H90.A2X (Sensorineural hearing loss, unilateral, with restricted hearing on the contralateral side) and H90.A3X (Mixed conductive and sensorineural hearing loss, unilateral, with restricted hearing on the contralateral side) are on lines 311 HEARING LOSS - AGE 5 OR UNDER, 326 and 446 HEARING LOSS - OVER AGE OF FIVE

ICD-10-CM H90.6 (Mixed conductive and sensorineural hearing loss, bilateral) and H90.7 (Mixed conductive and sensorineural hearing loss, unilateral) are on lines 311 and 446

GUIDELINE NOTE 31, COCHLEAR IMPLANTATION

Line 326

Patients will be considered candidates for cochlear implants if the following criteria are met:

A) Severe to profound sensorineural hearing loss in both ears (defined as 71dB hearing loss or greater at 500, 1000 and 2000 Hz)
B) Receive limited useful benefit from appropriately fitted hearing aids, defined as a speech discrimination score of <30% on age appropriate testing for children and as scores of 40% or less on sentence recognition test in the best-aided listening condition for adults
C) No medical contraindications
D) High motivation and appropriate expectations (both patient and family, when appropriate)

Bilateral cochlear implants are included on this line. Simultaneous implantation appears to be more cost-effective than sequential implantation.

GUIDELINE NOTE 143, TREATMENT OF UNILATERAL HEARING LOSS

Lines 311,446

Unilateral hearing loss treatment is Included on these lines only for children aged 20 and younger with the following conditions:

1. For mild to moderate sensorineural unilateral hearing loss (defined as 26-70 dB hearing loss at 500, 1000 and 2000 Hz), first line intervention should be a conventional hearing aid, with second line therapy being contralateral routing of signal (CROS) system
2. For severe to profound unilateral sensorineural hearing loss (defined as 71 dB hearing loss or greater at 500, 1000 and 2000 Hz), first line therapy should be a contralateral routing of signal (CROS) system with second line therapy being a bone anchored hearing aid (BAHA). BAHA SoftBand therapy may be first line therapy for children under age 5 or patients with severe ear deformities (e.g. microstia, severe canal atresia).

Cochlear implants are not included on these lines for unilateral hearing loss per Guideline Note 31 COCHLEAR IMPLANTATION.

Cochlear implant eligibility criteria, bilateral hearing loss

Expert guidelines

1) **American Academy of Otolaryngology-Head and Neck Surgery 2021**, Position Statement on general cochlear implantation candidacy
   a) https://www.entnet.org/resource/position-statement-cochlearimplants/#:~:text=The%20American%20Academy%20of%20Otolaryngology,with%20appropriately%20fit%20hearing%20aids.
   b) The American Academy of Otolaryngology-Head and Neck Surgery considers unilateral and bilateral cochlear implantation as appropriate treatment for adults and children over 9 months of age with moderate to profound hearing loss who have failed a trial with appropriately fit hearing aids.
      i) Definitions of moderate to profound not given
2) **American Academy of Otolaryngology-Head and Neck Surgery 2021**, Position Statement on pediatric cochlear implantation candidacy
   a) https://www.entnet.org/resource/position-statement-pediatric-cochlear-implantation-candidacy/
   b) There is ample evidence that early cochlear implantation of children with sensorineural hearing loss (SNHL) for whom hearing aids provide inadequate access to sound is advantageous. Early implantation improves auditory and language outcome and may be done safely.
   c) Children with bilateral severe to profound SNHL (4-frequency PTA > 80 dB HL or 2-frequency PTA > 85) will not receive adequate benefit from amplification and are candidates for bilateral cochlear implantation. Children with this degree of SNHL, including infants between 6 and 12 months, should receive cochlear implants as soon as practicable. Implantation below 12 months of age is correlated with better language outcome. Therefore, implantation should not be delayed by a hearing aid trial of an arbitrary prescribed length unsupported by current evidence. Infants below 12 months of age should have objective measures (auditory brainstem response/auditory steady state response testing) of SNHL with confirmatory audiometric results, when possible, prior to implantation.
   d) Children aged 12 months and older with a PTA between 65 and 85dB HL whose early aided auditory skill development and speech and language progress indicate a persistent, or widening, gap in age appropriate auditory and language skills are also eligible for implantation. The Pediatric Minimum Speech Test Battery is critical for providers working with this population to assess their functional benefit from amplification.
   e) For children to obtain the benefit of early implantation, referral of potentially eligible infants and children for candidacy evaluation should be a priority for professionals involved in diagnosis, audiological and medical management, and habilitation of childhood hearing loss. Pre- and post-cochlear implant auditory and spoken language habilitation therapy are essential services for this special population.

NICE 2019 https://www.nice.org.uk/guidance/ta566/resources/cochlear-implants-for-children-and-adults-with-severe-to-profound-deafness-pdf-82607085698245

1) Unilateral cochlear implantation is recommended as an option for people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids

a) For the purposes of this guidance, severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL (pure-tone audiometric threshold equal to or greater than 80 dB HL) at 2 or more frequencies (500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally without acoustic hearing aids.
b) Adequate benefit from acoustic hearing aids is defined for this guidance as:
   i) for adults, a phoneme score of 50% or greater on the Arthur Boothroyd word test presented at 70 dBA
   ii) for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability

2) Simultaneous bilateral cochlear implantation is recommended as an option for the following groups of people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids, as defined above:
   a) children
   b) adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness.
   c) Acquisition of cochlear implant systems for bilateral implantation should be at the lowest cost and include currently available discounts on list prices equivalent to 40% or more for the second implant.
3) Sequential bilateral cochlear implantation is not recommended as an option for people with severe to profound deafness.

Other payer policies

CMS 2022 Decision Memo regarding cochlear implantation https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=306

a. We have concluded that the evidence is sufficient to determine that cochlear implantation may be covered for treatment of bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 60% correct in the best-aided listening condition on recorded tests of open-set sentence cognition. Patients must meet all of the following criteria.
   i. Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
   ii. Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation; Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;
   iii. No contraindications to surgery; and
   iv. The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.

b. CMS may also provide coverage of cochlear implants for beneficiaries not meeting the coverage criteria listed above when performed in the context of FDA-approved category B investigational device exemption clinical trials as defined at 42 CFR 405.201 or as a routine cost in clinical trials under section 310.1 of the National Coverage Determinations Manual titled Routine Costs in Clinical Trials.

c. We are expanding coverage by broadening the patient criteria and removing the requirement that for individuals with hearing test scores of > 40 % and ≤ 60 %

2) Aetna 2022

a. Aetna considers uniaural (monaural) or binaural (bilateral) cochlear implantation a medically necessary prosthetic for adults aged 18 years and older with bilateral, pre- or post-linguistic, sensorineural, moderate-to-profound hearing impairment who meet *both* of the following criteria
   i. Member has bilateral severe to profound sensorineural hearing loss determined by an air conduction pure tone average of 70 dB or greater at 500 Hz, 1000 Hz, and 2000 Hz; *and*
   ii. Member has limited benefit from appropriately fitted binaural hearing aids. Limited benefit from amplification is defined by test scores of 40 % correct or less in best-aided listening condition on open-set sentence cognition (e.g., Central Institute for the Deaf (CID) sentences, Hearing in Noise Test sentences (HINT), and consonant-nucleus-consonant (CNC) test.

b. Aetna considers uniaural (monaural) or binaural (bilateral) cochlear implantation a medically necessary prosthetic for infants and children with bilateral sensorineural hearing impairment who meet *all* of the following criteria:
   i. Child has profound, bilateral sensorineural hearing loss determined by an air conduction pure tone average of 70 dB or greater at 500 Hz, and 90 dB or greater at 1000 and 2000 Hz; *and*
   ii. Child has limited benefit from appropriately fitted binaural hearing aids. For children 4 years of age or younger, limited benefit is defined as failure to reach developmentally appropriate auditory milestones measured using the Infant-Toddler Meaningful Auditory Integration Scale, the Meaningful Auditory Integration Scale, or the Early Speech Perception test, or less than 20 % correct on open-set word recognition test (Multisyllabic Lexical Neighborhood Test) in conjunction with appropriate amplification and participation in intensive aural habilitation over a 3 to 6 month period. For children older than 4 years of age, limited benefit is defined as less than 12 % correct on the Phonetically Balanced-Kindergarten Test, or less than 30 % correct on the Hearing in Noise Test for children, the open-set Multi-syllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending on the child's cognitive ability and linguistic skills

Cochlear implants for unilateral hearing loss

Evidence

1) **Benchetrit 2021**, systematic review and meta-analysis of cochlear implantation of children with single-sided deafness
   a. N=12 studies (119 children)
      i. N=6 studies in the meta-analysis
      ii. All were case series (N=3-23 patients)
   b. Most children showed clinically meaningful improvement in speech perception in noise (39 of 49 children [79.6%]) and in quiet (34 of 42 children [81.0%]). Sound localization as measured by degrees of error from true location (mean difference [MD], –24.78°; 95% CI, –34.16° to –15.40°; I 2 = 10%) improved statistically significantly after cochlear implantation.

c. Cochlear implantation was associated with statistically significant improvements in all 3 domains (speech hearing, spatial hearing, and hearing quality)
d. Conclusion: This systematic review and meta-analysis found that cochlear implantation for children with SSD was associated with clinically meaningful improvements in audiological and patient-reported outcomes; shorter duration of deafness may lead to better outcomes. The heterogeneity and small sample sizes of the included studies emphasize the need for robust clinical studies.

Other payer policies

1) **Anthem BCBS 2022**: A cochlear implant is considered **not medically necessary** for unilateral deafness
2) **Aetna 2022**
    a. Aetna considers uniaural (monaural) cochlear implantation medically necessary for individuals aged 1 year and older with single sided deafness (SSD) or asymmetric hearing loss (AHL) who meet the following criteria:
        i. Persons with single-sided deafness (SSD) who have profound sensorineural hearing loss in one ear and normal hearing or mild sensorineural hearing loss in the other ear, who have obtained limited benefit from a one-month or longer trial of an appropriately fitted unilateral hearing aid in the ear to be implanted; *or*
        ii. Persons with asymmetric hearing loss (AHL) who have profound sensorineural hearing loss in one ear and mild to moderately severe sensorineural hearing loss in the other ear who have obtained limited benefit from a one-month or longer trial of an appropriately fitted unilateral hearing aid in the ear to be implanted.
    b. For adults 18 years of age or older with SSD or AHL, limited benefit from unilateral amplification is defined by aided speech perception test scores of 5 % correct or less on monosyllabic consonant-nucleus-consonant (CNC) words in quiet when tested in the ear to be implanted alone. For children and adolescents with SSD or AHL, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of 5% or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone.
    c. Before implantation with a cochlear implant, individuals with SSD or AHL must have at least one month of experience wearing a hearing aid, a CROS hearing aid or other relevant device and not show any subjective benefit.
    d. For SSD and AHL indications, profound hearing loss is defined as having a PTA of 90 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Normal hearing is defined as having a PTA of up to 15 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild hearing loss is defined as having a PTA of up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz. Mild to moderately severe hearing loss is defined as having a PTA ranging from 31 to up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz.

HERC staff summary

Specialty society and CMS guidelines have changed their definitions of what is considered "useful benefit" from hearing aids.

For children, the AAO-HNS 2021 position statement states that "implantation should not be delayed by a hearing aid trial of an arbitrary prescribed length unsupported by current evidence." The AAO-HNS now recommends cochlear implants for all children with >80 DB hearing loss and for children aged 12 months and older with between 65 and 85dB hearing loss whose early aided auditory skill development and speech and language progress indicate a persistent, or widening, gap in age appropriate auditory and language skills. A recent recommendation by NICE is similar to the AAO-HNS recommendation.

For adults, CMS has changed the definition of benefit from hearing aids to ≤ 60% correct in the best-aided listening condition on recorded tests of open-set sentence cognition (broadening this from ≤ 40 % correct).

