Health Evidence Review Commission

May 20, 2021

1:30 PM - 3:30 PM

Online meeting

Join online meeting here

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Section 1.0

Call to Order

AGENDA

HEALTH EVIDENCE REVIEW COMMISSION

Online Meeting

May 20, 2021

1:30-3:30 pm

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

#	Time	Item	Presenter	Action Item
1	1:30 PM	Call to order	Kevin Olson	
2	1:35 PM	Approval of minutes (3/11/2021)	Kevin Olson	X
3	1:40 PM	Director's report	Jason Gingerich	
4	1:45 PM	Bylaws Revision	Jason Gingerich	X
5	1:55 PM	Value-based Benefits Subcommittee report	Ariel Smits	X
6	2:30 PM	Coverage Guidance Topic Scope statement on PANDAS/PANS/AE	Ariel Smits Bethany Godlewski Val King	X
7	3:15 PM	Other Public Comment		
8	3:20 PM	Next steps • Schedule next meeting – August 12, 2021 (online)	Kevin Olson	
9	3:30 PM	Adjournment	Kevin Olson	

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

MINUTES

HEALTH EVIDENCE REVIEW COMMISSION
Online meeting
March 11, 2021

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

Members Absent: Gary Allen, DMD; Michael Adler, MD.

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

Also Attending: Bethany Godlewski & Val King MD, MPH (Center for Evidence-based Policy); Tracy Futch, Cris Pinzon, RN; Devki Nagar (Myriad Genetics); Diane Quiring (Oregon Health Authority); Siobhan Hess.

Call to Order

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

Minutes Approval

MOTION: To approve the minutes of the 1/21/2021 meeting as presented. CARRIES 8-0. *(Absent: Hodges, Kansagara)*

Director's Report

Meetings
Gingerich said we will be meeting virtually through August at least.

Legislative
He gave a brief overview of a few bills up for considerations this session, including Senate Bill 457 which, if passed, would significantly impact Commission operations. Staff are watching this bill carefully.

Gingerich reminded Commissioners that if they are testifying or advocating about a piece of legislation, to please clarify if they are speaking as a Commission or 'wearing one of their other hats.'

Coverage Guidances
The Evidence-based Guidelines Subcommittee is meeting in April; we will start our actual coverage guidance review for Deep Brain Stimulation for Epilepsy. A scoping statement for pediatric immune disorders affecting the brain that cause behavioral symptoms (PANDA/PANS) has already been out for public comment.

Subcommittee Assignments
Gingerich said Cris Pinzon has been confirmed by the Senate, with her official term beginning on March 15, 2021. She will serve on the Value-based Benefits Subcommittee (VbBS). However, if appointed it could result in a quorum of the HERC present at VBBS meetings. In order to address that situation, he asked Dr. Gary Allen, a dentist, if he would consider stepping aside to make room for Pinzon on the subcommittee. Dr. Allen agreed with the caveat that he be involved with VbBS if there are dental topics to discuss. Staff will manage that situation when it comes up.

Pinzon said she would be happy to step aside when there are dental topics to make way for Dr. Allen.

MOTION: To appoint Cris Pinzon to VbBS: Carries: 10-0.

MOTION: To remove Gary Allen from VbBS: Carries: 10-0.

Value-based Benefits Subcommittee (VbBS) Report on Prioritized List Changes
Meeting materials, pages 41-102

Ariel Smits reported the VbBS met earlier in the day, 3/11/2021. She summarized the subcommittee's recommendations.

RECOMMENDED CODE MOVEMENT (changes to the 10/1/2021 Prioritized List unless otherwise noted)

- Add a new code for administration of a monoclonal antibody for treatment of COVID-19 to a covered line
- Move the diagnosis code for osteochondritis dissecans of the knee to the covered knee surgery line and add several procedure codes to that line with a new guideline
- Delete spinal chiropractic/osteopathic manipulation procedure codes from four lines without spinal diagnoses
- Make various straightforward coding changes

RECOMMENDED GUIDELINE CHANGES (changes to the 10/1/2021 Prioritized List unless otherwise noted)

- Reaffirm the ancillary guideline regarding nerve blocks without change
- Edit the hernia guideline to allow repair of inguinal hernias that are painful, affect function or prevent employment. It also allows repair of all inguinal and femoral hernias in women. *Effective January 1, 2022*
- Edit the telemedicine guideline to simplify and remove practice guideline type wording
- Edit the prenatal genetic testing guideline to remove requirements for family or ethnic history prior to certain screening tests
- Edit the acupuncture guideline to add two additional lines with SUD diagnoses to the SUD entry
- Delete all of the coding specifications from the Prioritized List and either merge them into existing guidelines, put them into new guidelines or delete them (2 coding specifications).
- Reaffirm lack of coverage for biomarkers for prostate cancer and update the GN173 entry to reflect the current review date
- Edit the bariatric surgery guideline to remove any requirement for presurgical weight loss

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Testimony:

Devki Nagar stated she was available for questions regarding genetic screening tests today and thanked the Commission for this opportunity.

MOTION: To accept the VbBS recommendations on *Prioritized List changes* as stated. See the VbBS minutes of 3/11/2021 for a full description. Carries: 10-0.

Bylaws Revisions

Meeting materials, pages 103-119
Handout

Gingerich gave a presentation from the meeting handout. He highlighted the proposed changes to the bylaws and conflict of interest policy and asked members to email him their thoughts before the next meeting. There was minimal discussion.

Public Comment

There was no additional public comment.

Adjournment

Meeting adjourned at 2:41 pm. Next meeting will be from 1:30-4:30 pm on Thursday, May 20, 2021, online.

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Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on March 11, 2021

For specific coding recommendations and guideline wording, please see the text of the 3/11/2021 VbBS minutes.

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VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
March 11, 2021
9:00 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, MBA, Vice-chair; Kathryn Schabel, MD; Brian Duty, MD; Mike Collins; Adriane Irwin, PharmD; Regina Dehen, ND, LAc.

Members Absent: Gary Allen, DMD.

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

Also Attending: Diane Quiring (OHA); Bethany Godlewski (CEBP); Cristine Pinzon, RN; Melissa Stoppler MD and Melissa Wood (Exact Sciences); Jeffrey Lawrence MD; Ashley Svenson and Devki Nagar (Myriad Genetics); Conniew; Teresa Turner; Justin; Stephanie Lattig; Mimi Boumatar; TBARR; Broc Finlayson; Rashelle Kukuk; Siobhan Hess; Brian Fahs.

- **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 1/21/21 VbBS meeting were reviewed and approved.

  Gingerich noted that Kevin Olson's term was extended by the Legislature and that Cristine Pinzon was confirmed for HERC membership, effective March 15, 2021. Ms. Pinzon attended today's meeting as an observer.

  Smits reviewed the errata document and the items discussed with leadership document. There was no discussion. The items discussed with leadership regarded the lack of coverage of cardiac PET scans. The recommendation is continued non-coverage.

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- **Topic: Straightforward/Consent Agenda**

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

  Recommended Actions:
  1) Add D2928 (Prefabricated porcelain/ceramic crown – permanent tooth) to line 591 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH)
     a. Advise HSD to remove D2928 from the Excluded File
  2) Ancillary Guideline 1 NERVE BLOCKS was reaffirmed without change as shown in Appendix A
  3) Advise HSD to add CPT 96127 (Brief emotional/behavioral assessment (eg, depression inventory, attention-deficit/hyperactivity disorder [ADHD] scale), with scoring and documentation, per standardized instrument) to the Diagnostic File and remove from the Ancillary file
  4) Remove CPT 99408 and 99409 (DAST, SBIRT) from all lines on the Prioritized List
     a. Advise HSD to add CPT 96160 and 96161 to the Diagnostic Procedures file

  MOTION: To approve the recommendations stated in the consent agenda. CARRIES 7-0.

- **Topic: 2022 Biennial Review Inguinal and Femoral Hernias**

  Discussion: Smits reviewed the summary document. Walker reviewed a summary document regarding standardized tools for measuring function and pain. Pinzon asked whether these tools were available in other languages, were assessed for cultural sensitivity, and were used in non-literate populations. Walker responded that several tools were available in multiple languages; Smits noted that these tools can be verbally administered to patients with low literacy.

  The group discussed the difficulty in determining what a clinically significant score was for these various tools. The group decided to not include any specific tools in the revised guideline and to not required a "clinically significant score" as this was indeterminable.

  Schabel suggested removing the 4th criteria regarding inability to keep or maintain gainful employment as some OHP patients are not in the workforce due to retirement or other reasons. However, Hodges replied that this clause was very important to the CCOs. Smits pointed out that it was an "or" requirement, so non-working persons could qualify if they had pain or trouble with activities of daily living.

  There was significant reworking of the third clause by the subcommittee.

  Recommended Actions:
  1) Modify GN24 as shown in Appendix A

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

- **Topic: COVID codes March 2021**

  Discussion: There was no discussion about this topic.

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Recommended Actions:

1) Add HCPCS M0245 (intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring) to line 399 INFLUENZA, COVID-19 AND OTHER NOVEL RESPIRATORY VIRAL ILLNESS
    a. Advise HSD to add HCPCS Q0245 (Injection, bamlanivimab and etesevimab, 2100 mg) to the Ancillary File

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

- **Topic: Simplification of Ancillary Guideline A5**

Discussion: Smits reviewed the summary document. There was a friendly amendment by staff to remove "remote monitoring devices" from the first paragraph, as remote patient monitoring was identified on specific lines in the List. There was no further discussion about this topic.

Recommended Actions:

1) Modify Ancillary Guideline A5 as shown in Appendix A

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

- **Topic: Prenatal genetic testing guideline equity edits**

Discussion: Smits reviewed the summary document.

Testimony:

Devki Nagar, a Myriad employee and genetic counselor, testified in favor of the proposed changes. These tests are standard prenatal screenings. Many patients with hemoglobinopathies (>50%) are not from a high-risk ethnic group.

Smits clarified for the subcommittee that the tests being discussed are standard prenatal screening tests offered by maternity care providers. Smits noted that the complementary changes for preconception screening in the non-prenatal genetic testing guideline were more complicated and would be discussed by the Genetic Advisory Panel at their next meeting.

Recommended Actions:

1) Modify Diagnostic Guideline D17 as shown in Appendix A

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

- **Topic: Revisions to the acupuncture guideline**

Discussion: There was no discussion about this topic.

Recommended Actions:

1) Modify GN92 as shown in Appendix A

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

- **Topic: Coding specification review 2021**

Discussion: There was no significant discussion about this topic.

Recommended Actions:

1) Delete all coding specifications on the Prioritized List
2) Modify Guideline Notes 21, 74, 106, 108, 167, and 170 as shown in Appendix A
3) Add the new guideline notes to various lines as shown in Appendix B
4) Add ICD-10 K90.89 (Other intestinal malabsorption) to line 552 OTHER NONINFECTIOUS GASTROENTERITIS AND COLITIS
5) Remove ICD10 F50.89 (Other specified eating disorder) from line 149 FEEDING AND EATING DISORDERS OF INFANCY OR CHILDHOOD
6) Delete GN42 and GN45

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

- **Topic: Biomarkers for prostate cancer**

Discussion: Smits reviewed the summary document.

Testimony:

Melissa Stoppler, MD, Exact Sciences senior advisor: Dr. Stoppler testified that the score informs the patient of their risk of high-risk disease if radical prostatectomy is done. NCCN has newly released its 2021 guideline. The recommendation to use biomarkers is now a 2A category recommendation (uniform consensus among panelists). ASCO 2020 guideline states "biomarkers are reasonable in low risk men in whom management decisions will be affected by the results." Medicare, 8 Medicaid programs (including CA and WA), and most private payers cover these tests.

Jeffrey Lawrence, MD, retired medical oncologist, former employee of Genomic Health and current consultant for Exact Sciences, declared no compensation for this testimony: Dr. Lawrence testified about his personal experience with prostate cancer. When he was diagnosed, he requested Oncotype Dx; the score helped him make a decision about treatment. He went on to have a radical prostatectomy and was found to have high risk disease at surgery. He had adjuvant radiation therapy, hormonal therapy. He is doing well now. He feels that active surveillance would have been a big mistake in his case. He noted that two studies show Oncotype Dx is equal or superior to MRI for determining a patient's risk status.

Ashley Svenson, genetic counselor and policy specialist at Myriad, the company that markets Prolaris: Ms. Svenson testified that the ASCO guideline is based on a 2019 systematic review of the literature and recommends consideration of use of these tests in specific clinical scenarios. Ms. Svenson strongly encouraged the Commission to take the ASCO recommendation into

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account. MediCal, California's state Medicaid program, is evidence-based and covers these tests. An AHRQ review did not find studies on biomarkers that met inclusion criteria; the review did not find evidence of ineffectiveness. The Oregon Health Plan covers breast cancer prognostics but not prostate prognostics.

Discussion:
Brian Duty remarked that although he is a urologist, he does not currently care for prostate cancer patients. The American Urological Association/Society of Urologic Oncology guideline states that tissue-based biomarkers have not been shown to have a role in low or very low risk disease. He asked the urologic oncology providers at OHSU, who did not feel that these tests should be covered. The statewide urologic association was given this information and invited to provide testimony, and no one responded. Prostate MRI is used more commonly to help with decision making.

Olson noted that NCCN concluded that biomarkers are an acceptable test but didn't go so far as to affirmatively encourage the use of biomarker prognostics. It's one tool in a provider's toolbox.

Duty noted that there are ongoing studies of these biomarkers but the results may not be published for some time. In his department, MRI of prostate is considered to be more reliable that biomarkers; however, they have an experienced radiologist reading their prostate MRIs. He noted that prostate biopsies are random. MRI allows more for a more targeted biopsy to help guide treatment.

Schabel asked about the relative cost of MRI versus biomarkers; Melissa Wood, employed by Exact Sciences, stated that it costs $3,800 for Oncotype Dx prostate.

Hodges noted that her CCO sees some requests for these types of tests. However, she noted that patients still need the MRI.

Recommended Actions:
1) Update GN173 entry for prostate cancer gene expression tests as shown in Appendix A
2) Modify GN148 as shown in Appendix A

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

- **Topic: Pre-surgical weight loss in the bariatric surgery guideline**

Discussion: There was no discussion about this topic.
Recommended Actions:
1) Modify GN8 as shown in Appendix A

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

- **Topic: Osteochondritis dissecans of the knee**

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Discussion: Smits reviewed the summary document. Schabel suggested removing criterion of skeletal maturity, as this procedure can be appropriate in children. While it is uncommon to see the condition in children, it can be important to fix.

Recommended Actions:

1) Remove ICD10 M93.26 family (Osteochondritis dissecans, knee) from line 356 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE
2) Add ICD10 M93.26 family to line 431 INTERNAL DERANGEMENT OF KNEE AND LIGAMENTOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT
3) Remove CPT 29866-29867 (Arthroscopy, knee, surgical; osteochondral autograft(s)/allograft(s) (eg, mosaicplasty)) from line 662 and modify GN173 as shown in Appendix A
4) Add CPT 29866-29867 to line 431 INTERNAL DERANGEMENT OF KNEE AND LIGAMENTOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT
5) Add a new guideline to line 431 as shown in Appendix B

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

- **Topic: Non-Spinal Chiropractic Manipulation**

Discussion: There was no discussion about this topic.

Recommended Actions:

1) Remove osteopathic and chiropractic spinal manipulation (CPT 98925-98929, 98940-98942) from the following lines:
    a. 416 PERIPHERAL NERVE ENTRAPMENT; PALMAR FASCIAL FIBROMATOSIS
    b. 418 DISORDERS OF SHOULDER, INCLUDING SPRAINS/STRAINS GRADE 4 THROUGH 6
    c. 463 OSTEOARTHRITIS AND ALLIED DISORDERS
    d. 467 BRACHIAL PLEXUS LESIONS

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

- **Public Comment:**

No additional public comment was received.

- **Issues for next meeting:**
-no carry over issues

- **Next meeting:**

May 20, 2021; Virtual meeting

- **Adjournment:**

The meeting adjourned at 11:45 AM.

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Appendix A
Revised Guideline Notes

Reaffirmed without change

ANCILLARY GUIDELINE A1, NERVE BLOCKS

The Health Evidence Review Commission intends that single injection and continuous nerve blocks (CPT 64400-64450, 64461-64463, 64505-64530) should be covered services if they are required for successful completion of perioperative pain control for, or post-operative recovery from a covered operative procedure when the diagnosis requiring the operative procedure is also covered. Additionally, nerve blocks, are covered services for patients hospitalized with trauma, cancer, or intractable pain conditions, if the underlying condition is a covered diagnosis.

ANCILLARY GUIDELINE A5, TELEHEALTH, TELECONSULTATIONS AND ONLINE/TELEPHONIC SERVICES

Telehealth services include a variety of health services provided by synchronous or asynchronous electronic communications, including secure electronic health portal, audio, or audio and video, ~~as well as remote monitoring devices~~ and clinician-to-clinician virtual consultations.

Criteria for coverage

The clinical value of the telehealth service delivered must reasonably approximate the clinical value of the equivalent services delivered in-person. Coverage of telehealth services requires the same level of documentation, medical necessity, and coverage determinations as in-person visits. ~~Specifically, covered telehealth services must meet all of the following criteria.~~

~~A) Documentation must include all of the following:~~
- ~~1) use model SOAP charting, or as described in program's OAR;~~
- ~~2) include patient history, provider assessment, treatment plan and follow-up instructions;~~
- ~~3) support the assessment and plan;~~
- ~~4) retain encounter in the patient's medical record and be retrievable.~~

~~B) Include medical decision making or service delivery (e.g. behavioral health intervention/psychotherapy, other forms of therapy).~~

~~C) Include permanent storage (online or hard copy) of the encounter.~~

~~D) Meet applicable HIPAA standards for privacy and security, except for regulations for which federal authorities are exercising enforcement discretion. (Certain requirements for encryption will not be enforced by federal authorities (or required by OHP) during the COVID-19 emergency.) This means services such as Facetime, Skype or Google Hangouts can be used for service delivery. See https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html for details.) HIPAA compliant platforms should be used whenever possible.~~

~~E) Include patient-clinician agreement of informed consent, discussed with and agreed to by the patient and documented in the medical record.~~

Examples of ~~reimbursable~~ covered telephone or online services include but are not limited to:

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

Examples of ~~non-reimbursable~~ non-covered telehealth services include but are not limited to:

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Appendix A
Revised Guideline Notes

A) Prescription renewal.
B) Scheduling a test.
C) Reporting normal test results.
D) Requesting a referral.
E) Services which are part of care plan oversight or anticoagulation management (CPT codes 99339-99340, 99374-99380 or 99363-99364).
F) Services which relate to or take place within the postoperative period of a procedure provided by the physician are not separately covered. (Such a service is considered part of the procedure and is not be billed separately.)

~~***Telehealth services billed using in-person codes***~~

~~Telehealth services described in this section are synchronous services, generally provided with both audio and video capability and billed with the same procedure codes that would be billed for in-person services, with mode of delivery indicated by the use of specific modifiers and/or place of service codes specified by the plan. Telephone visits are an acceptable replacement for the equivalent service provided by synchronous audio and video, if synchronous audio and video capabilities are not available or feasible.~~

~~The patient may be in the community or in a health care setting. The provider may be in any location in which appropriate privacy can be ensured. If language services are provided, the interpreter may be in any location in which appropriate privacy can be ensured.~~

Codes eligible for telehealth delivery ~~billed in this manner~~ include 90785, 90791, 90792, 90832-90834, 90836, 90837-90840, 90846, 90847, 90951, 90952, 90954, 90955, 90957, 90958, 90960, 90961, 90963, 90964-90970, 96116, 96156-96171, 96160, 96161, 97802-97804, 99201-99205, 99211-99215, 99231-99233, 99307-99310, 99354-99357, 99406-99407, 99495-99498, G0108-G0109, G0270, G0296, G0396, G0397, G0406-G0408, G0420, G0421, G0425-G0427, G0438-G0439, G0442-G0447, G0459, G0506, G0508, G0509, G0513, G0514, G2086-G2088. Additional codes are covered when otherwise appropriate according to this guideline note and other applicable coverage criteria.

The originating site code Q3014 is covered only when the patient is present in an appropriate health care setting and receiving services from a provider in another location.

~~Telehealth services are covered for inpatient, outpatient and emergency services for new or established patients.~~

Clinician to Patient Services billed using specified codes indicating telephone or online service delivery

Covered ~~T~~telephonic and online services~~,~~ include~~ing~~ services related to evaluation, assessment and management ~~diagnostic workup~~ as well as other technology-based services (CPT 98966-98968, 99441-99443, 99421-99423, 98970-98972, ~~G2010,~~ G2012, G2061-G2063, G2251-G2252) ~~are covered for services for new and established patients.~~

Covered telephone and online services billed using these codes do not include either of the following:

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Appendix A
Revised Guideline Notes

A) Services related to a service performed and billed by the physician or qualified health professional within the previous seven days, regardless of whether it is the result of patient-initiated or physician-requested follow-up.
B) Services which result in the patient being seen within 24 hours or the next available appointment.