CMS and AAO-HNS recommend consideration of cochlear implants for adults with moderate to profound hearing loss. Based on HERC staff review, there does not appear to be a standard definition of moderate, severe, and profound hearing loss. Currently, Prioritized List coverage is limited to severe to profound (>71 dB) hearing loss in both ears for both adults and children.

There is little evidence regarding treatment of single sided profound hearing loss with cochlear implants. Based on a 2021 systematic review and meta-analysis, the only data consists of small case series. Private payers are varied in their coverage for cochlear implants for unilateral hearing loss.

HERC staff recommendations:

1) Modify GN31 as shown below
2) Make no change in non-coverage of cochlear implants for unilateral hearing loss
    a. Children under age 21 will still require an individualized review prior to denial

GUIDELINE NOTE 31, COCHLEAR IMPLANTATION

Line 326

Patients will be considered candidates for cochlear implants if the following criteria are met:

A) Children who are either
    1) Any age with severe to profound sensorineural hearing loss in both ears (defined as 4-frequency PTA > 80 dB HL or 2-frequency PTA > 85) ~~(defined as 4 frequency 71 dB hearing loss or greater at 500, 1000 and 2000 Hz~~), OR
    2) Aged 12 months an older with between 65 and 85 dB hearing loss in both ears whose early aided auditory skill development and speech and language progress indicate a persistent, or widening, gap in age appropriate auditory and language skills
B) Adults with bilateral severe to profound sensorineural hearing impairment (defined as >71 dB hearing loss in both ears) with limited benefit from appropriate hearing (or vibrotactile) aids. Limited benefit from amplification is defined by test scores of less than or equal to 60% correct in the best-aided listening condition on recorded tests of open-set sentence cognition
~~C) Receive limited useful benefit from appropriately fitted hearing aids, defined as a speech discrimination score of <30% on age appropriate testing for children and as scores of 40% or less on sentence recognition test in the best-aided listening condition for adults~~

D) No medical contraindications
E) High motivation and appropriate expectations (both patient and family, when appropriate)

Bilateral cochlear implants are included on this line. Simultaneous implantation appears to be more cost-effective than sequential implantation.

CPAP Titration

Plain Language Summary:
Background: An overnight sleep test used to correctly set the pressure (continuous positive airway pressure (CPAP)) on an in-home machine used to treat people with sleep apnea. The first test is covered on OHP. Should OHP cover repeat tests to adjust the CPAP device?

Should OHP cover this treatment? Staff recommends covering up to two repeat sleep tests per year when certain factors occur (for example: weight change, worsening health conditions related to sleep apnea) based on expert input.

Question: Should the obstructive sleep apnea diagnostic guideline be modified to specify when and how often repeat sleep studies for Continuous Positive Airway (CPAP) titration are covered?

Question source: Providence CCO

Issue: The current guideline for diagnosis of obstructive sleep apnea (OSA) lists criteria for when initial sleep studies are covered. Providence CCO reviewers are seeing multiple requests for CPAP titrations (CPT 95811) after a diagnostic sleep study. The CCO is requesting clarification of coverage for repeat sleep studies/CPAP titration studies.

Current Prioritized List status
Both of the following are on the DIAGNOSTIC PROCEDURES file:

CPT **95810** Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, attended by a technologist

CPT **95811** Polysomnography; age 6 years or older, sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist

DIAGNOSTIC GUIDELINE D8, DIAGNOSTIC TESTING FOR OBSTRUCTIVE SLEEP APNEA (OSA)
For adults over the age of 18 years:

A) For patients with clinical signs and symptoms consistent with obstructive sleep apnea (OSA), a home sleep study is the first-line diagnostic test for most patients, when available.
   1) For portable devices, Type II-III are included on this line. Type IV sleep testing devices must measure three or more channels, one of which is airflow, to be included on this line. Sleep testing devices that are not Type I-IV and measure three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are included on this line.

B) Polysomnography in a sleep lab is indicated as a first-line test for patients with significant cardiorespiratory disease, potential respiratory muscle weakness due to a neuromuscular condition, awake hypoventilation or suspicion of sleep related hypoventilation, chronic opioid medication use, history of stroke or severe insomnia.

C) If a patient has had an inconclusive (or negative) home sleep apnea test and a clinical suspicion for OSA remains, then attended polysomnography is included on this line. Split night diagnostic protocols are required when a diagnosis of OSA is confirmed in the first portion of the night.

For children age of 18 or younger:

A) Obstructive sleep apnea (OSA) must be diagnosed by

1) nocturnal polysomnography with an AHI >5 episodes/h or AHI >1 episodes/h with history and exam consistent with OSA, OR

2) nocturnal pulse oximetry with 3 or more SpO2 drops <90% and 3 or more clusters of desaturation events, or alternatives desaturation (>3%) index >3.5 episodes/h,OR

3) use of a validated questionnaire (such as the Pediatric Sleep Questionnaire or OSA 18), OR

4) consultation with a sleep medicine specialist.

B) Polysomnography and/or consultation with a sleep medicine specialist to support the diagnosis of OSA and/or to identify perioperative risk is recommended for

1) high-risk children (i.e. children with cranio-facial abnormalities, neuromuscular disorders, Down syndrome, etc.)

2) children with equivocal indications for adenotonsillectomy (such as discordance between tonsillar size on physical examination and the reported severity of sleep-disordered breathing), children younger than three years of age

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 27, TREATMENT OF SLEEP APNEA

Line 202

For adults over the age of 18 years:

A) CPAP is covered initially when all of the following conditions are met:

1) 12 week 'trial' period to determine benefit. This period is covered if apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour; or if between 5 and 14 events with additional symptoms including one or more of the following:

2) excessive daytime sleepiness defined as either an Epworth Sleepiness Scale score>10 or daytime sleepiness interfering with ADLs that is not attributable to another modifiable sedating condition (e.g. narcotic dependence), or

3) documented hypertension, or

4) ischemic heart disease, or

5) history of stroke

6) Additionally:

a) Providers must provide education to patients and caregivers prior to use of CPAP machine to ensure proper use; and

b) Positive diagnosis through polysomnogram (PSG) or Home Sleep Test (HST).

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

C) Mandibular advancement devices (oral appliances) are covered for those for whom CPAP fails or is contraindicated.

D) Surgery for sleep apnea in adults is not included on this line (due to lack of evidence of efficacy). Surgical codes are included on this line only for children who meet criteria below

E) Hypoglossal nerve stimulation for treatment of obstructive sleep apnea is not included on this line due to insufficient evidence of effectiveness and evidence of harm.

For children age of 18 years or younger:

A) Adenotonsillectomy is an appropriate first line treatment for children with OSA. Adenoidectomy without tonsillectomy is only covered when a child with OSA has previously had a tonsillectomy,

when tonsillectomy is contraindicated, or when tonsillar hypertrophy is not present. More complex surgical treatments are only included on this line for children with craniofacial anomalies.

B) Intranasal corticosteroids are an option for children with mild OSA in whom adenotonsillectomy is contraindicated or for mild postoperative OSA.

C) CPAP is covered for a 3 month trial for children through age 18 who have
   1) undergone surgery or are not candidates for surgery, AND
   2) have documented residual sleep apnea symptoms (sleep disruption and/or significant desaturations) with residual
      daytime symptoms (daytime sleepiness or behavior problems)

D) CPAP will be covered for children through age 18 on an ongoing basis if:
   1) There is documentation of improvement in sleep disruption and daytime sleepiness and behavior problems with CPAP use, AND
   2) Annual re-evaluation for CPAP demonstrates ongoing clinical benefit and compliance with use, defined as use of CPAP for at least four hours per night on 70% of the nights in a consecutive 30 day period

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

Evidence

No reviews or expert guidelines were found regarding the frequency of repeat sleep studies. Sleep medicine specialists were consulted and recommended review of the American Academy of Sleep Medicine guidelines; however, no guidelines were found addressing repeat sleep studies.

Expert guidelines

1) **Choosing Wisely 2014**
   a. Don't perform positive airway pressure re-titration studies in asymptomatic, adherent sleep apnea patients with stable weight.
      i. Re-titration of positive airway pressure (PAP) is not indicated for adult obstructive sleep apnea patients with stable weight whose symptoms are well controlled by their current PAP treatment. Follow-up PSG or re-titration is indicated for adult patients who are again symptomatic despite the continued, proper use of PAP, especially if they have gained substantial weight (e.g. 10% of original weight) since the last titration study. A new diagnostic PSG or re-titration may be indicated for patients who have lost substantial weight, to determine whether PAP treatment is still necessary

Other payer policies

1) **Aetna 2022**
   a. It may be necessary to perform repeat sleep studies up to twice a year for *any* of the following indications:
      i. To determine whether positive airway pressure treatment (i.e., CPAP, bilevel positive airway pressure (BiPAP), demand positive airway pressure (DPAP), variable positive airway pressure (VPAP), or auto-titrating positive airway

pressure (AutoPAP)) continues to be effective in persons with new or persistent symptoms, after interrogation of current positive airway pressure device; *or*

ii. To determine whether positive airway pressure treatment settings need to be changed in persons with new or persistent symptoms, after interrogation of current positive airway pressure device. (**Note**: This criterion does not apply to AutoPAP devices, as these devices are automatically titrated and do not require manual adjustment of treatment settings.); *or*

iii. For persons with substantial weight loss (loss of 10 percent or more body weight) or some other change in their medical condition that would affect the need for continued positive airway pressure treatment (e.g., heart attack, stroke, heart failure), to determine whether continued treatment with positive airway pressure treatment is necessary; *or*

iv. To assess treatment response after upper airway surgical procedures and after initial treatment with oral appliances.

2) Cigna 2021

a. Repeat Titration study can be performed if any of the following criteria is met:
   i. OSA currently on CPAP
      1. Re-assessment of treatment results for an individual with known OSA currently on CPAP therapy can be performed when any of the following has occurred:
         a. Substantial weight gain (10% of body weight) with return of symptoms.
         b. BMI decreases by 10% and there is intolerance of PAP pressure
         c. Clinical response is insufficient despite treatment
         d. Symptoms return despite a good initial response to CPAP
         e. Development of hypertension or worsening of hypertension despite a minimum of three months of adherent PAP usage.
         f. New onset decompensated heart failure or new stroke or TIA in a patient adherent to PAP therapy
         g. PAP machine download with AHI ≥5/hr with return of symptoms
         h. Must demonstrate that recurrent or continued symptoms are not due to insufficient compliance (must be using PAP >70% of nights, 4+hrs/night with continued symptoms).
         i. Results of previous medically necessary sleep test were inadequate and not diagnostic due to limited sleep time or other specified variables.
         j. NOT to assess for the efficacy of PAP therapy in the absence of recurrent or changed symptoms
         k. NOT to supply new PAP equipment.

b. OSA currently treated with bi-level PAP, APAP, ASV Re-assessment of treatment results (with CPT® 95811) for a patient with known OSA currently treated with bilevel PAP, APAP, ASV can be performed when any of the following has occurred:
   i. Substantial weight gain (10% of body weight) with return of symptoms.
   ii. BMI decreases by 10% and there is intolerance of PAP pressure o Clinical response is insufficient despite treatment
   iii. Symptoms return despite a good initial response to CPAP. o PAP machine download with AHI ≥5/hr with return of symptoms or ≥15/hr with or without return of symptoms.

iv. Must demonstrate that recurrent or continued symptoms are not due to insufficient compliance (must be using PAP ≥70% of nights, 4+hrs/night with continued symptoms).
v. Results of previous medically necessary sleep test were inadequate and not diagnostic due to limited sleep time or other specified variables.
vi. NOT to assess for the efficacy of PAP therapy in the absence of recurrent or changed symptoms
vii. NOT to supply new PAP equipment.