Clinician-to-Clinician Consultations (telephonic, online or using electronic health record)

Covered ~~Coverage of~~ interprofessional consultations include consultations delivered online, through electronic health records or by telephone (CPT 99446-99449, 99451-99452). ~~is included as follows:~~

~~*Consulting Providers (CPT 99451, 99446-99449)*~~
~~A) For new or established patients.~~
~~B) Consult must be requested by another provider.~~
~~C) Can be for a new or an exacerbated condition.~~
~~D) Cannot be reported more than 1 time per 7 days for the same patient.~~
~~E) Must report cumulative time spent, even if time occurs over multiple days.~~
~~F) Cannot be reported if a transfer of care or request for face-to-face visit occurs as a result of the consultation within the following 14 days.~~
~~G) Cannot be reported if the patient was seen by the consultant within the past 14 days.~~
~~H) The request and reason for consultation is documented in the patient's medical record.~~
~~I) Requires a minimum of 5 minutes of medical consultation, discussion and/or review.~~

~~*Requesting Providers (CPT 99452)*~~
~~A) Consult must be reported by requesting provider. (not for the transfer of a patient or request for face-to-face consult)~~
~~B) Reported only when the patient is not on site with the requesting provider at the time of consultation.~~
~~C) Cannot be reported more than 1 time per 14 days per patient.~~
~~D) Requires a minimum of 16 minutes. Includes time for referral prep and/or communicating with the consultant.~~
~~E) Can be reported with prolonged services, non-direct.~~

~~Limited information provided by one clinician to another that does not constitute collaboration (e.g., interpretation of an electroencephalogram, report on an x-ray or scan, or reporting the results of a diagnostic test) is not considered a consultation.~~

DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

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

A) Genetic counseling (CPT 96040, HPCPS S0265) for high-risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect.
B) Genetic counseling (CPT 96040, HPCPS S0265) prior to consideration of chorionic villus sampling (CVS), amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening

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Appendix A
Revised Guideline Notes

C) Validated questionnaire to assess genetic risk in all pregnant women
D) Screening ~~high-risk ethnic groups~~ for hemoglobinopathies (CPT 83020, 83021)
E) Screening for aneuploidy with any of six screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, contingency, and cell free fetal DNA testing] (CPT 76813, 76814, 81508, ~~-~~81510, 81511, 81420, 81507, 81512, 82105, 82677,84163)
F) Ultrasound for structural anomalies between 18 and 20 weeks gestation (CPT 76811, 76812)
G) CVS or amniocentesis (CPT 59000, 59015, 76945,76946, 82106, 88235, 88261-88264, 88267, 88269, 88280, 88283, 88285, 88289,88291) for a positive aneuploidy screen, maternal age >34, fetal structural anomalies, family history of inheritable chromosomal disorder or elevated risk of neural tube defect.
H) Array CGH (CPT 81228, 81229) when major fetal congenital anomalies are apparent on imaging, or with normal imaging when array CGH would replace karyotyping performed with CVS or amniocentesis in (H) above.
I) FISH testing (CPT 88271, 88272, 88274, 88275, 81171, 81172) only if karyotyping is not possible due a need for rapid turnaround for reasons of reproductive decision-making (i.e. at 22w4d gestation or beyond)
J) ~~Screening for Tay-Sachs carrier status (CPT 81255) in high-risk populations. First step is hex A, and then additional DNA analysis in individuals with ambiguous Hex A test results, suspected variant form of TSD or suspected pseudodeficiency of Hex A~~
K) Screening for cystic fibrosis carrier status once in a lifetime (CPT 81220-81224)
L) Screening for fragile X status (CPT 81243, 81244, 81171. 81172) once in a lifetime ~~in patients with a personal or family history of~~
    ~~a. fragile X tremor/ataxia syndrome~~
    ~~b. premature ovarian failure~~
    ~~c. unexplained early onset intellectual disability~~
    ~~d. fragile X intellectual disability~~
    ~~e. unexplained autism through the pregnant woman's maternal line~~
M) Screening for spinal muscular atrophy (CPT 81329) once in a lifetime
N) Screening for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255) once in a lifetime. Ashkenazi Jewish carrier panel testing (CPT 81412) is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing.
O) Expanded carrier screening only for those genetic conditions identified above

The following genetic screening tests are not covered:

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

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

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GUIDELINE NOTE 8, BARIATRIC SURGERY

Line 320

Bariatric/metabolic surgery (limited to Roux-en-Y gastric bypass, and sleeve gastrectomy) is included on Line 320 when the following criteria are met:

A) Age ≥ 18
B) The patient has obesity with a:
    1) BMI ≥ 40 OR
    2) BMI ≥ 35 with:
        a) Type 2 diabetes, OR
        b) at least two of the following other serious obesity-related comorbidities: hypertension, coronary heart disease, mechanical arthropathy in major weight bearing joint, sleep apnea
C) Repeat bariatric surgery is included when it is a conversion from a less intensive (such as gastric band or sleeve gastrectomy) to a more intensive surgery (e.g. Roux-en-Y). Repair of surgical complications (excluding failure to lose sufficient weight) are also included on this and other lines. Reversal of surgical procedures and devices is included on this line when benefits of reversal outweigh harms.
D) Participate in the following four evaluations and meet criteria as described.
    1) Psychosocial evaluation: (Conducted by a licensed mental health professional)
        a) Evaluation to assess potential compliance with post-operative requirements.
        b) Must remain free of abuse of or dependence on alcohol during the six-month period immediately preceding surgery. No current use of any nicotine product or illicit drugs and must remain abstinent from their use during the six-month observation period. Testing will, at a minimum, be conducted within 1 month of the quit date and within 1 month of the surgery to confirm abstinence from illicit drugs. Tobacco and nicotine abstinence to be confirmed in active users by negative cotinine levels at least 6 months apart, with the second test within one month of the surgery date.
        c) No mental or behavioral disorder that may interfere with postoperative outcomes[1].
        d) Patient with psychiatric illness must be stable for at least 6 months.
    2) Medical evaluation: (Conducted by OHP primary care provider)
        a) Pre-operative physical condition and mortality risk assessed with patient found to be an appropriate candidate.
        b) Optimize medical control of diabetes, hypertension, or other co-morbid conditions.
        c) Female patient not currently pregnant with no plans for pregnancy for at least 2 years post-surgery. Contraception methods reviewed with patient agreement to use effective contraception through 2nd year post-surgery.
    3) Surgical evaluation: (Conducted by a licensed bariatric surgeon associated with program[2])
        a) Patient found to be an appropriate candidate for surgery at initial evaluation and throughout period leading to surgery.
        b) Received counseling by a credentialed expert on the team regarding the risks and benefits of the procedure and understands the many potential complications of the surgery (including death) and the realistic expectations of post-surgical outcomes.
    4) Dietician evaluation: (Conducted by licensed dietician)

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a) ~~Evaluation of adequacy of prior dietary efforts to lose weight. If no or inadequate prior dietary effort to lose weight, must undergo six-month clinically supervised weight reduction program (including intensive nutrition and physical activity counseling as defined by the USPSTF).~~
b) Counseling in dietary lifestyle changes
c) Counseling on post-operative dietary change requirements

E) Participate in additional evaluations:
1) Post-surgical attention to lifestyle, an exercise program and dietary changes and understands the need for post-surgical follow-up with all applicable professionals (e.g. nutritionist, psychologist/psychiatrist, exercise physiologist or physical therapist, support group participation, regularly scheduled physician follow-up visits).

[1] Many patients (>50%) have depression as a co-morbid diagnosis that, if treated, would not preclude their participation in the bariatric surgery program.
[2] All surgical services must be provided by a program with current accreditation (as a comprehensive center or low acuity center) by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP)

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

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

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

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 or mucous membrane involvement.

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

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

For severe atopic dermatitis/eczema, first-line agents include topical moderate- to high- potency corticosteroids and narrowband UVB. Second line agents include topical calcineurin inhibitors (e.g.

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

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

1) causes symptoms of intestinal obstruction and/or strangulation; OR
2) is incarcerated (defined as non-reducible by physical manipulation); OR
3) causes pain and functional limitations as assessed and documented by a medical professional OR
4) Affects the patient's ability to obtain or maintain gainful employment.

Repair of inguinal and femoral hernias in women are included on Line 168 due to the different natural history of disease in this population.

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), parastomal hernias and most incisional hernias (ventral incisional hernias). 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 42, CHEMODENERVATION FOR CHRONIC MIGRAINE**~~

~~*Line 410*~~

~~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.~~

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~~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~~

~~**GUIDELINE NOTE 45, CHEMODENERVATION OF THE BLADDER**~~

~~*Line 327*~~

~~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~~

GUIDELINE NOTE 74, GROWTH HORMONE TREATMENT

Lines 40,386,469,652

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.

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,4,5,12,62,64,65,92,111,112,114,125,129,133,135,157,158,191,199-201,208,210,214,215,229, 234,237,238,258,259,262,271,276,286,287,294,314-316,329,342,361,396,397,402,410,420,434,463, 540,558

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

Line 1 PREGNANCY

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

Hyperemesis gravidarum

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

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

Breech presentation

ICD-10-CM: O32.1

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

Back and pelvic pain of pregnancy

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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.

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

Acupuncture is included on ~~this line~~ these lines only when used as part of a program that offer 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, 420, 434 and 558

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 463 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 463 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions per year.

*Line 540 TENSION HEADACHES

Acupuncture is included on Line 540 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.

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GUIDELINE NOTE 106, PREVENTIVE SERVICES

Lines 3,622

Included on Line 3 are the following preventive services:

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

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

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

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

Colorectal cancer screening is included on Line 3 for average-risk adults aged 50 to 75, using one of the following screening programs:

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

Colorectal cancer screening for average-risk adults aged 76 to 85 is covered only for those who

A) Are healthy enough to undergo treatment if colorectal cancer is detected, and
B) Do not have comorbid conditions that would significantly limit their life expectancy.

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

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

GUIDELINE NOTE 108, CONTINUOUS GLUCOSE MONITORING

Line 8

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

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

B) Adults with type 1 diabetes on insulin pump management (including the CGM-enabled insulin pump):
   1) Who have received or will receive diabetes education specific to the use of CGM AND
   2) Who have used the device for at least 50% of the time at their first follow-up visit.

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

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

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

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 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.

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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 or HCPCS S3854) for breast tumors that are estrogen receptor or progesterone receptor positive, HER2 negative, lymph node negative, and only in those cases categorized as high clinical risk.

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

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

For melanoma, BRAF gene mutation testing (CPT 81210) is included on Line 229.

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

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

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

For prostate cancer, Oncotype DX Genomic Prostate Score, Prolaris Score Assay (CPT 81541), and Decipher Prostate RP (CPT 81542) are included on Line 662.

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.

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GUIDELINE NOTE 167, CHOLECYSTECTOMY FOR CHOLECYSTITIS AND BILIARY COLIC

Lines 55,641

Cholecystectomy for cholecystitis and biliary colic are including on Line 55 when meeting the following criteria:

A) For cholecystitis, with either:
   1) The presence of right upper quadrant abdominal pain, mass, tenderness or a positive Murphy's sign, AND
   2) Evidence of inflammation (e.g. fever, elevated white blood cell count, elevated C reactive protein) OR
   3) Ultrasound findings characteristic of acute cholecystitis or non-visualization of the gall bladder on oral cholecystegram or HIDA scan, or gallbladder ejection fraction of < 35%.

B) For biliary colic (i.e. documented clinical encounter for right upper quadrant or epigastric pain with gallstones seen on imaging during each episode) without evidence of cholecystitis or other complications is included on Line 55 only when
   1) Recurrent (i.e. 2 or more episodes in a one year period) OR
   2) A single episode in a patient at high risk for complications with emergent cholecystitis (e.g. immunocompromised patients, morbidly obese patients, diabetic patients) OR
   3) When any of the following are present: elevated pancreatic enzymes, elevated liver enzymes or dilated common bile duct on ultrasound.

Otherwise, biliary colic is included on Line 641.

ICD-10 K82.8 (Other specified diseases of gallbladder) is included on Line 55 when the patient has porcelain gallbladder or gallbladder dyskinesia with a gallbladder ejection fraction <35%. Otherwise, K82.8 is included on Line 641.

GUIDELINE NOTE 170, INTRATHECAL OR EPIDURAL DRUG INFUSION

Lines 71,285,292,491

Implantation, revision and replacement of devices for intrathecal or epidural drug infusion systems is only included on these lines when the patient meets the criteria for at least one of the categories (A or B) below:

A) Placed for administration of baclofen for spasticity where all of the following (1-3) occur:
   1) The patient has had an adequate trial of non-invasive methods of spasticity control and not had adequate control of spasticity or had intolerable side effects with these methods.
   2) The spasticity is causing difficulties with at least one of the following (a, b or c):
      a) Posture or function
      b) Balance or locomotion
      c) Self-care (or ease of care by parents or caregivers)
   3) The patient has a favorable response to a trial intrathecal dosage of the anti-spasmodic drug prior to pump implantation.

B) Palliation for severe, intractable pain due to life-limiting active cancer which

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1) Has not been responsive to non-invasive systemic pain control strategies or had intolerable side effects from such strategies, AND
2) Where the patient has a favorable response to a trial of an intrathecal dose of the analgesic drug prior to pump implantation

Intrathecal or epidural drug infusion pump insertion, revision, and replacement are included on Line 662 for use with chronic non-malignant pain and all other indications not listed above. See Guideline Note 173 INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS. Removal of pumps placed for such indications is included on Line 285.

Maintenance (i.e. reprogramming, medication refill) of epidural or intrathecal medication infusion pumps for any condition is only included on these lines for patients who

A) have no significant complications with the current medication regimen or pump delivery system AND
B) are continuing to receive adequate benefit from the pump-delivered medication.

Maintenance (but not replacement) of these infusion systems may be paired with ICD-10-CM Z45.49 (Encounter for adjustment and management of other implanted nervous system device).

CPT codes 62320-62323 (Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), interlaminar epidural or subarachnoid) are only included on Lines 71 and 292 for trials of antispasmodics in preparation for placement of a baclofen pump.

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
~~29866-29867~~	~~Arthroscopy, knee, surgical; osteochondral autograft(s)/allograft(s) (eg, mosaicplasty)~~	~~Insufficient evidence of effectiveness~~	~~November 2007~~

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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~~ Insufficient evidence of effectiveness	~~January, 2018~~ March 2021 Coverage guidance
81541	Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping)	~~Unproven Intervention~~ Insufficient evidence of effectiveness	~~August, 2015~~ 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	~~January 2018~~ March 2021

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GUIDELINE NOTE XXX PANCREAS/KIDNEY TRANSPLANTS

Line 83

Simultaneous pancreas kidney transplant (SPT) is only included on this line for type I diabetes mellitus with end stage renal disease (E10.2). Pancreas after kidney transplant (PAK) is only included on this line for other type I diabetes mellitus with secondary diagnosis of Z94.0 (Kidney transplant status).

GUIDELINE NOTE XXX OTHER DISEASES OF VOCAL CORDS

Lines 205, 559

ICD-10 J38.3 (Other diseases of vocal cords) is included on Line 205 for treatment of abscesses and cellulitis of the vocal cords; it is included on Line 559 for treatment of spastic dysphonia.

GUIDELINE NOTE XXX OTHER INTESTINAL MALABSORPTION

Line 227,552

ICD-10-CM code K90.89 (Other intestinal malabsorption) is included on this line only for chronic steatorrhea, exudative enteropathy, and protein-losing enteropathy. Otherwise, it is included on line 552.

GUIDELINE NOTE XXX CARCINOMA IN SITU OF PENIS

Line 258

CPT 96567-96573 (Photodynamic therapy) and 96574 (Debridement of premalignant hyperkeratotic lesion) are included on this line only for pairing with ICD-10-CM D07.4 (Carcinoma in situ of penis).

GUIDELINE NOTE XXX COMPRESSION OF VEIN

Line 262,639

ICD-10-CM code I87.1 (Compression of vein) is included on line 262 for superior vena cava syndrome only. Otherwise it is included on line 639.

GUIDELINE NOTE XXX CATHETER DIRECTED THROMBOLYSIS

Line 280

Catheter directed thrombolysis (CPT 37212-37214) is not paired on this line with peripheral DVT (ICD-10-CM I82.6, I82.7, I82.A, I82.B, I82.8, I82.9).

GUIDELINE NOTE XXX BENIGN NEOPLASM OF PAROTID GLAND

Line 287,627

ICD-10-CM code D11.0 (Benign neoplasm of parotid gland) is included on line 287 only for parotid gland pleomorphic adenomas. Otherwise it is included on line 627.

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GUIDELINE NOTE XXX KNEE ARTHROSCOPY

Line 356

Knee arthroscopy (29871, 29873-29876, 29884-29887) is not included on this line when paired with osteoarthritis/osteoarthrosis of the knee (M17.0-M17.9).

GUIDELINE NOTE XXX OTHER SPECIFIED EATING DISORDER

Line 381,631

ICD-10 F50.89 (Other specified eating disorder) is included on Line 381 for psychogenic loss of appetite. ICD-10 F50.89 is included on Line 631 for pica in adults and for all other diagnoses using this code.

GUIDELINE NOTE XXX IMPLANTATION OF INTRAVITREAL DRUG DELIVERY SYSTEM

Line 383

CPT 67027 (Implantation of intravitreal drug delivery system) is included on this line for use with medications other than intraocular steroid implants.

GUIDELINE NOTE XXX ORTHOPTIC AND/OR PLEOPTIC TRAINING

Line 393

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

GUIDELINE NOTE XXX WIGS

Line 424,586

ICD-10-CM codes L58.0 (Acute radiodermatitis), L64.0 (Drug-induced androgenic alopecia) and L65.8 (Other specified nonscarring hair loss) are only included on this line for pairing with HCPC A9282 (Wig). Otherwise these ICD10 codes are included on line 586.

GUIDELINE NOTE XXX PLANTAR FASCIA INJECTION

Line 539

CPT 20550 (Plantar fascia injection) only appears on this line for corticosteroid injections. The treatment is appropriate to the condition, but has limited evidence of effectiveness.

GUIDELINE NOTE XXX CERVICOGENIC HEADACHE

Line 540

Osteopathic manipulative treatment and chiropractic manipulative treatment (CPT 98926-98929, 98940-98943) pair on this line only with cervicogenic headache (R51).

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Appendix B
New Guideline Notes

GUIDELINE NOTE XXX CHEMODENERVATION

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

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 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 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:

E) have chronic migraine defined as headaches on at least 15 days per month of which at least 8 days are with migraine
F) has not responded to or have contraindications to at least three prior pharmacological prophylaxis therapies (e.g. beta-blocker, anticonvulsant or tricyclic antidepressant)
G) their condition has been appropriately managed for medication overuse
H) treatment is administered in consultation with a neurologist or headache specialist.

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Appendix B
New Guideline Notes

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 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 L74.52, R61)

GUIDELINE NOTE XXX OSTEOCHONDRAL ALLOGRAFT/AUTOGRAFT TRANSPLANTATION (OAT) OF THE KNEE

Line 431

Osteochondral Allograft/Autograft Transplantation (OAT) is included on this line only when ALL of the following conditions are met:

1) The patient is younger than age 50; AND
2) There is no malignancy, degenerative or inflammatory arthritis in the joint; AND
3) The patient has focal full thickness lesions (Grade III or IV) of the weight bearing surface with absent degenerative changes of the surrounding articular cartilage (Outerbridge grade II or less) and normal appearing cartilage around the defect; AND
4) The patient is not a candidate for total knee replacement; AND
5) The patient has failed standard conservative treatment including medication management and completed course of physical therapy; AND
6) The patient has normal knee alignment and stability

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Appendix C
Revised Coding Specifications

All (33) coding specifications were deleted from the Prioritized List:

Line 3
~~CPT code 96110 can be billed in addition to other CPT codes, such as evaluation and management (E&M) codes or preventive visit codes.~~

Line 8
~~CPT 95250 and 95251 are included on this line for services related to real-time continuous glucose monitoring but not retrospective (professional) continuous glucose monitoring.~~

Line 40
~~ICD-10-CM E23.0 is included on this line for conditions other than adult human growth hormone deficiency.~~

Line 55
~~ICD-10 K82.8 (Other specified diseases of gallbladder) is included on Line 55 when the patient has porcelain gallbladder or gallbladder dyskinesia with a gallbladder ejection fraction.~~

Line 71
~~CPT codes 62320-3 are only included on Lines 71 and 292 for trials of antispasmodics in preparation for placement of a baclofen pump.~~

Line 83
~~SPK included for type I diabetes mellitus with end stage renal disease (E10.2), PAK only included for other type I diabetes mellitus with secondary diagnosis of Z94.0.~~

Line 174
~~CPT 61885 is included on this line only for vagal nerve stimulation. It is not included on this line for deep brain stimulation.~~

Line 205
~~ICD-10 J38.3 is included on Line 205 for treatment of abscesses and cellulitis of the vocal cords; it is included on Line 559 for treatment of spastic dysphonia.~~

Line 227
~~ICD-10-CM code K90.89 (Other intestinal malabsorption) is included on this line only for chronic steatorrhea, exudative enteropathy, and protein-losing enteropathy.~~

Line 258
~~CPT 96567, 96573 and 96574 are included on this line only for pairing with ICD-10-CM D07.4.~~

Line 262
~~ICD-10-CM code I87.1 is included on this line for superior vena cava syndrome only.~~

Line 280

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Appendix C
Revised Coding Specifications

~~Catheter directed thrombolysis (CPT 37212-37214) is not paired on this line with peripheral DVT (ICD-10-CM I82.6, I82.7, I82.A, I82.B, I82.8, I82.9).~~

Line 287
~~ICD-10-CM code D11.0 is included on this line only for parotid gland pleomorphic adenomas.~~

Line 292
~~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.)~~

~~CPT codes 62320-3 are only included on Lines 71 and 292 for trials of antispasmodics in preparation for placement of a baclofen pump.~~

Line 327
~~ICD-10-CM codes N40.1 and N40.3 are only included on this line when post-void residuals are at least 150 cc's.~~

Line 351
~~Chemodenervation with botulinum toxin injection (CPT 67345) is included on this line for the treatment of strabismus due to other neurological disorders (ICD-10 H50.89).~~

Line 356
~~Knee arthroscopy (29871, 29873-29876, 29884-29887) is not included on this line when paired with osteoarthritis/osteoarthrosis of the knee (M17.0-M17.9).~~

Line 362
~~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
~~Chemodenervation with botulinum toxin injection (CPT 43201) is included on this line for treatment of achalasia (ICD-10 K22.0).~~

Line 381
~~ICD-10 F50.89 is included on Line 381 for psychogenic loss of appetite. ICD-10 F50.89 is included on Line 631 for pica in adults and for all other diagnoses using this code.~~

Line 383
~~CPT 67027 (Implantation of intravitreal drug delivery system) is included on this line for use with medications other than intraocular steroid implants.~~

Line 386
~~ICD-10-CM E23.0 is included on this line for conditions other than adult human growth hormone deficiency.~~

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Appendix C
Revised Coding Specifications

Line 393
~~CPT 92065 is included on Line 393 only for pairing with ICD-10 H50.31 intermittent monocular esotropia), H50.32 (Intermittent alternating esotropia), H50.33 (Intermittent monocular exotropia), and H50.34 (Intermittent alternating exotropia).~~

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

Line 424
~~ICD-10-CM codes L58.0, L64.0 and L65.8 are only included on this line for pairing with HCPC A9282.~~