3. Carecentrix 2021

a. A repeat PSG, HSAT, or Split Night Study to confirm the diagnosis of sleep disorders meets the definition of medical necessity when the member meets previously stated criteria for a PSG, HSAT, or Split Night as outlined above and at least ONE of the following conditions is met:
    i. Recent HSAT (less than 1 year old) confirmed to be non-diagnostic:
        1. A previous home sleep study was technically inadequate and there was a valid attempt to retest the member via HSAT OR
        2. A previous home sleep study failed to establish the diagnosis of OSA in a member with a high pretest probability of OSA.
    ii. Member has had a significant change in weight that has impacted signs/symptoms of obstructive sleep apnea, specifically weight gain or weight loss of greater than or equal to 10% of total body weight, when re-evaluation is warranted to modify therapy.
    iii. Reassessment of clinical indicators of obstructive sleep apnea to determine the effectiveness of treatment after surgical intervention:
        1. Tonsillectomy,
        2. Adenoidectomy,
        3. Uvulopalatoplasty (UPPP),
        4. Maxillomandibular Advancement Surgery (MMA)
        5. Other upper airway surgery/implantation for treatment of obstructive sleep apnea
    iv. Implementation and evaluation of a fabricated oral mandibular advancement appliance (OAT) by a qualified healthcare professional:
        1. Treatment efficacy of an oral mandibular appliance may be assessed using HSAT, OR
        2. An oral mandibular appliance may be adjusted manually during polysomnography to eliminate sleep disordered breathing in the sleep laboratory by a sleep technologist, and as prescribed by the qualified healthcare professional.
b. A repeat in-lab PAP titration (95811) meets the definition of medical necessity for a member who is known to have OSA when (1&2):
    i. A diagnostic sleep test has been submitted to confirm the diagnosis of OSA AND, any of the following:
        1. The member is documented to have a recurrence of OSA related symptoms, such as snoring, excessive daytime somnolence, fatigue, disrupted sleep, etc. or persistent elevation in AHI documented from PAP device download while adherent to PAP therapy (use ≥4 hours per night on 70% of nights during a consecutive thirty (30) day period),

2. The member has a 10% change in body weight which has resulted in a recurrence of OSA-related symptoms,
3. The member has upper airway surgery, which has resulted in a recurrence of OSA-related symptoms,
4. Significant oxygen desaturation found during diagnostic testing:
    a. O2 saturation <90% for greater than 15 % of recording time during a diagnostic home sleep apnea test or diagnostic facility based PSG, OR
    b. O2 saturation < 80% for greater than 1% of recording time during a diagnostic home sleep apnea test or diagnostic facility based PSG

ii. The member is not a candidate for APAP based on the presence of co-morbid medical conditions or concomitant sleep disorders

Expert input:

Dr. Derek Lam, OHSU sleep medicine

Dr. Lam agreed with the HERC staff recommended wording regarding repeat studies. He had some concerns about applying these criteria to children, but the section with the added wording only applies to adults aged 18 and over.

CPAP Titration

HERC staff summary

There is a dearth of data on how often sleep studies need to be performed for patients on CPAP. The American Academy of Sleep Medicine does not have a specific guideline regarding repeat sleep studies other than a statement that re-titration is not needed in asymptomatic, adherent patients with stable weight. Major insurers have similar criteria for repeat sleep studies: recurrence of OSA symptoms, weight change of 10% of body weight, new or worsening health conditions related to OSA, and to assess treatment response after upper airway surgical procedures and after initial treatment with oral appliances. Some major insurers limit repeat sleep studies to twice per year.

HERC staff recommendation:

1) Modify Diagnostic Guideline D8 as shown below

DIAGNOSTIC GUIDELINE D8, DIAGNOSTIC TESTING FOR OBSTRUCTIVE SLEEP APNEA (OSA)

For adults over the age of 18 years:

A) For patients with clinical signs and symptoms consistent with obstructive sleep apnea (OSA), a home sleep study is the first-line diagnostic test for most patients, when available.
   1) For portable devices, Type II-III are included on this line. Type IV sleep testing devices must measure three or more channels, one of which is airflow, to be included on this line. Sleep testing devices that are not Type I-IV and measure three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are included on this line.

B) Polysomnography in a sleep lab is indicated as a first-line test for patients with significant cardiorespiratory disease, potential respiratory muscle weakness due to a neuromuscular condition, awake hypoventilation or suspicion of sleep related hypoventilation, chronic opioid medication use, history of stroke or severe insomnia.

C) If a patient has had an inconclusive (or negative) home sleep apnea test and a clinical suspicion for OSA remains, then attended polysomnography is included on this line. Split night diagnostic protocols are required when a diagnosis of OSA is confirmed in the first portion of the night.

D) Repeat sleep studies are covered up to twice a year when one of the following has occurred since the most recent test:
   1) recurrence of OSA symptoms
   2) weight change of more than 10% of body weight
   3) new or worsening health conditions related to OSA
   4) upper airway surgical procedures or initial treatment with oral appliances

For children age of 18 or younger:

A) Obstructive sleep apnea (OSA) must be diagnosed by
   1) nocturnal polysomnography with an AHI >5 episodes/h or AHI >1 episodes/h with history and exam consistent with OSA, OR
   2) nocturnal pulse oximetry with 3 or more SpO2 drops <90% and 3 or more clusters of desaturation events, or alternatives desaturation (>3%) index >3.5 episodes/h,OR
   3) use of a validated questionnaire (such as the Pediatric Sleep Questionnaire or OSA 18), OR
   4) consultation with a sleep medicine specialist.

B) Polysomnography and/or consultation with a sleep medicine specialist to support the diagnosis of OSA and/or to identify perioperative risk is recommended for
   1) high-risk children (i.e. children with cranio-facial abnormalities, neuromuscular disorders, Down syndrome, etc.)

2) children with equivocal indications for adenotonsillectomy (such as discordance between tonsillar size on physical examination and the reported severity of sleep-disordered breathing), children younger than three years of age

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

Apnea-Hypopnea Index Scoring for Sleep Apnea Evaluation

Plain Language Summary:
Background: Should a guideline about episodes of lack of oxygen during sleep be changed to spell out how a particular marker (apnea-hypopnea index (AHI)) is presented?

Should OHP cover this treatment? Staff recommends using a marker of over 4% AHI because the literature shows the effectiveness for a breathing machine (CPAP) is difficult to study and draw conclusions. Also, the Centers for Medicaid and Medicare Services (CMS) states it would not use under 4% without additional studies.

Question: Should the sleep apnea guideline be modified to specify how the apnea-hypopnea index (AHI) needs to be calculated and reported?

Question source: CCO medical directors

Issue: The severity of OSA is usually graded based on the number of disordered breathing events per hour of sleep. These are generally calculated as the apnea-hypopnea index (AHI), equal to number of "apneas" (cessation or near cessation of airflow) plus the number of "hypopneas" (reductions in airflow associated with certain physiologic consequences) per hour of sleep. The AHI thus becomes a measure of severity and can have implications for whether and what type of treatment is indicated. As the underlying criteria to determine AHI, the definition of hypopnea has a significant influence on how many patients are found to have an AHI high enough to qualify for a diagnosis of sleep apnea, and thus qualify for treatments such as CPAP. The CCO medical directors are asking for clarification of which method should be used for determination of eligibility for treatment of OSA (CPAP, surgery, etc.).

The most recent AASM manual for scoring of sleep and associated events (2020) recommends using a 3% oxygen desaturation as the definition of an AHI. Earlier AASM scoring manuals recommended a 4% oxygen desaturation, which is what CMS continues to recommend using.

As reported in Berry (2022): In 2001, the CMS accepted the use of an AHI based on a hypopnea defined by ≥ 30% drop in airflow associated with a ≥ 4% drop in the oxygen saturation (H4, AHI4). In 2007, the AASM Scoring Manual listed a recommended hypopnea definition consistent with H4 and an alternative definition based on a ≥ 50% drop in airflow for ≥ 10 seconds associated with a ≥ 3% desaturation or an arousal. In 2012, based on consensus, the Sleep Apnea Definition Task Force recommended a hypopnea definition based on a ≥ 30% drop in airflow for ≥ 10 seconds associated with a ≥ 3% drop in the oxygen saturation or an arousal (H3A), with the rationale that this would allow a wider spectrum of symptomatic patients to qualify for treatment. The AASM Scoring Manual subsequently included a recommended hypopnea definition (H3A, AHI3A) and an acceptable definition (H4, AHI4). AASM representatives met with CMS in both June 2013 and June 2018 to discuss the AASM's recommendation to use the more inclusive H3A definition, rather than the H4 hypopnea definition, in the national coverage determination for PAP therapy for OSA. Through the discussion, it was clear that CMS would require more published data concerning the long-term health consequences of hypopneas scored using the H3A definition before considering adopting this change.

HERC review history
The HERC reviewed sleep studies as part of a coverage guidance in 2013. There did not appear to be any discussion about how to define an AHI in the coverage guidance materials. The last review of diagnosis

of sleep apnea was in March 2018. The 2018 review noted the AASM 2017 guidelines, but did not specifically addresses the definition of hypopnea.

Current Prioritized List status

DIAGNOSTIC GUIDELINE D8, DIAGNOSTIC TESTING FOR OBSTRUCTIVE SLEEP APNEA (OSA)

For adults over the age of 18 years:

A) For patients with clinical signs and symptoms consistent with obstructive sleep apnea (OSA), a home sleep study is the first-line diagnostic test for most patients, when available.
   1) For portable devices, Type II-III are included on this line. Type IV sleep testing devices must measure three or more channels, one of which is airflow, to be included on this line. Sleep testing devices that are not Type I-IV and measure three or more channels that include actigraphy, oximetry, and peripheral arterial tone, are included on this line.

B) Polysomnography in a sleep lab is indicated as a first-line test for patients with significant cardiorespiratory disease,
   potential respiratory muscle weakness due to a neuromuscular condition, awake hypoventilation or suspicion of sleep related hypoventilation, chronic opioid medication use, history of stroke or severe insomnia.

C) If a patient has had an inconclusive (or negative) home sleep apnea test and a clinical suspicion for OSA remains, then attended polysomnography is included on this line. Split night diagnostic protocols are required when a diagnosis of OSA is confirmed in the first portion of the night.

For children age of 18 or younger:

A) Obstructive sleep apnea (OSA) must be diagnosed by
   1) nocturnal polysomnography with an AHI >5 episodes/h or AHI >1 episodes/h with history and exam consistent with
      OSA, OR
   2) nocturnal pulse oximetry with 3 or more SpO2 drops <90% and 3 or more clusters of desaturation events, or
      alternatives desaturation (>3%) index >3.5 episodes/h,OR
   3) use of a validated questionnaire (such as the Pediatric Sleep Questionnaire or OSA 18), OR
   4) consultation with a sleep medicine specialist.

B) Polysomnography and/or consultation with a sleep medicine specialist to support the diagnosis of OSA and/or to identify
   perioperative risk is recommended for
   1) high-risk children (i.e. children with cranio-facial abnormalities, neuromuscular disorders, Down syndrome, etc.)
   2) children with equivocal indications for adenotonsillectomy (such as discordance between tonsillar size on physical
      examination and the reported severity of sleep-disordered breathing), children younger than three years of age

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 27, TREATMENT OF SLEEP APNEA

Line 202

For adults over the age of 18 years:

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

B) CPAP coverage subsequent to the initial 12 weeks is based on documented patient tolerance, compliance, and clinical benefit. Compliance (adherence to therapy) is defined as use of CPAP for at least four hours per night on 70% of the nights during a consecutive 30-day period.
C) Mandibular advancement devices (oral appliances) are covered for those for whom CPAP fails or is contraindicated.
D) Surgery for sleep apnea in adults is not included on this line (due to lack of evidence of efficacy). Surgical codes are included on this line only for children who meet criteria below
E) Hypoglossal nerve stimulation for treatment of obstructive sleep apnea is not included on this line due to insufficient evidence of effectiveness and evidence of harm.

For children age of 18 years or younger:

A) Adenotonsillectomy is an appropriate first line treatment for children with OSA. Adenoidectomy without tonsillectomy is only covered when a child with OSA has previously had a tonsillectomy, when tonsillectomy is contraindicated, or when tonsillar hypertrophy is not present. More complex surgical treatments are only included on this line for children with craniofacial anomalies.
B) Intranasal corticosteroids are an option for children with mild OSA in whom adenotonsillectomy is contraindicated or for mild postoperative OSA.
C) CPAP is covered for a 3 month trial for children through age 18 who have
   1) undergone surgery or are not candidates for surgery, AND
   2) have documented residual sleep apnea symptoms (sleep disruption and/or significant desaturations) with residual
      daytime symptoms (daytime sleepiness or behavior problems)
D) CPAP will be covered for children through age 18 on an ongoing basis if:
   1) There is documentation of improvement in sleep disruption and daytime sleepiness and behavior problems with CPAP
      use, AND

2) Annual re-evaluation for CPAP demonstrates ongoing clinical benefit and compliance with use, defined as use of CPAP
for at least four hours per night on 70% of the nights in a consecutive 30 day period

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

Evidence

1) **AHRQ 2021 *DRAFT*** review of the effectiveness of CPAP for treatment of OSA
    a. Across 47 eligible studies, reporting and choice of criteria to define sleep study breathing measures and OSA were highly inconsistent. The majority of studies did not explicitly report full criteria or definitions. For example, only 41 percent of studies fully explicitly reported apnea and hypopnea definitions…Most studies citing published criteria to define sleep study measures (26/30) cited some version of the American Academy of Sleep Medicine (AASM) criteria. However, there was no discernable consistency in choice of a threshold and citation of a specific AASM version. Of interest was whether the different definitions of sleep measures used had an impact on study findings regarding clinical effect of CPAP. However, as described below, there were no discernable differences across studies, so we could not assess the impact of the variable definitions.
    b. Based on RCT data alone, there is low SoE that CPAP use does not affect the risk of all-cause mortality, stroke, myocardial infarction, composite CV outcomes, driving accidents, and incident diabetes
    c. There is low SoE that CPAP does not yield clinically meaningful changes in depression and anxiety symptoms, cognitive function, or QoL.
    d. Conclusion: The effect of CPAP on most long-term clinical outcomes is unclear, due to insufficient evidence from sparse studies and/or highly imprecise estimates. Additional studies are needed before we have a clear understanding of the potential effects of CPAP on long-term outcomes for patients with OSA
2) **Korotinsky 2016**, comparison of AASM vs CMS definition of AHI and eligibility for CPAP treatment
    a. N=112 patients, prospective cohort study
    b. For the entire cohort, median AHI by AASM criteria was 21.8 (IQR 7.9–33.7) and that by CMS criteria was 12.3 (IQR 3.0– 28.9) (P = .002). AHI was greater by both AASM and CMS criteria for those ≥65 years old than for younger patients. The difference in median AHI measured by AASM and CMS criteria was significant for subjects < .001), but not for subjects ≥65 (P = .184).
    c. According to CMS treatment criteria, AHI ≥ 15 qualifies patients for treatment with CPAP with no further comorbid conditions. For the younger patients (N = 85), 42 (49.4 %) qualified by AASM scoring, compared with 28 (32.9 %) by CMS scoring (P = .043). For the older patients (N = 27), 23 (85.2 %) qualified by AASM scoring, compared with 10 (37.0 %) by CMS scoring criteria (P < .001).
    d. Conclusion: In Medicare age subjects, applying more stringent rules for scoring hypopneas did not change the proportion eligible for CPAP treatment. However, in younger subjects, applying the CMS criteria, even with specified comorbid conditions, would have resulted in fewer being eligible for treatment according to CMS criteria
3) **Wimms 2020**, MERGE trial of CPAP vs standard care for people with mild sleep apnea
    a. N=115 CPAP vs N=118 standard care: all qualified under the 3% criteria
        i. 3 month follow up
        ii. Intention to treat analysis
        iii. Scoring of hypopnea was done using both the AASM 2012 criteria (3%) and the AASM 2007 criteria (4%)
        iv. ResMed Ltd sponsored the trial
    b. N=95 patients who qualified only under the 3% criteria (AASM 2012 criteria)
        i. N=50 CPAP vs N=45 standard care

ii. Participants in the very mild OSA group (normal using AASM 2007 scoring criteria and mild using AASM 2012 scoring criteria) were symptomatic, with a baseline mean ± SD ESS of 10·3 ± 4·7, FSS of 37·9 ± 13·8, and ISI of 12·8 ± 6·1. They were shown to significantly improve when provided with CPAP treatment
iii. CPAP patients in this group had statistically significant improvement in Epworth Sleepiness Scale (ESS) and Fatigue severity scale (FSS) scores, and in HADS: depression index
    1. Clinically meaningful change in the ESS is between -2 and -3
        a. The reported change in ESS was -2.0 (CI -3.0 to -1.1) which falls outside a clinically meaningful change
    2. Clinically meaningful change in the FSS is 0.45 points
        a. The reported change in FSS was -7.8 (CI -10.6 to -5.1) which indicates a clinically meaningful change
iv. CPAP patients had inconsistent improvement in SF-36 subscales
    1. Vitality, physical role, general health, social functioning, emotional role and mental health were all statistically improved
    2. Clinically meaningful change in SF-36 is defined as a change in 5 points
        a. Clinically meaningful change of >5 beyond the confidence interval was only reported in SF-36 vitality
v. No data was presented on any differences between the group who only met criteria using the 4% cut off vs the group that met the cutoff with either scale (i.e. sex, age, comorbidities)

c. Author conclusion: Patients with mild obstructive sleep apnea diagnosed using AASM 2007 scoring criteria showed similar significant improvements in QoL measures to patients diagnosed using AASM 2012 criteria. Subgroup analysis of the 95 participants on the mildest end of the disease spectrum (ie, patients diagnosed with mild obstructive sleep apnea using the 2012 criteria, but classed as normal with the 2007 criteria) also showed a significant improvement in vitality score and other QoL measures when comparing CPAP treatment with standard car

Expert input:

Kim Hutchinson, MD OHSU sleep medicine

It is important to honor the 3% desaturation because many patients (particularly thinner and younger) do not desaturation as significantly as older, larger patients.

When these home studies are negative, we often end up ordering a more costly in-lab polysomnogram, which is a more sensitive test for picking up sleep apnea. Not honoring the 3% desaturation would result in many more in-lab diagnostic studies, resulting in higher costs and treatment delays.

HERC staff summary

The definition of hypopnea in the AHI calculation for sleep studies has a major effect on the number of patients who are diagnosed with obstructive sleep apnea. Using the higher cut off criteria (4% oxygen desaturation), the group that would not qualify for CPAP is mainly younger patients (under age 65). AHRQ has concluded that the variation in definition of hypopnea makes the literature on the effectiveness of CPAP for OSA very difficult to analyze. Only one RCT is available that differentiates patients based on hypopnea definition (3% vs 4%). On subgroup analysis of this mild OSA study population (only diagnosed by the 3% definition), there was very little clinically meaningful change in the measured outcomes with or without CPAP treatment. CMS currently defines hypopnea using the 4% oxygen desaturation definition: "CMS would require more published data concerning the long-term health consequences of hypopneas scored using the H3A definition [3% oxygen desaturation qualifying as a hypopnic event] before considering adopting this change."

Staff will review the final AHRQ report on CPAP when it is available to determine if any other coverage changes should be recommended.

HERC staff recommendation

1) Modify GN27 as shown below

GUIDELINE NOTE 27, TREATMENT OF SLEEP APNEA

Line 202

For adults over the age of 18 years:

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

B) CPAP coverage subsequent to the initial 12 weeks is based on documented patient tolerance, compliance, and clinical benefit. Compliance (adherence to therapy) is defined as use of CPAP for at least four hours per night on 70% of the nights during a consecutive 30-day period.
C) Mandibular advancement devices (oral appliances) are covered for those for whom CPAP fails or is contraindicated.
D) Surgery for sleep apnea in adults is not included on this line (due to lack of evidence of efficacy). Surgical codes are included on this line only for children who meet criteria below
E) Hypoglossal nerve stimulation for treatment of obstructive sleep apnea is not included on this line due to insufficient evidence of effectiveness and evidence of harm.

For children age of 18 years or younger:

A) Adenotonsillectomy is an appropriate first line treatment for children with OSA. Adenoidectomy without tonsillectomy is only covered when a child with OSA has previously had a tonsillectomy, when tonsillectomy is contraindicated, or when tonsillar hypertrophy is not present. More complex surgical treatments are only included on this line for children with craniofacial anomalies.

B) Intranasal corticosteroids are an option for children with mild OSA in whom adenotonsillectomy is contraindicated or for mild postoperative OSA.

C) CPAP is covered for a 3 month trial for children through age 18 who have
   1) undergone surgery or are not candidates for surgery, AND
   2) have documented residual sleep apnea symptoms (sleep disruption and/or significant desaturations) with residual
      daytime symptoms (daytime sleepiness or behavior problems)

D) CPAP will be covered for children through age 18 on an ongoing basis if:
   1) There is documentation of improvement in sleep disruption and daytime sleepiness and behavior problems with CPAP
      use, AND
   2) Annual re-evaluation for CPAP demonstrates ongoing clinical benefit and compliance with use, defined as use of CPAP
      for at least four hours per night on 70% of the nights in a consecutive 30 day period

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

Plain Language Summary:
Background: Should an imaging test (PET Scan) used to look at cancer be used to look at types of cancer?

Should OHP cover this treatment? Staff recommends extending this test for additional types of cancer (diagnosis and staging) because studies show its use is effective at helping decide on treatment.

Question: Should the covered indications for PET scan be expanded?

Question source: Mary Engrav, CCO medical director

Issue: PET scans are a nuclear medicine study that can be used to evaluate the extent of a cancer for initial determination of treatment or when there is suspicion that the cancer has returned. Diagnostic Guideline D22 PET SCANS limits coverage of PET scans to certain cancers where there is evidence of benefit, either in assisting in diagnosis, prognosis, guiding treatment, or evaluating recurrence.

Dr. Engrav requested consideration of PET scans for multiple other cancers based on requests from community oncologists.

HSC/HERC history
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.