Line 426
~~ICD-10-CM Q82.8 is included on this line only for Darier disease.~~

Line 444
~~ICD-10-CM codes Z71.89, Other specified counseling, and Z63.4 Disappearance and death of family member are only included in this line when identified as secondary diagnoses with a primary diagnosis of F43.8, Other reactions to severe stress.~~

Line 517
~~Chemodenervation with botulinum toxin injection (CPT 64650, 64653) is included on this line for the treatment of axillary hyperhidrosis and palmar hyperhidrosis (ICD-10 L74.52, R61).~~

Line 539
~~CPT 20550 only appears on this line for corticosteroid injections. The treatment is appropriate to the condition, but has limited evidence of effectiveness.~~

Line 540
~~Osteopathic manipulative treatment and chiropractic manipulative treatment (CPT 98926-98929, 98940-98943) pair on this line only with cervicogenic headache (R51).~~

Line 559
~~ICD-10 J38.3 is included on Line 205 for treatment of abscesses and cellulitis of the vocal cords; it is included on Line 559 for treatment of spastic dysphonia.~~

Line 631
~~ICD-10 F50.89 is included on Line 381 for psychogenic loss of appetite. ICD-10 F50.89 is included on Line 631 for pica in adults and for all other diagnoses using this code.~~

Line 641
~~ICD-10 K82.8 (Other specified diseases of gallbladder) is included on Line 55 when the patient has porcelain gallbladder or gallbladder dyskinesia with a gallbladder ejection fraction.~~

Line 652
~~ICD-10-CM E23.0 is included on this line only for adult human growth hormone deficiency.~~

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MINUTES

Evidence-based Guidelines Subcommittee

Virtual Meeting
April 8, 2021
2:00-5:00pm

Members Present: Devan Kansagara, MD, Chair; Alison Little, MD, MPH; Lynnea Lindsey, PhD; Leslie Sutton; Max Kaiser, DO; Vern Saboe, DC.

Members Absent: Eric Stecker, MD, MPH, Vice-Chair; Leda Garside, RN, MBA; Michael Adler, MD

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

Also Attending*: Valerie King MD, MPH and Bethany Godlewski, PhD (OHSU Center for Evidence-based Policy), Dr. Paul Motika and Dr. Ahmed Raslan (OHSU), Sarah Lemley and Kym McCornack, Northwest PANDAS/PANS Nework; Paul Ryan and Molly Ochoa, PACE; Roxy Mayer on behalf of Oregon House Representative Rachel Prusak; BranDee Trejo, Cristy Simila RN; Cyndy Novak (Medtronic), Julie O.; Katy McDowell (Tonkon Torp); Marci Herrall; Nicole Thompson; Robert Garcia; Jacek/Jack Haciak, PsyD; Chris Demars (OHA); Rachel Daniels; Lynda Finch; Sara Fletcher; Ivan Vejar; Cathy's iphone; Tamara; Jennifer Rowan; Heather Korbmacher; Rob Millis; Meggan Short.
**some attendees are identified using the names displayed in the online meeting*

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1. Call to Order

Devan Kansagara called the meeting of the Evidence-based Guidelines Subcommittee (EbGS) to order at 2:00 pm. A quorum of members was present at the meeting.

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2. Minutes Review

Minutes from the 9/10/2020 meeting were reviewed and approved 6-0.

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3. Staff Report

Gingerich reported that Cris Pinzon has joined the HERC and VbBS, replacing Leda Garside. However, Ms. Pinzon will not be joining the EGBS, and Ms. Garside will continue serving on the EbGS.

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4. Deep Brain Stimulation for Refractory Epilepsy Draft Coverage Guidance

Gingerich introduced the appointed experts for this topic, Dr. Paul Motika, a neurologist at OHSU who specializes in epilepsy treatment, and Dr. Ahmad Raslan, a neurosurgeon at OHSU who serves as the head of the epilepsy surgery team. The following biographies were read aloud for each expert:

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Dr. Paul Motika is Associate Professor of Neurology at OHSU. He specializes in the treatment of epilepsy. He has advanced training in the diagnosis and treatment of many types of epilepsy, including difficult-to-treat forms. He also has experience with interpretation of electroencephalograms (EEG), as well as surgical treatments for epilepsy. He has no conflicts of interest to declare other than his employment.

Dr. Ahmed Raslan is Associate Professor and Vice Chair of Neurosurgery at OHSU and serves as Director of Epilepsy and Brain Mapping. His focused practice is epilepsy surgery, brain mapping for tumors and epilepsy which often involves awake craniotomy, surgery for chronic and cancer pain (Trigeminal neuralgia, spinal pain and many other chronic pain syndromes), and movement disorders. He declared no conflicts of interest other than his employment.

Dr. Valerie King and Dr. Bethany Godlewski from OHSU's Center for Evidence Based Policy presented the draft report on deep brain stimulation (DBS) for refractory epilepsy. Dr. Ariel Smits reviewed patient values and preferences, resource allocation, and other decision factors related to DBS. Dr. Smits presented the staff's weak recommendation against coverage. Kansagara asked if there is evidence of decrease in seizures with DBS. King responded that in the SANTE trial, the intervention group had a 44% reduction in seizures compared to 12% in the control group, which works out to approximately a 6-seizure-a-month reduction. Six patients were seizure free 2 years after implantation.

Dr. Motika and Dr. Raslan gave expert input. Motika noted that the population under consideration has a severe disease with a high seizure burden at baseline. The likelihood of improvement in seizures is very low with medication changes in this population. Raslan noted that the two RCTs that were reviewed had a very short time period where the intervention was blinded. DBS reduces CNS excitability, but this takes many months or years to occur. The peak treatment clinical effect occured during the unblinded phase in the RCTs. He noted that there was a 56% reduction in seizure freqency after 2 years (in the unblinded, observational portions of studies).

Sutton asked about the experts' interpretation of seizure severity and how that impacts patients' lives. Motika noted that this population has a higher risk of sudden death in epilepsy; therefore, even a small reduction in seizure frequency brings down the risk of death over time. There are harms of having many seizures over time in terms of cognition and life expectancy. Raslan noted that many of his patients have a 50% reduction in seizure frequency and a 50% reduction in length of seizures after DBS. He tells his patients that if they do not see any improvement after 1-2 years that they will not see any benefit from the therapy. Motika agreed that it can take years to see the maximal effect of the therapy. Raslan noted that the more a patient has seizures, the more excitable their brain is and the more likely they are to continue to have seizures. It takes a while to reduce this excitability. Both experts noted that vagus nerve stimulation (VNS) has similar outcomes and it is widely covered. VNS and DBS are both global therapies; they have the same target in the brain despite the location of the seizure. VNS is indicated for patients who have depression. Many patients who fail VBS have DBS as the remaining treatment option. Kansagara asked about the volume of OHP patients who would qualify for DBS. Motika responded that OHSU is the referral center for much of the region; he believes there are a dozen a year on OHP for whom this surgery might be recommended; Raslan reported that OHSU implanted DBS in six OHP patients last year (2020).

The subcommittee discussed coverage of DBS. Little agreed with the staff recommendation against coverage. The data are not supportive, although she expressed empathy for the lack of other choices in

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this patient population. Sutton noted that this was the only option for some patients and that some patients do receive benefit from this procedure. Epilepsy has a large impact on patients' day to day lives. This would be another tool in the toolbox and would not be highly used. Sutton supported a recommendation for coverage. Kaiser also supported coverage given the lack of other options for these patients but noted that this was a borderline decision based on the weak level of evidence. Lindsey was also in favor of coverage. Kansagara said that since seizure frequency was an important outcome listed in the report, the chance of reduction in seizure frequency may be worth the risk for some individuals. Saboe agreed with a weak recommendation for coverage.

HERC staff suggested possible coverage wording that could be used if the subcommittee recommendation is in favor of coverage. The subcommittee wanted wording added to the staff language regarding the balance of benefit and harms: "However, data from the unblinded portion of the reviewed study showed a cumulative reduction in seizure severity and frequency, suggesting that there is a subgroup of patients that achieve a clinically meaningful benefit from DBS." King noted that some of this reduction is due to non-responders dropping out of the study. Raslan suggested coverage of multifocal epilepsy as well as temporal lobe epilepsy. Motika also recommended removing the restriction to temporal lobe epilepsy as many of these patients cannot have their seizure focus localized. Several members agreed that that site of seizure focus should not be specified in the recommendation.

A motion was made to approve the recommendation for coverage as revised. **Motion approved 5-1 (Nay: Little).**

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Deep brain stimulation for treatment of refractory epilepsy is recommended for coverage for patients who have failed multiple anti-seizure medications and who are ineligible for or who have failed resective surgery or vagus nerve stimulation (weak recommendation).

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5. PANDAS/PANS/AE

Gingerich introduced the topic. King reviewed the draft scope statement. There were no questions or discussion from subcommittee members.

Public testimony

Sarah Lemley, Executive Director of the Northwest PANDAS/PANS Network: Ms. Lemley requested that the subcommittee seek national experts to inform the scope statement and coverage guidance report. She said that Oregon has no experts in these disorders and that none are part of Ms. Lemley's PANDAS/PANS network. She said that local providers lag behind the science for these conditions. The scope needs to focus on the current standard of care. She said the scope should ask, "what is the already established standard of care for these children?" and "What can be learned from centers of excellence about the best care for these children?" She concluded by introducing Paul Ryan and Molly Ochoa.

Molly Ochoa, Board Member of the PACE Foundation: Ms. Ochoa yielded her time to Paul Ryan.

Paul Ryan, President of the PACE Foundation: Mr. Ryan described the Centers of Excellence for PANDAS/PANS, particularly the University of Arizona who was the first Center, established in 2016. These clinics have multidisciplinary teams that see patients in a single day, including psychologists and neurologists. All patients are treated regardless of ability to pay, including Medicare and Medicaid beneficiaries. Those who are not diagnosed with PANDAS/PANS are referred to other specialty care. Mr. Ryan also said these centers conduct robust research into these areas, acting as education sources for their regions about what PANDAS is. Mr. Ryan said that if PANDAS/PANS is caught early, 90% of these children would never have to go to a clinic. Pamphlets and brochures are given to primary care and pediatricians to educate these providers. Demographically, clinics exist in all regions of the country, with the exception of the Pacific Northwest. Mr. Ryan said that Ms. Lemley has a lot of informational media to share with members if they are interested.

Kym McCornack, Outreach Coordinator of the NW PANDAS/PANS Network: Ms. McCornack requested that definitions used in the population description of the scope statement should be revised with definitions from the NIMH website. She requested further definition of the comparators, and the outcomes and harms of these comparators. Important outcomes should include suicidality, suicide, ER visits, mental health/police crisis calls, inpatient psychiatric treatment, inability to attend school, out of pocket expenses, as well as caregiver and family outcomes.

Roxy Mayer on behalf of Rep. Rachel Prusak's office: Ms. Mayer stated Oregon Representative Prusak wants the committee to know her support of evidence-based discussion of this topic and she is pleased to see that the HERC is addressing this topic. Rep. Prusak is in support of access for children to the needed treatments for these disorders and will be monitoring the process.

Subcommittee Discussion

Kansagara led the discussion after public testimony was given. Gingerich provided an overview of the coverage guidance process and stated that only five outcomes are examined in order to capture the most clinically meaningful outcomes to determine coverage. The subcommittee looked at the Scope statement and edited each of the sections of the scope statement. Kansagara reviewed several concerns raised in written testimony.