Current Prioritized List status

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 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; 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 OR for thyroid cancer if recurrence is suspected and l131 scintography is negative, 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

a. **Fuchs 2019**, Evidence-based indications for PET or PET/CT
    a. There is a (relative) consensus that there is sufficient evidence for sub-indications in eight indications in favor of PET or PET–CT examinations (in Table 2 highlighted green). The first six were already determined in the 2015 report—(1) bronchial carcinoma (update: mainly pretreatment, contradictory in re-staging and response control and in therapy monitoring), (2) colon carcinoma, (3) malignant lymphoma, (4) malignant melanoma (update: contradictory for diagnosis of recurrence), (5) mamma carcinoma (treatment response, for diagnosis of recurrence), and (6) head–neck tumors (in 2015 report: CUP, thyroid carcinoma; update: mainly for diagnosis of recurrence)— while two new treatment areas were added by the update: (7) myeloma and (8) neuroendocrine tumors.
        i. Note: current PET coverage on the Prioritized List does not include all subtypes of bronchial carcinoma (specifically small cell lung cancer), myeloma or neuroendocrine tumors. Only limited coverage is included for thyroid cancer

Expert guidelines

1) **NCCN 1.2022** Neuroendocrine and adrenal tumors
    a. Initial diagnosis:
        i. Because most neuroendocrine tumors (NETs) overexpress high-affinity receptors for somatostatin, a peptide hormone generated by the hypothalamus that blocks the release of growth hormones, somatostatin receptor (SSR)- based imaging may be considered in the initial evaluation of patients with NETs. Such imaging can provide useful information on overall tumor burden and location; additionally, positive imaging confirms the presence of SSRs, which can have therapeutic implications. A major advance in imaging NETs came with the 2016 FDA approval of PET/CT imaging using the radiolabeled somatostatin analog gallium-68 (68Ga) DOTATATE. Several studies have shown the diagnostic utility, safety, specificity, and high sensitivity of 68Ga-DOTATATE PET/CT.69-73 A systematic review and meta-analysis of 22 studies determined that 68Ga-DOTATATE had a pooled sensitivity and specificity of 91% and 94%, respectively, for the initial diagnosis of NETs. One study even showed that it was able to more correctly identify patients for peptide receptor radiotherapy than 111indium-diethylenetriaminepentaacetic acid (111In-DPTA) scintigraphy. The 2018 Appropriate Use Criteria for Somatostatin Receptor PET Imaging in NETs recommends the use of SSR PET over 111In-DPTA scintigraphy. Unless otherwise indicated, the preferred SSR-based imaging in this discussion includes SSR-PET/CT or SSR-PET/MRI imaging using 68Ga-DOTATATE, 68Ga-DOTATOC, or 64Cu-DOTATATE. SSR scintigraphy using 111In-octreotide (with SPECT/CT) is appropriate only if SSR-PET is not available. SSR-PET imaging is more sensitive than SSR scintigraphy for determining SSR status
    b. Surveillance of resected NETs
        i. Surveillance of bronchopulmonary and GI NETs should include complete patient history and physical (H&P) examination and a multiphasic CT or an MRI scan with contrast (usually abdominal with or without pelvis). For patients with primary lung and thymic tumors, chest CT scans with or without contrast are recommended

ii. SSR-based imaging or 18F-fluorodeoxyglucose (FDG)-PET/CT scans (for high-grade tumors) are not routinely recommended for surveillance after definitive resection, but may be indicated to assess disease location and disease burden for comparison in cases of subsequent possible recurrence.

2) **NCCN 2.2022** Thyroid cancer
   a. Post-treatment iodine-131 imaging
      i. PET scan is indicated for patients with a negative whole body scan who have suspected structural disease based on other imaging methods and/or elevated Tg to a degree that would indicate distant metastasis
   b. Evaluating recurrent disease
      i. When recurrent disease is suspected based on progressively rising Tg values (basal or stimulated) and negative imaging studies (including PET scans), RAI therapy can be considered using an empirically determined dose of greater than or equal to 100 mCi of iodine-131
   c. Hurthle cell carcinoma
      i. Iodine-131 therapy (100–150 mCi) may be considered after thyroidectomy for patients with rising or newly elevated Tg levels who have negative scans (including FDG-PET)
      ii. Since Hürthle cell carcinoma tends to be non–iodine-avid, negative scans that were done without single-photon emission CT (SPECT) are likely to have missed distant structural disease. Therefore, if Tg is high and/or pathology is high-risk, then FDG-PET is indicated.
   d. Anaplastic thyroid cancer
      i. PET/CT or MRI scans are recommended to accurately stage the patient.
3) **NCCN 1.2023** Multiple myeloma
   a. Initial imaging for diagnostic work up:
      i. Whole-body imaging with low-dose CT or FDG PET/CT is recommended for initial diagnostic workup of patients suspected of having MM or solitary plasmacytoma
      ii. whole-body FDG PET/CT is the first choice for initial evaluation of solitary extraosseous plasmacytoma
   b. Imaging for follow-up
      i. Imaging studies with MRI without contrast, whole-body low-dose CT and/or CT and/or whole-body FDG PET/CT are recommended annually or as clinically indicated. The NCCN Panel recommends considering using the same imaging modality used during the initial workup for the follow-up assessments.
      ii. Residual focal lesions detected by either FDG PET/CT or MRI have been shown to be of adverse prognostic significance.
4) **NCCN 1.2023** Small cell lung cancer
   a. Initial diagnosis
      i. PET scans can increase staging accuracy in patients with SCLC, because SCLC is a highly metabolic disease. PET/CT is superior to PET alone. Approximately 19% of patients who undergo PET are upstaged from limited-stage to extensive-stage disease, whereas only 8% are downstaged from extensive-stage to limited-stage disease. For most metastatic sites, PET/CT is superior to CT imaging… Changes in management based on PET staging were reported in approximately 27% of patients, mainly because of alterations in the planned radiation field as a result of improved detection of intrathoracic sites of disease. Although PET/CT seems

to improve staging accuracy in SCLC, pathologic confirmation is still required for PET/CT-detected lesions that would alter the stage

b. Follow up/surveillance
    i. PET/CT is not recommended for routine follow-up

HERC staff summary

Evidence based reviews and expert guidelines support use of PET for initial staging of neuroendocrine tumors, multiple myeloma, and small cell lung cancer and in certain clinical scenarios with thyroid cancer. PET scans are not recommended for routine surveillance after treatment for any of these cancers.

HERC staff recommendation

1) Modify Diagnostic guideline D22 as shown below

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:

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 ~~OR for thyroid cancer if recurrence is suspected and I131 scintography is negative~~, 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.

Section 3.0

QALY Review

Policy Statement on HERC Use of Quality Adjusted Life Years
Disposition of Public Comments

Introduction

The comments below were received during the public comment period requested by HERC on two policy options presented on October 6, 2022.
No decision is planned on adopting a policy related to QALYs at the November 17, 2022 HERC meeting.

Themes from Public Comments

IDs/#s	Summary of Issue
B1, C1, D1, E1	Neither of the two options are acceptable for HERC policy adoption because QALYs are inherently discriminatory.
B4, D3, E2	QALYs devalue the life of a person with a disability, chronic illness or rare disease and does not reflect the lives of people with lived experience.
B5, C4, D4	Any study that uses QALYs should be excluded entirely from HERC's evidence review and discussion.
B3, B4, C4, C5, D4, E5	HERC's past use of QALYs may still be reflected in the Prioritized List and may violate existing laws such as the Americans with Disabilities Act.
A1, B3, D2	The HERC members do not adequately understand QALYs or the history of HERC's past use of QALYs in developing the Prioritized List.
A2, B6, C4, D1, E6	The HERC should form a panel of advocates, patients, and experts to educate HERC on QALYs.
A2, B2, D5, E4	The HERC should delay their vote until QALYs and their use is better understood.

Commenters

Identification	Stakeholder
A	Lorren Sandt, Executive Director, Caring Ambassadors Program, Inc *[Submitted 10/31/2022]*
B	Meghan Moyer, Policy Director, Disability Rights Oregon *[Submitted 10/31/2022]*
C	Paul Terdal, unaffiliated *[Submitted 10/31/2022]*
D	Sara van Geertruyden, Partnership to Improve Patient Care *[Submitted 11/1/2022]*
E	Tony Coelho, Chairman, Partnership to Improve Patient Care *[Submitted 11/1/2022]*

Policy Statement on HERC Use of Quality Adjusted Life Years
Disposition of Public Comments

Public Comments

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A1	The Caring Ambassadors Program is a national nonprofit advocacy organization based in Oregon City, Oregon. Caring Ambassadors has empowered patients to be advocates for their health since 1997. We provide education, support, and advocacy for people living with chronic diseases, focusing on lung cancer and hepatitis C. We respectfully submit our written public comment on the Policy Statement on HERC Use of Quality Adjusted Life Years (QALYs). As the state focuses on health care equity, HERC must consider using QALYs very carefully moving forward. It was clear from the October meeting that many members of the Value-based Benefits Subcommittee and the HERC committee needed to, but did not, clearly understand how QALYs have been used in Oregon and the discriminatory nature of their continued use in Oregon.
A2	Please table your decision and convene a panel of experts at the upcoming meeting to educate the members about QALYs before making this critical decision that will affect all Oregonians on the Oregon Health Plan. Through discussion with consumers, advocates, physicians, and the committee, HERC can develop a novel way to review evidence that will help create a healthcare system based on the state's health care equity focus.
B1	Disability Rights Oregon (DRO) would like to express our strong objections to both options being considered for the use of quality adjusted life years (QALYs) by the HERC. As patients and people with disabilities have commented in the past, the use of QALYs has no place in healthcare decisions due to its inherent discriminatory algorithms that drive health inequity.
B2	DRO urges the HERC to delay its vote on the use of QALYs, and instead take the time to meet with experts representing patients and people with disabilities as part of its November 2022 meeting. This issue is too important to rush to a vote. The current alternatives before the HERC do not sufficiently address the shortcomings of QALYs.
B3	Based on DRO's observations of the HERC's most recent meeting, there is a clear lack of understanding of the QALY metric and undereducation of what it was or how Oregon has used QALYs over the last 30 year when determining what would and would not be covered in the Oregon Health Plan. A thorough assessment of how a QALY score is created, why so many groups have opposed the use of QALYs, and why the Centers for Medicare & Medicaid Services has previously rejected Oregon's attempts to directly use QALYs in its prioritization process is sorely needed. At no point during the October 2022 HERC meeting was the background and history of QALY explained. There was no mention of how QALYs were used extensively before 2017 around when the HERC was formed – and how QALYs played a significant role in establishing the initial Prioritized List of Health Services that is largely still intact.
B4	DRO and many other groups care deeply about keeping QALY scores out of coverage discussions. First, because the QALY devalues a year of life lived with a disability, including chronic illness and rare diseases by attributing it with a numerical value below a 1 for optimal health. The QALY endows disabled lives with a fraction of the value of "healthy" lives or, in some cases, a negative valuation, meaning a year of life in that health state is worse than death. The "Quality" portion of the formula is derived from general population surveys, not those with lived experience. Additionally, the

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	research driving QALY calculations are not peer reviewed, and the data cannot be replicated by others. QALY calculations often do not represent key subpopulations for whom treatments may have a differential impact from the averages, or for whom treatment is more valuable due to a history of systemic racism or discrimination that has stymied access to effective treatments. DRO, in partnership with patients and people with disabilities, shared a letter on October 4, 2022 with the HERC in advance of its consideration of several proposals to consider QALYs. We hope members of the HERC will review the letter again. DRO strongly believes that advancing the two options for use of QALYs will put Oregon Health Authority at risk of violating disability and civil rights laws that bar discrimination based on race, color, national origin, sex, age, or disability.
B5	If the QALY-based cost effectiveness determination informs any study or report's overall conclusions and policy recommendations, it should not be considered in its entirety. DRO strongly opposes referencing studies that incorporate the use of QALYs into its analysis, recommendations, and determinations. Even conceptual considerations that may be included in a report relying on QALYs will be unduly influenced by the narrow scope of evidence that is fit for use in a QALY-based calculation and will fail to comprehensively represent the diversity of the impacted population. There is no part of a study relying on QALYs that is fit for use in making real world decisions about access to health care.
B6	We urge the HERC to convene an expert panel representing the disability community at its next meeting and delay its vote on this issue until the personal, societal, and legal implications of this decision are more fully expressed and understood.
C1	I am writing as a member of the public, and as the father of two Medicaid-eligible children with disabilities, to provide comment on the Draft Policy Statement on HERC Use of Quality Adjusted Life Years. I oppose both of the two options proposed for consideration.
C2	As the Hon. Tony Coelho – author of the Americans with Disabilities Act – testified on October 6, "the use of discriminatory metrics does not serve a purpose" – even in the approach outlined in Option 1, where QALYs are only used "to compare treatments for the same population." The QALY metric is inherently biased, and uses perceptions from non-disabled people about the value of the life of a person with disabilities. Further, the assertion in Option 1 that "QALYs will not inform scoring used to rank lines for the Prioritized List" won't really be true in practice – if QALYs are used in any way to determine what services are included on a list, or guidance notes for how services on the list are to be covered, then any service that is not included (or excluded in part based on guidance notes) is automatically ranked "below the line" and is excluded from coverage.
C3	Option 2 – where QALYs aren't discussed openly at Commission meetings, and references to QALYs are redacted – simply hides use of QALYs from public view, if Commission reports are based on research findings derived from use of QALYs. Hiding this use of QALYs from public view by redacting them may also violate ORS 192.314, Right to inspect public records.