Population description: The CEBP will look at the 2020 definition of these conditions and see if any change needs to be made to the population description.

Interventions: Per input from the PANDAS/PANS network, adenoidectomy should be added to the list in addition to tonsillectomy. Smits agreed with this change and the subcommittee agreed to this change.

Comparator(s): Kansagara clarified that nothing will be excluded. The search strategy will not exclude any literature based on named comparators; these are not limiting factors. King stated that any comparator will be included. For effectiveness studies, non-comparason studies will not be included as single-arm studies are not appropriate for effectiveness questions.

Outcomes: Suicide is hard to compare as it is a rare outcome and thus is typically excluded from coverage guidance reports, since studies are normally underpowered to report this outcome meaningfully. The outcome of hospitalization was expanded to include instituationalization to include psychiatric hospitalization and emergency room visits. School performance was suggested as an

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outcome; King indicated that this would be included in the qualify of life measure. Caregiver burden was discussed as an outcome; Quality of life was expanded to include patients and caregivers.

Key Questions: King suggested adding comparative effectiveness of care at a center of excellence as one category. A comparative effectiveness subsection was added for provider characteristics (e.g. center of excellence). Condition characteristics, to include severity of illness and types of symptoms, was added as a comparative effectiveness subsection. Timing of treatment was suggested as a possible intervention characteristic but was ultimately excluded.

Contextual questions: A member suggested that current guidelines for PANDA/PANS treatment might be addressed as a contextual question. King responded that current guidelines is a standard portion of coverage guidance reports.

There was a discussion about the lack of availability of experts in Oregon for this topic. Gingerich noted that experts are appointed by Dr. Hargunani, the Chief Medical Office of the Oregon Health Authority, who will decide which expert or experts to appoint. Interested parties can apply at herc.info@dhsoha.state.or.us.

The revised scope statement will be published on the HERC's website and will be brought for approval by HERC at their May 20 meeting. An in-depth discussion of the resulting report is currently planned for the September EbGS meeting.

A motion was made to refer this revised scope statement to the HERC. **Motion approved 6-0.**

Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections, Pediatric Acute-onset Neuropsychiatric Syndrome, Autoimmune Encephalitis (PANDAS/PANS/AE)

Population description	Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS): Children with acute onset of severe obsessive-compulsive disorder (OCD) and/or tics associated with infection of streptococci group A whose symptoms are not explained by another neurological disorder. Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS): Children with abrupt, dramatic onset of OCD or severely restricted food intake, as well as additional neuropsychiatric symptoms (≥2 of the following: anxiety; emotional lability and/or depression; irritability, aggression and/or severely oppositional behavior; behavioral regression; deterioration in school performance; sensory or motor abnormalities; somatic symptoms including sleep disturbances, enuresis or urinary frequency) whose symptoms are not better explained by another neurological or medical disorder. Autoimmune Encephalitis (AE): Children with all three of the following criteria: 1. Subacute onset (rapid progression within <3 months) of working memory deficits (short-term memory loss), altered mental status, or psychiatric symptoms

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	2. At least one of the following: • New focal central nervous system (CNS) findings • Seizures not explained by a previously known seizure disorder • Cerebrospinal fluid (CSF) pleocytosis (white blood cell count of more than five cells per mm3) • MRI features suggestive of encephalitis 3. Reasonable exclusion of alternative causes *Population scoping notes: Patients without any of the above conditions are excluded*
Intervention(s)	Therapeutic plasma exchange; intravenous immunoglobulin (IVIG); cognitive behavioral therapy (CBT) or other behavioral interventions; selective serotonin reuptake inhibitors (SSRIs); antibiotics; tonsillectomy and/or adenoidectomy; corticosteroids *Intervention exclusions: None*
Comparator(s)	Usual care or other interventions
Outcome(s) (up to five)	Critical: Change in psychiatric symptom scores (e.g., Children's Yale-Brown Obsessive Compulsive Scale, Clinical Global Impressions-Improvement, Yale Global Tic Severity scale); Hospitalizations, including institutionalization or emergency visits Important: Harms; Standardized measures of function or quality of life for patients and caregivers *Considered but not selected for GRADE Table: None*
Key questions	What is the effectiveness of treatments for PANDAS/PANS/AE as compared to the named comparators? Does the comparative effectiveness of treatments for PANDAS/PANS/AE differ by: a. Patient characteristics b. Condition characteristics c. Intervention d. Provider characteristics (e.g., Center of Excellence What are the harms of interventions for PANDAS/PANS/AE in children?
Contextual questions	What are the evidence-based criteria available for the diagnosis of PANDAS/PANS/AE, and what are the diagnostic accuracy of available criteria or tests?

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6. Government Ethics and Bylaws Revisions

Gingerich reviewed the proposed ethics and bylaws revisions that would apply to the HERC and its subcommittees, including the Evidence Based Guidelines Subcommitee. There was no discussion.

7. Adjournment

The meeting was adjourned at 4:45 pm. The next meeting is scheduled for June 3, 2021 from 2:00-5:00pm as a virtual meeting.

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Section 2.0

Bylaws Revisions 2021

HEALTH EVIDENCE REVIEW COMMISSION
Bylaws

ARTICLE I
The Commission and its Members

(A) The Health Evidence Review Commission (hereinafter "HERC" or "Commission") is established pursuant to ORS 414.688 within the Oregon Health Authority. The Commission's function as prescribed by ORS 414.688 to 414.704 is to:

(1) Develop and maintain a list of health services ranked by priority, from the most important to the least important, representing the comparative benefits of each service to the population to be served

(2) Develop or identify and shall disseminate evidence-based health care guidelines for use by providers, consumers and purchasers of health care in Oregon

(3) Conduct comparative effectiveness research of health technologies

(B) In addition, the Commission's responsibilities include reviewing the women's services in ORS 414.694 and reporting to the Legislature on recommended changes in November of each even-numbered year.

(C) The Oregon Health Authority's Health Policy and Analytics Division and other state agencies will support the work of the Commission in a manner mutually agreed upon by the Director and the respective entity(ies).

(D) The members of the Commission shall be appointed by the Governor and confirmed by the Oregon State Senate in accordance with ORS 414.688. Commission members shall serve four-year terms (initially staggered). A member whose term has expired, but whose successor has not been appointed and confirmed, may continue to serve until replaced. A member may serve a second four-year term assuming reappointment by the Governor and Senate confirmation.

(E) Members of the Commission are not entitled to compensation for services as a member but are entitled to expenses as provided in ORS 292.495.

ARTICLE II
Commission Officers and Duties

(A) The Commission shall select a Chairperson and a Vice Chairperson from among its members. An officer's term shall continue for the duration of their appointment to the Commission. The Commission may change the Chairperson by an affirmative vote of at least nine (9) members. If an officer resigns as an officer or as a member of the Commission, a replacement will be selected at the next meeting.

(1) Duties of the Chairperson:

(a) Preside at all meetings of the Commission.

(b) Coordinate meeting agendas after consultation with the Director.

(c) Review all draft Commission meeting minutes prior to the meeting at which they are to be approved.

(d) Be advised of all presentations or appearances of the Director or staff before the

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Legislature, Oregon Health Policy Board, or Executive committees or subcommittees within the Oregon Health Authority or other agencies that relate to the work of the Commission.

(e) The Chairperson may designate, in the absence of the Vice Chairperson or when expedient to Commission business, other Commission members to perform duties related to Commission business such as, but not limited to, presiding over meetings, attending other agency or public meetings, representing the Commission at Legislative hearings or before the media, and approval and review of documents that require action of the Chairperson. In such cases, the Commission member assigned the responsibility will be entitled to expenses as provided in ORS 292.495.

(2) Duties of the Vice Chairperson are:

(a) Perform all of the Chairperson's duties in his/her absence or inability to perform; and

(b) Perform any other duties assigned by the Chairperson after consultation with the Commission.

ARTICLE III
Subcommittees

(A) The Commission may establish subcommittees to undertake work chartered by the Commission. The subcommittees may include Commission members and other persons with relevant expertise and interest in the work of the subcommittee. Specifically, a subcommittee member must have expertise in one or more of the following:

(1) Clinical expertise or training

(2) Evaluation of clinical evidence regarding medical conditions and health services

(3) Health benefit policy and administration

(4) Health care consumer issues

(B) A subcommittee shall cease to exist upon a majority vote of the Commission to disband the subcommittee. Subcommittee membership and the designation of a Chairperson shall be made by majority of members of the Commission. Prior to appointment of a member to a subcommittee, the Chairperson shall review the candidate's HERC Annual Disclosure form described in Article VI and summarize this information for members prior an appointment vote. Prior to May 1 of each calendar year, the Chairperson shall review all HERC Annual Disclosure forms completed by subcommittee members and summarize any important findings at the following Commission meeting.

(C) Advisory panels, including the Behavioral Health Advisory Panel, are not subcommittees. Advisory panel meetings shall be open to the public.

ARTICLE IV
Commission and Subcommittee Meetings

(A) The Commission shall meet at the call of the Chairperson in consultation with the Commission members and staff or at the call of the majority of the members. The Commission shall meet at least quarterly. A subcommittee shall meet at the call of the Chairperson of the subcommittee in consultation with subcommittee members and staff or at the call of the majority of members.

(B) The Commission and subcommittees established by the Commission shall conduct all business meetings in public and in conformity with Oregon Public Meetings Laws.

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(C) The preliminary agenda for Commission and subcommittee meetings will be available from the Commission staff and posted on the Commission website [*http://www.oregon.gov/oha/hpa/dsi-herc/pages/index.aspx*] at least two business days prior to the meeting. The final agenda will be established at the beginning of each meeting.

(D) All actions of the Commission and subcommittees shall be expressed by motion or resolution. Official action by the Commission or a subcommittee requires a quorum consisting of a majority of members of the Commission or subcommittee, and the approval of a majority of the quorum[1].

(E) On motions, resolutions, or other matters, a voice vote may be used at Commission and subcommittee meetings. At the discretion of the Chairperson, or upon the request of a member, a roll call vote may be conducted. Proxy votes are not permitted.

(F) If a Commission or subcommittee member is unable to attend a meeting in person, the member may participate by telephone or Internet conferencing provided that the absent member can be identified when speaking, all participants can hear each other and members of the public attending the meeting can hear any member who speaks during the meeting. A member participating by such electronic means shall be considered in constituting a quorum.

(G) Commission members and subcommittee members shall inform the Director with as much notice as possible if unable to attend a scheduled meeting. Commission staff preparing the minutes shall record the attendance of members at the meeting for the minutes.

(H) The Commission and subcommittees will conduct their business through discussion, consensus building and informal meeting procedures. The Chairperson may, from time to time, establish procedural processes to ensure the orderly, timely and fair conduct of business.

ARTICLE V
Amendments to the Bylaws and Rules of Construction

(A) These Bylaws may be amended upon the affirmative vote of nine (9) members of the Commission.

(B) All rules and procedures in these Bylaws shall be liberally construed so that the public's health, safety and welfare shall be secured in accordance with the intents and purposes of applicable State laws and regulations.

ARTICLE VI
Disclosure of Interests

(A) At the beginning of each meeting, or prior to a vote of the Commission or a subcommittee, the presiding officer (HERC Chairperson, committee chair or designee), shall ask if any members have a potential conflict of interest, actual conflict of interest or personal interest to declare related to the matter at hand. A Commission or subcommittee member shall:

[1] See Oregon Public Meetings Manual, Appendix K, Table II.

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(1) When met with a potential conflict of interest or a personal interest, announce at the meeting or before the vote the nature of the interest prior to taking any action thereon as a Commission or subcommittee member.

(a) After announcing a potential conflict of interest or personal interest, a member may actively participate in the discussion and vote on the matter. The potential conflict of interest or personal interest will be recorded in the minutes of the meeting.

(b) After a subcommittee member discloses a personal interest or potential conflict of interest, the member may elect not to participate in discussions or votes related to the specified interest. If the member does not so elect, the presiding officer may choose to excuse the member from participation in discussion or votes related to the specified interest.

(2) When met with an actual conflict of interest, announce at a Commission or subcommittee meeting the nature of the actual conflict and:

(a) Except as provided in subparagraph (b), refrain from participation as a Commission or subcommittee member in any discussion, debate or vote on the issue out of which the actual conflict arises.

(b) If a Commission or subcommittee member's vote is necessary to meet a requirement of a minimum number of votes to take official action, the member must refrain from discussion or deliberation of the issue but may vote.

(B) Nothing in subsection (A) requires any Commission or subcommittee member to announce a conflict of interest more than once on the occasion which the matter out of which the conflict arises is discussed or debated.

(C) The Commission's or subcommittee's minutes shall reflect any disclosure of actual conflicts of interest, potential conflicts of interests and personal interests and how the conflicts or interests were managed.

(D) Within 30 days of appointment and once per calendar year, each member of the Commission and any subcommittee shall fill out the HERC Annual Disclosure Form which appears on the HERC website. This form will be reviewed by OHA staff and Commission leadership in making decisions and recommendations about membership and shall be available to members of the public as required by Oregon Public Records law. Materials released by public records request shall be redacted only as required by law. A member who fails to update the annual disclosure form by March 1 of each year shall be ineligible to vote until the form is completed.

(E) The Commission and its subcommittees may allow public verbal testimony at meetings at the discretion of the Chairperson. When public testimony is allowed, the presiding officer shall request that those testifying to state their name, any organization or business they are representing or affiliated with which has interests or position on the matter.

(F) If a member of the Commission or a subcommittee fails to make a required disclosure, either in the HERC Annual Disclosure Form or prior to a vote, the presiding officer may choose to excuse the member from participation in discussion or votes related to the specified interest. If the Chairperson becomes aware of a failure to make a required disclosure after a vote, the Chairperson shall report the discovered conflict to the Commission, and in the case of a Commission member, the Chairperson or shall report the discovered conflict to the Commission and to the Governor's office.

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(G) Definitions for this Article VI:

(1) "Personal interest" means any interest of the member that could interfere with the individual's ability to consider evidence with an open mind and to make unbiased recommendations (e.g., employment, provision of the health service in question, stock held, public advocacy, publications, financial interest of a relative or relative's employer). Personal interest" does not include any interest arising from the member's employment or professional activities which are disclosed as a part of a member's current conflict of interest form on file with OHA and which are specifically described on the HERC website.

(2) "Actual conflict interest" has the meaning defined in ORS 244.020.
(3) "Potential conflict of interest" has the meaning defined in ORS 244.020.

(H) Nothing in this Article eliminates any requirements of ORS chapter 244 or any guidance of the Oregon Government Ethics Commission.

Note: Appendices A and B are attached to provide additional information but are not part of the bylaws.

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Appendix A: Relevant definitions from ORS 244.020

(1) "Actual conflict of interest" means any action or any decision or recommendation by a person acting in a capacity as a public official, the effect of which would be to the private pecuniary benefit or detriment of the person or the person's relative or any business with which the person or a relative of the person is associated unless the pecuniary benefit or detriment arises out of circumstances described in subsection (13) of this section.

(2) "Business" means any corporation, partnership, proprietorship, firm, enterprise, franchise, association, organization, self-employed individual and any other legal entity operated for economic gain but excluding any income-producing not-for-profit corporation that is tax exempt under section 501(c) of the Internal Revenue Code with which a public official or a relative of the public official is associated only as a member or board director or in a nonremunerative capacity.

(3) "Business with which the person is associated" means:

(a) Any private business or closely held corporation of which the person or the person's relative is a director, officer, owner or employee, or agent or any private business or closely held corporation in which the person or the person's relative owns or has owned stock, another form of equity interest, stock options or debt instruments worth $1,000 or more at any point in the preceding calendar year;

(b) Any publicly held corporation in which the person or the person's relative owns or has owned $100,000 or more in stock or another form of equity interest, stock options or debt instruments at any point in the preceding calendar year; or

(c) Any publicly held corporation of which the person or the person's relative is a director or officer.

(13) "Potential conflict of interest" means any action or any decision or recommendation by a person acting in a capacity as a public official, the effect of which could be to the private pecuniary benefit or detriment of the person or the person's relative, or a business with which the person or the person's relative is associated, unless the pecuniary benefit or detriment arises out of the following:

(a) An interest or membership in a particular business, industry, occupation or other class required by law as a prerequisite to the holding by the person of the office or position.

(b) Any action in the person's official capacity which would affect to the same degree a class consisting of all inhabitants of the state, or a smaller class consisting of an industry, occupation or other group including one of which or in which the person, or the person's relative or business with which the person or the person's relative is associated, is a member or is engaged.

(c) Membership in or membership on the board of directors of a nonprofit corporation that is tax-exempt under section 501(c) of the Internal Revenue Code.

(15) "Public official" means any person who is serving as a member of HERC or a subcommittee.

(16) "Relative" means:

(a) The spouse, parent, stepparent, child, sibling, stepsibling, son-in-law or daughter-in-law of the public official;

(b) The parent, stepparent, child, sibling, stepsibling, son-in-law or daughter-in-law of the spouse of the public official;

(c) Any individual for whom the public official has a legal support obligation; or

(d) Any individual for whom the public official provides benefits arising from the public official's public employment or from whom the public official receives benefits arising from that individual's employment.

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NOTE: Definitions omit provisions not relevant to HERC.

Appendix B: Considerations for HERC members regarding personal interests and conflicts of interest

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The following is not legal advice, but is provided by OHA staff to assist members in complying with HERC bylaws and Oregon's conflict of interest law (ORS 244.120). For additional information, consult the Oregon Ethics Commission's Guide for Public Officials.

1. Use common sense: If someone might think your employment, financial interests or reputation might be affected by a vote, disclose it prior to the vote, or at the beginning where the matter is discussed. Do you provide the service you are voting on? Did you write a scientific or opinion paper related to the matter? Have you advocated before the legislature? Say so. For example: "I perform about 20 of these procedures per year." Or "I own stock in the manufacturer." Or "I am an author on an academic paper related to this service." Whether you vote after making a disclosure is your decision; make it considering the nature of the impact the decision would have on your employment, finances and reputation. Occasionally, the presiding officer may excuse you from voting or participating in discussion based on a disclosure.
2. Fill out the HERC annual disclosure. Take your time and do it carefully. It is a membership responsibility.
3. On the annual disclosure, make sure to disclose your employment and how it relates to HERC work in the biographical information posted on the HERC web site. With this disclosure, you effectively disclose to other members and the public how your employment relates to HERC work. Disclosing general things (e.g. I am an internist who works for XYZ clinic.) means you don't need to disclose things which may appear to meet the technical definition of a personal interest but are unlikely to influence your vote. (For example, 'My employer, XYZ health system provides this highly specialized service, which is completely unrelated to my professional responsibilities.')
4. Your appointment is based on requirements for membership. If you are a HERC member, the requirements appear in ORS 414.688; if you are a subcommittee member, the qualifications are a part of the bylaws. If a potential conflict would appear to arise based solely on a HERC member's qualification for membership, it is NOT a potential or actual conflict of interest in terms of ORS 244. However, HERC bylaws DO require that you disclose certain matters prior to voting if it meets a broader definition of "interest of the member that could interfere with the individual's ability to consider evidence with an open mind and to make unbiased recommendations."

5. Take cues from staff. Occasionally HERC staff will prompt members for disclosures that may not seem intuitive. This will happen when a vote might affect only a small number of providers in Oregon. This is the time to take a mental run through of your employer's business and your family tree.
6. Take special care to think about what you know about your relatives and their employers. Even if the relative isn't a health professional and especially if the employer is a large health system or health plan, this is worth thinking about. As you do:
    a. Consider the focus of a vote. If the vote is on a service provided by one of a handful of providers in the state (e.g. transplants, specialized radiology), you might want to disclose it even if it seems a stretch that it could be a conflict. If the service is provided by a large number of providers across the state (e.g. common surgeries or devices), or the conflict relates to health plans (of which there are more than a few), ORS 244.120(13)(b) contains an exception for conflicts which affect members of a class to the same degree.
    b. If it's a small class of impacted person or organizations, consider the following with respect to ORS 244, which requires disclosures of some things you wouldn't otherwise need to disclose according to HERC bylaws:
        i. ORS 244 and the HERC bylaws define relative broadly, including in-laws, parents and children and their employers. If you know you have relatives who work in the health care industry, and especially if they work in a narrow field where only a few businesses or persons would be impacted by a decision, consider disclosing this prior to voting on the matter. You don't need to name the relative but you do need to disclose. For example, you might say "I have a relative who works for XYZ health system, which is one of three providers of this service in Oregon."
        ii. Employment matters—even if the person's job function appears unrelated to health care.

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HEALTH EVIDENCE REVIEW COMMISSION

~~**By-Laws**~~

Bylaws

ARTICLE I
The Commission and its Members

(A) The ~~CommissionHealth~~ Health Evidence Review Commission (hereinafter "HERC" or "Commission") is ~~created~~established pursuant to ~~House Bill 2100 (2011 Oregon Legislative Assembly)~~ORS 414.688 within the Oregon Health Authority. The Commission's function as ~~outlined in HB 2100~~prescribed by ORS 414.688 to 414.704 is to:

(1) Develop and maintain a list of health services ranked by priority, from the most important to the least important, representing the comparative benefits of each service to the population to be served

(2) Develop or identify and shall disseminate evidence-based health care guidelines for use by providers, consumers and purchasers of health care in Oregon

(3) Conduct comparative effectiveness research of health technologies

(B) In addition, the Commission's responsibilities include reviewing the women's services in ORS 414.694 and reporting to the Legislature on recommended changes in November of each even-numbered year.

(C) The ~~Office for~~ Oregon Health Authority's Health Policy and ~~Research (OHPR)~~Analytics Division and other state agencies will support the work of the Commission in a manner mutually agreed upon by the Director and the respective entity(ies).

(D) The ~~Members~~members of the Commission shall be appointed by the Governor and confirmed by the Oregon State Senate in accordance with ~~HB 2100~~ORS 414.688. Commission ~~Members~~members shall serve four-year terms (initially staggered). A ~~Member~~member whose term has expired, but whose successor has not been appointed and confirmed, may continue to serve until replaced. A ~~Member~~member may ~~be~~ serve a second four-year term assuming reappointment by the Governor and Senate confirmation.

(E) Members of the Commission are not entitled to compensation for services as a ~~Member,~~member but are entitled to expenses as provided in ORS 292.495.