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C4	Instead of moving quickly to adopt one of these two options, I urge you to convene an expert panel representing the disability community at its next meeting, and then to work with stakeholders. Ultimately, HERC should instead adopt a policy explicitly renouncing use of discriminatory measures such as QALYs, such as this: "Prohibition on Reliance on Discriminatory Measures. The Oregon Health Evidence Review Commission shall not develop or utilize, directly or indirectly, in whole or in part, through a contracted entity or other third-party, a dollars-per- quality-adjusted life year or any similar measures or research in determining whether a particular health care treatment is cost-effective, recommended, the value of a treatment, or in determining coverage, reimbursement, appropriate payment amounts, cost-sharing, or incentive policies or programs." To recap the background on this issue, Oregon's initial Medicaid waiver application was denied in 1992 on grounds that "Oregon's plan in substantial part values the life of a person with a disability less than the life of a person without a disability. This premise is discriminatory and inconsistent with the Americans with Disabilities Act." (I have provided a copy of this HHS denial letter to the HERC staff). Nevertheless, Oregon has consistently used discriminatory "Quality Adjusted Life Year" (QALY) metrics as a factor in ranking services on the prioritized list. QALY is a tool that estimates the value of a treatment according to years of additional life – discounted by the level of disability. This approach places a lower value on years of life for those with disabilities – such as my children – than on years of life for people without disabilities – and is inherently discriminatory. Over the past year, I have studied the Oregon Health Plan's use of QALY metrics in detail, and have met with senior OHA leadership for input. Here are my initial observations: Oregon Health Authority records show that when the US Department of Health and Human Services directed Oregon NOT to use the QALY metric in 1992, on grounds that it violated the Americans with Disabilities Act, the HRC simply worked around this by voting to adopt essentially the same discriminatory results derived from the QALY-based formula. (1) Despite Federal guidance to the contrary, Oregon continued to use the QALY as an explicit input in the "cost effectiveness" factor in the prioritization formula until 2017 Most of the condition-treatment pairs now on the list continue to be ranked using the old QALY-based factor HERC continues to rely upon QALY-based cost effectiveness reports from ICER, NICE, and other organizations. When staff prepare summaries of those reports for the commissioners, they frequently cite and call attention to the QALY scores, as is clearly documented in meeting materials Other factors in the formula, such as "Impact on Healthy Life" closely resemble the QALY concept. When HERC commissioners vote on these factors, they do so immediately after reviewing staff briefings and reports with QALY scores
C5	When the Oregon Health Plan ranks services on the prioritized list, using QALYs in any way, it engages in discrimination against individuals in violation of the Americans with Disabilities Act and contrary to the mission of the Oregon Health Policy Board to promote health equity. As the U.S. Department of Health and Human Services wrote to the State of Oregon in 1992, there are many ways that Oregon can allocate medical resources without violating the ADA: "Of course, there is a wide range of factors that Oregon may consider in allocating medical resources consistent with the ADA. These factors include, but are not limited to, the cost of medical procedures, the length of hospital stays, prevention of death, and prevention of contagious diseases. In general, Oregon may consider, consistent with the ADA, any content neutral factor that does not take disability into

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	account or that does not have a particular exclusionary effect on persons with disabilities." Please work with the disability policy community to revise your processes and adopt methods that are not discriminatory, and comply with civil rights protections.
D1	We are writing to comment on the HERC proposed guide for use of QALYs in meeting materials, processes and decisions, particularly related to the prioritized list of services. As patients and people with disabilities have commented, QALYs have no place in health care decisions due to their inherent discriminatory algorithms that drive health inequity. We urge HERC to delay its vote on the use of QALYs and instead take time to meet experts representing patients and people with disabilities as part of its November meeting. This issue is too important to rush a vote. The alternatives in front of the HERC do not sufficiently address QALY shortcomings.
D2	HERC states QALYs are a way for researchers to measure and predict the value of a medical service and its effect on a person's length and quality of life. It is apparent from prior conversations at the HERC that the commissioners do not fully understand the QALY metric and its flaws. QALYs fails to value health care for patients and people with disabilities, particularly people of color disproportionately represented among people with disabilities and chronic conditions, in several ways.
D3	First, QALY devalues a year of life lived with a disability, including chronic illness and rare diseases by attributing it with a numerical value below a 1 for optimal health, endowing disabled lives with a fraction of the value of "healthy" lives or, in some cases, a negative valuation, meaning a year of life in that health state is worse than death. Second, QALY and similar metrics such as the evLYG are overly simplistic. The patient-reported outcomes (PRO) instruments used to collect data to feed the QALY are incredibly broad, failing to capture the nuance of the disease or attribute value to the outcomes that matter to people living with the condition. The "weights" applied to the PRO data are determined from surveys of the general population. Reliance on population-based surveys to calculate health utility weights is especially troubling, as research has shown that disability bias is rampant among the general population. (1) Combined, this lead to metrics that fail to account for the gains in quality of life that are attributed to improvements such as the ability to sit up, the impact on caregiving needs, and ability to work, instead relying on broad surveys to determine whether a treatment's impact is valuable. Third, over-reliance on life extension as part of the calculation disadvantages people whose expected life span may be shorter due to their age, disability, condition, race and ethnicity, or other factors. Lastly, research driving QALY calculations often does not represent key subpopulations for whom treatments may have a differential impact from the averages or for whom treatment is more valuable due to a history of systemic racism or discrimination that has stymied access to effective treatments.
D4	Patients and people with disabilities sent HERC a letter in advance of its consideration of several proposals to consider QALYs in advance of its October, 2022 meeting that we hope you will review again. Advancing the two options for use of QALYs by the HERC will put the state at risk of violating disability and civil rights laws that bar discrimination based on race, color, national origin, sex, age, or disability. Comments below focus on Option 2. We strongly oppose referencing studies that incorporate the use of QALYs into its analysis, recommendations, and determinations. It is not

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	enough to simply redact the term. In a traditional cost effectiveness analysis, you cannot extricate the QALY portion and retain the validity of the remainder of the report. The entirety of the report will inevitably rely on the data and studies used to feed the cost-effectiveness model. These are often very narrow data sets and omit critical research and resources that do not fit within the QALY-based model's paradigm. This omitted data can include high-quality patient surveys conducted by reputable patient and disability advocacy organizations, patient registries, and real-world evidence. Many of these reports include "policy recommendations," which provide suggestions around whether and how to cover treatments and what utilization management strategies to employ. It would be incredibly rare for this section of the report to specifically reference QALYs, yet all of the recommendations are derived from the QALY-based cost-effectiveness model. Should the HERC reference this portion of the study, the HERC would still be referencing a QALY-based model. In effect, the QALY-based cost effectiveness determination informs the report's overall conclusions and policy recommendations. Even conceptual considerations that may be included in a report relying on QALYs will be unduly influenced by the narrow scope of evidence that is fit for use in a QALY-based calculation and will fail to comprehensively represent the diversity of the impacted population. There is no part of a study relying on QALYs that is fit for use in making real world decisions about access to health care.
D5	We urge the HERC convene an expert panel representing the disability community, and delay its vote until more fully understanding the personal, societal, and legal implications of this decision.
E1	We are writing to provide comments on the HERC proposed guide for use of quality-adjusted life years (QALYs) in HERC's meeting materials, processes and decisions, particularly related to the prioritized list of services for coverage under Medicaid. As patients and people with disabilities have commented, QALYs have no place in health care decisions due to their inherent discriminatory algorithms that drive health inequity. The alternatives in front of HERC do not sufficiently address QALY shortcomings. This letter describes our concerns with Option 1.
E2	We are concerned that HERC staff believes "making adjustments" when referencing QALYs is sufficient to prevent the inappropriate use of QALYs. Using QALYs to compare treatments for the same population does not mitigate the inherent flaws of the metric that not only devalue the lives of people with disabilities and older adults, but also devalues the quality-of-life improvements that matter to people living with the condition and fails to consider the impact of treatments for subpopulations that are the focus of efforts to advance health equity. While QALYs may not be used to rank the prioritized list, their use will impact the utilization management strategies that, in effect, create hurdles for accessing affordable care.
E3	We are similarly concerned that HERC proposes to search for alternative measures of cost effectiveness to cite without standards for the quality of the cost effectiveness measures being used. There are alternative metrics for assessing cost effectiveness that are potentially less inherently discriminatory if they rely on high quality evidence that captures the real-world experiences and priorities of patients and people with disabilities. We encourage HERC to shift its focus away from finding a way to endorse the use of QALYs. Instead, HERC should be abandoning QALYs and leading

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	the field of research and health economics to establish standards for high quality evidence that is credible and reliable for use in decision-making. In establishing standards, we would encourage the HERC to review the Equity and Inclusion Guiding Principles published by the Patient-Centered Outcomes Research Institute's (PCORI) Patient Engagement Advisory Panel calling for "critical engagement with historically disenfranchised groups whose interests have not been consistently centered due to systemic devaluations based on race, ethnicity, income, geography, age, sexual orientation, disability, and other characteristics." Inclusion and equitable partnerships were cornerstones of their principles for ensuring equity in research. As part of a landscape review, PCORI also identified aspects in measuring value that the HERC should consider in any effort to set standards for high quality research, including patient engagement, patient-centered impacts, patient preferences, patient-reported outcomes, real-world evidence, patient heterogeneity and diversity, measurement of social needs and social determinants of health, and transparency. (1) We welcome the opportunity to work with the HERC in a standard-setting process. Multi-Criteria Decision Analysis (MCDA) provides an interesting and potentially positive framework for assessing the value of treatments. While we do not support the use of QALYs as a component of MCDA, we do understand that MCDA provides an opportunity to assess including benefits, harms, costs, values and preferences and delivery system issues relevant to the topic at hand using a variety of nondiscriminatory measures. The use of multiple analytic frameworks for estimating value has strong potential for capturing patient preferences that are not captured in more traditional value frameworks if it is informed by affected stakeholders, i.e. patients and people with disabilities, and high quality evidence representing the diversity of the patient population. We urge the HERC to start with a process for creating standards for the quality of evidence it will use to make decisions.
E4	We strongly support early and increased engagement with consumer advocate members of the HERC. We remain concerned that advocates representing people with lived experience and impacted directly by the HERC's recommendations are not sufficiently engaged in the HERC process. In cases such as this, the HERC should not vote before convening experts from the disability, patient and provider communities to share their expertise directly with the HERC as part of a panel discussion. Also, the word limit on comments is a barrier to full engagement. The HERC members would learn more about the issue on which they are voting, in this case the discriminatory implications of QALYs, if they allowed for more input from outside experts.
E5	We strongly oppose the use of QALYs by the HERC and will continue to advocate against their use in decisions affecting people's lives. Oregon has been on notice for 30 years that its reliance on QALYs is contrary to civil and disability rights laws. As the author of the Americans with Disabilities Act testified to the HERC, "Oregon had 30 years to find new - nondiscriminatory - strategies for prioritizing its Medicaid list of services…The ADA was enacted to counter that bias and stigma for future generations. Combined with Section 504 of the Rehab Act and Section 1557 of the Affordable Care Act, there is no question that metrics like QALYs are not fit for use in our health system."

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E6	We urge the HERC to convene an expert panel representing the disability community at its next meeting, and delay its vote on this issue until more fully understanding the personal, societal, and legal implications of this decision.

References Provided by Commenters

ID	References
C4	Bob DiPrete and Darren Coffman, "A Brief History of Health Services Prioritization in Oregon," Oregon Health Authority, March 2007. https://www.oregon.gov/oha/HPA/DSI-HERC/Documents/Brief-History-Health-Services-Prioritization-Oregon.pdf
D3	https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.00504
E3	https://www.pcori.org/sites/default/files/PCORI-Landscape-Review-Summary-Patient-Stakeholder-Perspectives-Value-Health-Health-Care-August-2022.pdf

Impact of proposed QALY policies on HERC's work

At the October 6, 2022 meeting of the Health Evidence Review Commission (HERC), staff presented 4 policy options for consideration and formal adoption to guide the role of QALYs, if any, in future HERC deliberations and decisions:

Options 1 and 3 were posted for a 21-day public comment period, and a Commissioner asked staff to describe how option 1 would affect staff work.

Staff's normal process for a topic is to use evidence indexing tools (for example, PubMed and Google Scholar) to research the topic in question, searching for articles and policies that are relevant to the coverage question at hand. The materials frequently found include:

- systematic reviews or meta-analyses
- practice guidelines
- professional society position statements
- individual studies on clinical effectiveness
- policies from other payers (including Medicare, other Medicaid agencies, commercial insurance plans and payers from other high-income countries)

Many of these materials have a list of citations, and some of these references may also be reviewed by staff.

Staff then includes (or links) the relevant sources in the meeting materials, and uses them to guide development of the issue summary documents which are presented during public meetings. Any of these articles that are found may include QALYs. Generally, staff does not reference cost effectiveness unless it would be important to inform decisions about effectiveness or cost-effectiveness.

Any of the policy options would require some additional work from staff, but any option could generally be accomplished without jeopardizing timelines. For coverage guidances, contracted staff would need to follow similar procedures.

Impact of proposed QALY policies on HERC's work

The table below describes the steps that would need to be taken for each option:

Option	Impact on staff preparations	Other comments or impacts on work
1. HERC staff will incorporate the following adjustments when referencing QALYs as part of their recommendation development for the HERC in order to prevent the inappropriate use of QALYs: a) Only use QALYs to compare treatments for the same population. QALYs will not inform scoring used to rank lines for the Prioritized List. b) Perform a literature search for alternative measures of cost effectiveness and cite any that are relevant. c) Explicitly describe the role of QALYs vis a vis other decision factors considered using a simplified Multi-Criteria Decision Analysis (defined below), including benefits, harms, costs, values and preferences and delivery system issues relevant to the topic at hand. d) Offer HERC's consumer advocate members an opportunity to review and comment on meeting materials prior to public meeting material release. These comments will inform potential modifications and will be shared as part of public meeting materials. e) Continue to explore opportunities to improve accessibility for public testimony as part of HERC deliberations.	1. For topics where QALYs need to be referenced: a. Perform an additional literature search for alternative cost effectiveness measures b. Write a rationale describing why QALYs are relevant, affirming that they are only being used to compare treatments for the same condition c. Reconcile elements of a Multi-Criteria Decision Analysis (see example below) d. Email a draft of the issue summary and any referenced articles to consumer representatives with enough time for them to review. Correspond or meet with them as needed to address any concerns. 2. No impact for issues where QALYs appear in included articles but are not referenced in the issue summary.	1. QALYs would still appear in studies included or referenced in the meeting materials 2. Potential delays in presenting a topic that requires additional analysis and feedback related to QALYs 3. HERC staff is already planning ways to improve accessibility for public testimony as part of HERC deliberations

Impact of proposed QALY policies on HERC's work

Option	Impact on staff preparations	Other comments or impacts on work
2. Do not mention QALYs in staff-prepared meeting materials and avoid discussion of QALYs at Commission and subcommittee meetings.	1. For any articles with QALY references, ensure that they are not included in issue summaries and do not bring them up in meetings. If a member were to bring them up, staff should remind them of the policy. 2. In rare cases where QALY information in an article is potentially relevant, staff would need to perform other research or analysis. For example, staff might choose to report the impact of an intervention on quality of life from component studies rather than referring to a QALY calculation. Alternately, staff might search for additional cost-effectiveness analysis which does not use QALYs.	1. Minimal impact on staff work and committee discussion. 2. In rare cases, additional research may be required.
3. Do not mention QALYs in staff-prepared meeting materials and do not discuss QALYs at Commission meetings. Staff will also search all studies for "QALY" and redact any mention of QALYs from published articles.	1. Same as option 2 plus: a. Search each article included or linked in meeting materials for QALY use during packet preparations b. Include (rather than link) any articles mentioning QALYs in the packet. c. Redact any mention of QALYs from articles included in packet	1. Same as #2 but some additional work to redact QALYs. 2. Meeting materials will be longer because studies would be included in full, with redactions (instead of current practice now which is to link studies)

Impact of proposed QALY policies on HERC's work

Option	Impact on staff preparations	Other comments or impacts on work
4. Do not mention QALYs in staff-prepared meeting materials and do not discuss QALYs at Commission meetings. Search all studies for "QALY" and exclude from consideration any studies reporting QALYs.	1. Medical director would need to perform a preliminary review on relevant articles for reference to QALYs and eliminate the studies from consideration. The Medical Director would then review remaining articles and develop a recommendation.	1. Staff would lose access to information unrelated to QALYs because QALYs were referenced in one part of a document. For instance, summaries from NICE and ICER often include cost-effectiveness analysis, including QALYs, but also include basic information on effectiveness as well as extensive background on the condition and service in question.

HERC Use of Quality Adjusted Life Years

This document was presented at the October 6, 2022 HERC and VbBS meetings and options 1 and 3 were posted for public comment. It is included here for reference only. No decision is planned for the November 17, 2022 meeting.

Question: Should the Health Evidence Review Commission (HERC) adopt a policy to limit the consideration of quality adjusted life years (QALYs) in HERC processes and decision-making?

Question source: Individuals with disabilities, disability rights advocates and pharmaceutical industry representatives

Issue: The HERC has previously used QALYs as a factor in decision-making regarding which services will be covered by the Oregon Health Plan according to the Prioritized List of Health Services. It is important for the HERC to consider the potential impact of using QALYs on health inequities.

Staff recommendation:

- Choose one of the following options (below) as draft HERC policy on use of QALYs to post for public comment for a 21-day public comment period.
- Staff will bring a revised proposal, along with all comments received, to the November 17, 2022 HERC meeting.

Options for the use of QALYs by the HERC

1. HERC staff will incorporate the following adjustments when referencing QALYs as part of their recommendation development for the HERC in order to prevent the inappropriate use of QALYs:
    a) Only use QALYs to compare treatments for the same population. QALYs will not inform scoring used to rank lines for the Prioritized List.
    b) Perform a literature search for alternative measures of cost effectiveness and cite any that are relevant.
    c) Explicitly describe the role of QALYs vis a vis other decision factors considered using a simplified Multi-Criteria Decision Analysis (defined below), including benefits, harms, costs, values and preferences and delivery system issues relevant to the topic at hand.
    d) Offer HERC's consumer advocate members an opportunity to review and comment on meeting materials prior to public meeting material release. These comments will inform potential modifications and will be shared as part of public meeting materials.
    e) Continue to explore opportunities to improve accessibility for public testimony as part of HERC deliberations.

2. Do not mention QALYs in staff-prepared meeting materials and avoid discussion of QALYs at Commission and subcommittee meetings.

3. Do not mention QALYs in staff-prepared meeting materials and do not discuss QALYs at Commission meetings. Staff will also search all studies for "QALY" and redact any mention of QALYs from published articles.
4. Do not mention QALYs in staff-prepared meeting materials and do not discuss QALYs at Commission meetings. Search all studies for "QALY" and exclude from consideration any studies reporting QALYs.

Background

What are QALYs?

QALYs are a tool used in health services research to estimate the effectiveness of a medical intervention. QALYs combine measurements of effectiveness including mortality (life years) as well as morbidity (quality of life) as part of one assessment for medical intervention effectiveness, allowing for researchers to compare changes in health status within and across conditions (Carlson et al, 2020).

Medical interventions have often been assessed based on the impact they have on mortality, which can also be defined as the extension of "life years." When calculating an impact on life years, a researcher may assess how many years of life, on average, are extended with a medical intervention compared to no intervention at all or compared to another intervention.

In the case of a QALY calculation, a life year is further adjusted for its perceived quality. The quality-of-life determination is represented as a fraction of a healthy life year and is assigned a numeric or fractional value between 0-1, where 1 would represent the highest quality of life while a 0 would represent the lowest. For example, if a healthy life year is given the value of 1, then a year of life experienced with illness or disability may be valued at less than 1 year. This quality-of-life factor can be derived through a variety of means. However, it is most often elicited through surveys that seek to determine how a health condition is perceived to affect a person's quality of life. If an intervention improves quality of life, this difference in quality of life can be factored into the evaluation. This fractional number representing the improvement resulting from the intervention is then multiplied by the total life years extended to calculate the QALY as shown here:

Improvement in quality of life (0-1) x Life years extended = Number of QALYs gained

Example: A medical intervention is shown to extend life for a population with pre-existing disability on average by 10 years. The disability is estimated to reduce quality of life by 50% each year. However, the intervention does not improve the quality of life. The QALY for this medical intervention would be: 0.5 x 10 = 5 QALYs. For a population with no disability, this calculation would be 1 (instead of 0.5) x 10 = 10 QALYs.

Some interventions improve both quality of life and life expectancy, so QALYs will show benefits for interventions which substantially improve quality of life, length of life, or both.

QALYs are also used to assess the balance between the cost of an intervention and the benefit from that intervention, also known as the cost-effectiveness. If the cost of the intervention in the example above is $100,000, then the cost per QALY ($100,000 divided by 5 QALYs) would be $20,000 for the individual

with pre-existing disability, compared to $10,000 ($100,000 divided by 10 QALYs) for the for a person living without disability. In some cases, a service may be assessed to have a low-level health benefit and relatively low cost resulting in a high cost-per-QALY. Alternatively, an effective service may have a high initial cost, but a low cost-per-QALY because it provides substantial health benefit over many years.

This cost per QALY has been used to evaluate cost vs. benefit for individual medical interventions, and to compare cost effectiveness across multiple interventions. Cost-effectiveness data including cost per QALY have been used internationally and in the US to make healthcare coverage decisions, including by the HERC on a limited basis.

Concerns raised regarding HERC's use of QALYs

The HERC's inclusion of QALYs has been an area of concern for individuals with disabilities, disability rights advocates and pharmaceutical industry representatives. The overarching concern is that the use of QALYs is discriminatory against those with disabilities and chronic illness and that QALYs devalue life with a disability.

Some specific concerns that have been raised include but are not limited to:

- QALYs may result in a higher prioritization for treatments that extend life years for healthy or younger individuals compared to those with disability, chronic disease or older age.
- The surveys used to determine impact on quality of life for the purposes of QALY calculations have validity and reliability concerns.
- QALYs may not account for subgroup differences or for individuals with rare conditions.
- Use of QALYs in determining coverage will systematically create inequities for people whose disabilities and chronic conditions can be managed but not cured.

For a detailed review of the concerns with the use of QALY, see the 2019 report from the National Council on Disability, Quality-Adjusted Life Years and the Devaluation of Life with Disability: Part of the Bioethics and Disability Series.

HERC's use of QALYs to date

Transparency is a priority for the HERC's work. In keeping with this priority, HERC staff conducted an analysis of the role of QALYs in HERC decision-making since 2017. The results appear in Appendix A.

Since 2017, all prior HERC considerations for adopting a more central role of the use of QALYs have been either rescinded, not adopted or never implemented due to concerns for their potential discriminatory effects.

In recent years, the HERC has used QALYs in a limited fashion to inform decisions about coverage based on cost-effectiveness. When HERC has considered QALY data, it has almost always resulted in expanded coverage. Further, QALYs are always used to compare treatments for the same condition, rather than different conditions. Since QALY calculations remain prominent in the medical literature, QALY data are sometimes included in the meeting materials reviewed by Commissioners, and HERC staff may reference QALYs in issue summaries to support recommendations or inform HERC considerations. This information may inform a general understanding of relative effectiveness or cost-effective of services, even when not used in the active decision-making process. Any use of QALYs in meeting materials is referenced

along with other factors, including relevant information about benefits and harms, professional society recommendations, and patient values and preferences.

Alternatives to using QALYs in decision making about cost effectiveness

Cost effectiveness analysis remains a necessary component of medical decision making and, because of this, QALYs have remained in prominent use within the medical literature despite noted challenges and concerns. However, there are alternatives to QALYs when determining cost effectiveness.

Listed below are alternative measures to the use of QALYs as proposed in the NCD's report about QALYs, pp. 61-68. Examples include:

- Equal Value Life Years Gained Supplemental Measure (EvLYG)
  - An unweighted measure of years of extended life without a reduction in value of a life year by the use of a disability weight. The Institute for Cost Effectiveness Research (ICER) has announced its intent to calculate this measure as a supplement to QALYs in its reviews going forward.
- Not using QALYs when determining cost effectiveness, but evaluating the cost per positive outcome
  - For instance, a drug for rheumatoid arthritis might be evaluated in terms of "cost per remission" achieved.
- Multi-Criteria Decision Analysis
  - Consider different factors relevant to a health care decision, using QALYs as one component in that decision analysis. All factors are assigned a weight according to their importance for the decision at hand; however, there are known equity challenges in the determination and application of weights in health services decision making (Wailoo, 2009; Claxton, 2015).
- Patient Perspective Value Framework
  - A five-domain healthcare decision tool that centers patient goals, patient-centered outcomes, financial costs, quality of the evidence, and usability to determine the value of the treatment. Note that this framework has never been operationalized (Jalpa, 2018).
- The Efficiency Frontier
  - A visual modeling metric that expresses treatments as points on a graph, where cost per patient is one axis (x), and benefit is another (y); cost effectiveness is determined when a treatment scores "above" a pre-determined efficiency slope.

These alternative measures are cited in the 2019 NDC report as potential substitutions for QALYs. However, these are infrequently referenced in the published medical literature. As noted above, some of these measures are hypothetical. The absence of robust alternatives to QALY metrics in the literature poses a longstanding challenge among health services researchers who acknowledge the limitations of QALYs but find few feasible alternatives (Carlson, 2020). To the extent that cost effectiveness will remain a necessary component of medical decision-making for health payers, future research to develop alternative measures or models is warranted.

References

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Claxton, K., Sculpher, M., Palmer, S., & Culyer, A. J. (2015). Causes for concern: is NICE failing to uphold its responsibilities to all NHS patients?. Health economics, 24(1), 1-7.

Jalpa A. Doshi, Ellen Miller Sonet, Justin T. Puckett, and Henry Glick, "The Need for a New Patient Centered Decision Tool for Value-Based Treatment Choices in Oncology," HealthAffairs (blog), Health Affairs, March 19, 2018, https://www.healthaffairs.org/do/10.1377/hblog20180309.241877/full/

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Appendix A: Historic use of QALY calculations in HERC decisions

All meeting materials and minutes are available on HERC's Archived Meeting Materials page.

Previous examples of HERC's use of QALYs in decision-making processes

Use Cost/QALY as a threshold for topic review or in adding new treatments

In 2017, HERC considered using a cost-per-QALY threshold for determining which services should be considered cost-effective. Discussion occurred at the March 9, 2017 and May 18, 2017 meetings. The policy had been proposed to inform research plans by the state's Pharmacy and Therapeutics Committee and the Commission regarding potential decisions to give low priority to certain non-pharmaceutical services for selected indications, or all indications. The proposed use of a cost-per-QALY threshold was abandoned due to other considerations. (March 2017 Materials Minutes, May 2017 Materials Minutes, August 2017 Materials, Minutes)

As a part of this same dialogue, the Commission discussed an algorithm (Figure 1.9, shown in Appendix A) previously developed to aid in determining which new services should be added to the Prioritized List for potential coverage or which existing services should be removed from the list based on new information.[1] The Commission voted to stop using Figure 1.9 in its biennial report and did not adopt any new rubric since each decision requires unique consideration. The meeting minutes indicate that "parts [of Figure 1.9] are unclear and other parts are incorrect."

Consideration of QALYs in end-of-life cancer care

The Health Services Commission (HERC's predecessor, which maintained the Prioritized List through 2011) added policy in October 2009 related to the treatment of cancer with little or no benefit. While this statement of intent greatly expanded coverage for advanced cancer care, it still excluded coverage for some treatments based on their predicted impact on expected median survival. It also included this language related to QALYs: "The Health Services Commission is reluctant to place a strict $/QALY (quality adjusted life-year) or $/LYS (life-year saved) requirement on end-of-life treatments, as such measurements are only approximations and cannot take into account all of the merits of an individual case. However, cost must be taken into consideration when considering treatment options near the end of life. For example, in no instance can it be justified to spend $100,000 in public resources to increase an individual's expected survival by three months when hundreds of thousands of Oregonians are without any form of health insurance." Due to staff concerns about discrimination, this policy was completely revised for the October 2014 Prioritized List, and the resulting new guideline note omitted the criteria related to QALYs, further expanding coverage for advanced cancer treatment.

Other use of QALYs on individual topics

In late 2021, staff searched meeting materials and minutes for any references to QALYs to better understand how they have been used in the Commission's decision-making. All discrete topics where

[1] In 2005, the legislature added a requirement for the HSC to consider cost effectiveness in developing the Prioritized List. In response, the HSC developed a figure which used QALYs to inform an effectiveness score which had a significant role in the ranking methodology. The role of QALYs was not determinative, but was one factor considered in the methodology. In practice, however, QALYs were only used, when available, to compare multiple treatments for the same condition.

QALYs were presented in studies provided to the Commission or referenced in discussion or issue summaries since 2017 are included in the table below. Some decisions prior to 2017 are also included in the table when relating to disability. Each decision is characterized by how the use of QALYs influenced (or may have influenced, if not discussed) a given decision.

Decisions resulting in new, expanded or reaffirmed coverage

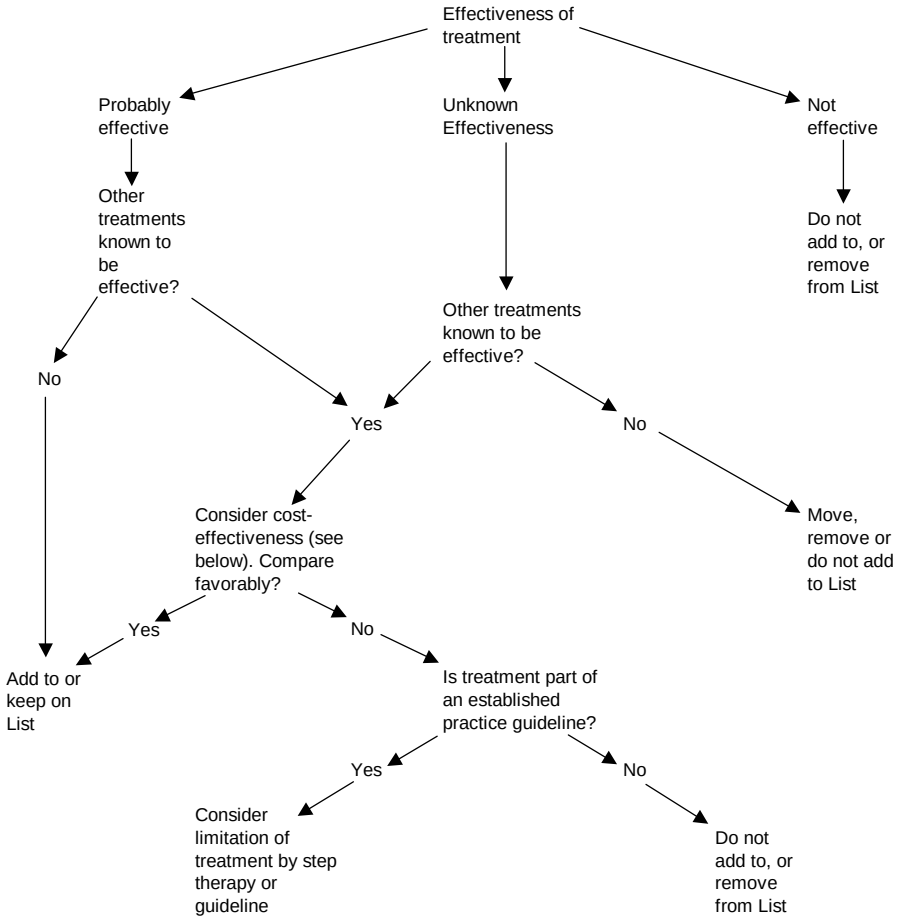
Service	Use of Cost per QALY or QALY	Meeting date(s)
Treatments for varicose veins	Minor factor supporting coverage	1/16/2020 11/14/2019 11/9/2017
Drug eluting stents	Significant impact on the decision to cover, as initial higher cost is offset by savings from fewer reoperations.	8/9/2019
Sacroiliac joint fusion	Minor factor in support of coverage	1/17/2019
Diabetes prevention program added	Significant factor supporting coverage	8/9/2018
Community health workers [race/ethnicity related]	Moderate factor supporting use of community health workers to increase cancer screening attendance	3/8/2018
Cataract coverage expansion [disability/age related]	Preventable loss in QALYs a significant factor in favor of coverage	1/18/2018
Subcutaneous cardiac rhythm monitors	Minor factor in support of coverage	11/8/2018
Deep brain stimulation for Parkinson's disease [disability/age related]	Significant factor in support of coverage	1/18/2018
Medical treatment for early stage liver fibrosis from hepatitis C	One report cited higher cost/QALY for early-stage disease. HERC made no change to coverage	2/2/2017
Cochlear implants—clarified coverage for bilateral implants [disability related]	Higher cost/QALY for second cochlear implant Cost/QALYs mentioned in 2015 report cited but not relevant to question about hearing loss threshold	3/12/2015 5/9/2013

Decisions resulting in noncoverage or restricted coverage

Service	Use of Cost per QALY, or QALY	Meeting date(s)
PET scanning for staging and restaging for breast cancer	Mentioned but not a factor in the decision (Coverage was later added in 2021, based on updated clinical practice guidelines)	3/8/2018
Digital breast tomography	High cost/QALY cited as a reason for noncoverage (due to low clinical benefit) 2/2/2017 VBBS/HERC meeting	2/2/2017

FIGURE 1.9
PROCESS FOR INCORPORATING INFORMATION ON CLINCAL INFORMATION AND COST-EFFECTIVENESS INTO THE PRIORITIZED LIST

HERC will review evidence as outlined in Figure 1.9. Evidence regarding the effectiveness of a treatment will be used according to the following algorithm:



The cost of a technology will be considered according to the grading scale below, with "A" representing compelling evidence for adoption, "B" representing strong evidence for adoption, "C" representing moderate evidence for adoption, "D" representing weak evidence for adoption and "E" being compelling evidence for rejection:

- A = more effective and cheaper than existing technology
- B = more effective and costs < $25,000/LYS or QALY > existing technology
- C = more effective and costs $25,000 to $125,000/LYS or QALY > existing technology
- D = more effective and costs > $125,000/LYS or QALY > existing technology
- E = less or equally as effective and more costly than existing technology

List of Abbreviations

- EvLYG: Equal Value Life Years Gained Supplemental Measure
- LYS: Life-year saved
- HERC: Health Evidence Review Commission
- HSC: Health Services Commission
- NDC: National Council on Disabilities
- PET: Positron emission tomography
- QALY: Quality Adjusted Life Year
- VBBS: Value-based Benefits Subcommittee