ARTICLE II
Commission Officers and Duties

(A) The Commission shall select a ~~Chair~~Chairperson and a Vice ~~Chair~~Chairperson from among its ~~Members. The terms of office~~members. An officer's term shall continue for the duration of their appointment to the Commission. The Commission may change the Chairperson by an affirmative vote of at least nine (9) members. If an officer resigns as an officer or as a member of the Commission, a replacement will be ~~24 months~~selected at the next meeting.

- (1) Duties of the ~~Chair are~~Chairperson:
  - ~~o~~(a) Preside at all meetings of the Commission.
  - ~~o~~(b) Coordinate meeting agendas after consultation with the Director.

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~~o~~(c) Review all draft Commission meeting minutes prior to the meeting at which they are to be approved.

~~o~~(d) Be advised of all presentations or appearances of the Director or staff before the Legislature, Oregon Health Policy Board, or Executive committees or subcommittees within the Oregon Health Authority or other agencies that relate to the work of the Commission.

~~o~~(e) The ~~Chair~~Chairperson may designate, in the absence of the Vice ~~Chair~~ Chairperson or when expedient to Commission business, other Commission ~~Members~~members to perform duties related to Commission business such as, but not limited to, presiding over meetings, attending other agency or public meetings, representing the Commission at Legislative hearings or before the media, and approval and review of documents that require action of the ~~Chair~~Chairperson. In such cases, the Commission ~~Member~~member assigned the responsibility will be entitled to expenses as provided in ORS 292.495.

~~•~~(2) Duties of the Vice ~~Chair~~Chairperson are:

~~o~~(a) Perform all of the ~~Chair's~~Chairperson's duties in his/her absence or inability to perform; and

~~o~~(b) Perform any other duties assigned by the ~~Chair~~Chairperson after consultation with the Commission.

ARTICLE III
~~Commission~~ Subcommittees

(A) The Commission may establish subcommittees to undertake work chartered by the Commission. The subcommittees may include Commission ~~Members~~members and other persons with ~~particular~~relevant expertise and interest in the work of the subcommittee. Specifically, a subcommittee member must have expertise in one or more of the following:

(1) Clinical expertise or training
(2) Evaluation of clinical evidence regarding medical conditions and health services
(3) Health benefit policy and administration
(4) Health care consumer issues

(B) A subcommittee shall cease to exist upon a majority vote of the Commission to disband the subcommittee. Subcommittee membership and the designation of a ~~chair shall be made by majority of Members of the Commission.~~Chairperson shall be made by majority of members of the Commission. Prior to appointment of a member to a subcommittee, the Chairperson shall review the candidate's HERC Annual Disclosure form described in Article VI and summarize this information for members prior an appointment vote. Prior to May 1 of each calendar year, the Chairperson shall review all HERC Annual Disclosure forms completed by subcommittee members and summarize any important findings at the following Commission meeting.

(C) Advisory panels, including the Behavioral Health Advisory Panel, are not subcommittees. Advisory panel meetings shall be open to the public.

ARTICLE IV
Commission and Subcommittee Meetings

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(A) The Commission shall meet at the call of the ~~Chair~~Chairperson in consultation with the Commission ~~Members~~members and staff or at the call of the majority of the ~~Members~~members. The Commission shall meet at least quarterly. A subcommittee shall meet at the call of the Chairperson of the subcommittee in consultation with subcommittee members and staff or at the call of the majority of members.

(B) The Commission and subcommittees established by the Commission shall conduct all business meetings in public and in conformity with Oregon Public Meetings Laws.

(C) The preliminary agenda for Commission and subcommittee meetings will be available from the Commission staff and posted on the Commission website [*http://www.oregon.gov/~~OHA/OHPR/HERC~~oha/hpa/dsi-herc/pages/index.aspx*] at least two ~~working~~business days prior to the meeting. The final agenda will be established at the beginning of each ~~Commission~~ meeting.

~~Seven (7) Commission Members shall constitute a quorum for the transaction of business.~~

(D) All actions of the Commission and subcommittees shall be expressed by motion or resolution. Official action by the Commission or a subcommittee requires a quorum consisting of a majority of members of the Commission or subcommittee, and the approval of a majority of the ~~Members of the Commission present at the meeting~~quorum[1].

(E) On motions, resolutions, or other matters, a voice vote may be used~~.~~ at Commission and subcommittee meetings. At the discretion of the ~~Chair~~Chairperson, or upon the request of a ~~Commission Member~~member, a roll call vote may be conducted. Proxy votes are not permitted.

(F) If a Commission ~~Member~~or subcommittee member is unable to attend a meeting in person, the ~~Member~~member may participate by ~~conference~~ telephone or ~~internet~~Internet conferencing provided that the absent ~~Commission Member~~member can be identified when speaking, all participants can hear each other and members of the public attending the meeting can hear any ~~Member of the Commission~~member who speaks during the meeting. A ~~Commission Member~~member participating by such electronic means shall be considered in constituting a quorum.

(G) Commission ~~Members~~members and subcommittee members shall inform the Director with as much notice as possible if unable to attend a scheduled ~~Commission~~ meeting. Commission staff preparing the minutes shall record the attendance of ~~Commission Members~~members at the meeting for the minutes.

(H) The Commission and subcommittees will conduct ~~its~~their business through discussion, consensus building and informal meeting procedures. The ~~Chair~~Chairperson may, from time to time, establish procedural processes to ~~assure~~ensure the orderly, timely and fair conduct of business.

ARTICLE V

Amendments to the ~~By-Law~~Bylaws and Rules of Construction

[1] See Oregon Public Meetings Manual, Appendix K, Table II.

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(A) These ~~By-laws~~Bylaws may be amended upon the affirmative vote of nine (9) ~~Members~~members of the Commission.

(B) All rules and procedures in these ~~By-laws~~Bylaws shall be liberally construed so that the public's health, safety and welfare shall be secured in accordance with the intents and purposes of applicable State laws and regulations.

ARTICLE VI
Disclosure of Interests

(A) At the beginning of each meeting, or prior to a vote of the Commission or a subcommittee, the presiding officer (HERC Chairperson, committee chair or designee), shall ask if any members have a potential conflict of interest, actual conflict of interest or personal interest to declare related to the matter at hand. A Commission or subcommittee member shall:

(1) When met with a potential conflict of interest or a personal interest, announce at the meeting or before the vote the nature of the interest prior to taking any action thereon as a Commission or subcommittee member.

(a) After announcing a potential conflict of interest or personal interest, a member may actively participate in the discussion and vote on the matter. The potential conflict of interest or personal interest will be recorded in the minutes of the meeting.

(b) After a subcommittee member discloses a personal interest or potential conflict of interest, the member may elect not to participate in discussions or votes related to the specified interest. If the member does not so elect, the presiding officer may choose to excuse the member from participation in discussion or votes related to the specified interest.

(2) When met with an actual conflict of interest, announce at a Commission or subcommittee meeting the nature of the actual conflict and:

(a) Except as provided in subparagraph (b), refrain from participation as a Commission or subcommittee member in any discussion, debate or vote on the issue out of which the actual conflict arises.

(b) If a Commission or subcommittee member's vote is necessary to meet a requirement of a minimum number of votes to take official action, the member must refrain from discussion or deliberation of the issue but may vote.

(B) Nothing in subsection (A) requires any Commission or subcommittee member to announce a conflict of interest more than once on the occasion which the matter out of which the conflict arises is discussed or debated.

(C) The Commission's or subcommittee's minutes shall reflect any disclosure of actual conflicts of interest, potential conflicts of interests and personal interests and how the conflicts or interests were managed.

(D) Within 30 days of appointment and once per calendar year, each member of the Commission and any subcommittee shall fill out the HERC Annual Disclosure Form which appears on the HERC website. This form will be reviewed by OHA staff and Commission leadership in making decisions and recommendations about membership and shall be available to members of the public as required by Oregon Public Records law. Materials released by public records request shall be redacted only as

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required by law. A member who fails to update the annual disclosure form by March 1 of each year shall be ineligible to vote until the form is completed.

(E) The Commission and its subcommittees may allow public verbal testimony at meetings at the discretion of the Chairperson. When public testimony is allowed, the presiding officer shall request that those testifying to state their name, any organization or business they are representing or affiliated with which has interests or position on the matter.

(F) If a member of the Commission or a subcommittee fails to make a required disclosure, either in the HERC Annual Disclosure Form or prior to a vote, the presiding officer may choose to excuse the member from participation in discussion or votes related to the specified interest. If the Chairperson becomes aware of a failure to make a required disclosure after a vote, the Chairperson shall report the discovered conflict to the Commission, and in the case of a Commission member, the Chairperson or shall report the discovered conflict to the Commission and to the Governor's office.

(G) Definitions for this Article VI:

(1) "Personal interest" means any interest of the member that could interfere with the individual's ability to consider evidence with an open mind and to make unbiased recommendations (e.g., employment, provision of the health service in question, stock held, public advocacy, publications, financial interest of a relative or relative's employer). Personal interest" does not include any interest arising from the member's employment or professional activities which are disclosed as a part of a member's current conflict of interest form on file with OHA and which are specifically described on the HERC website.

(2) "Actual conflict interest" has the meaning defined in ORS 244.020.

(3) "Potential conflict of interest" has the meaning defined in ORS 244.020.

(H) Nothing in this Article eliminates any requirements of ORS chapter 244 or any guidance of the Oregon Government Ethics Commission.

Note: Appendices A and B are attached to provide additional information but are not part of the bylaws.

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Appendix A: Relevant definitions from ORS 244.020

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(2) "Business" means any corporation, partnership, proprietorship, firm, enterprise, franchise, association, organization, self-employed individual and any other legal entity operated for economic gain but excluding any income-producing not-for-profit corporation that is tax exempt under section 501(c) of the Internal Revenue Code with which a public official or a relative of the public official is associated only as a member or board director or in a nonremunerative capacity.

(3) "Business with which the person is associated" means:

(a) Any private business or closely held corporation of which the person or the person's relative is a director, officer, owner or employee, or agent or any private business or closely held corporation in which the person or the person's relative owns or has owned stock, another form of equity interest, stock options or debt instruments worth $1,000 or more at any point in the preceding calendar year;

(b) Any publicly held corporation in which the person or the person's relative owns or has owned $100,000 or more in stock or another form of equity interest, stock options or debt instruments at any point in the preceding calendar year; or

(c) Any publicly held corporation of which the person or the person's relative is a director or officer.

(13) "Potential conflict of interest" means any action or any decision or recommendation by a person acting in a capacity as a public official, the effect of which could be to the private pecuniary benefit or detriment of the person or the person's relative, or a business with which the person or the person's relative is associated, unless the pecuniary benefit or detriment arises out of the following:

(a) An interest or membership in a particular business, industry, occupation or other class required by law as a prerequisite to the holding by the person of the office or position.

(b) Any action in the person's official capacity which would affect to the same degree a class consisting of all inhabitants of the state, or a smaller class consisting of an industry, occupation or other group including one of which or in which the person, or the person's relative or business with which the person or the person's relative is associated, is a member or is engaged.

(c) Membership in or membership on the board of directors of a nonprofit corporation that is tax-exempt under section 501(c) of the Internal Revenue Code.

(15) "Public official" means any person who is serving as a member of HERC or a subcommittee.

(16) "Relative" means:

(a) The spouse, parent, stepparent, child, sibling, stepsibling, son-in-law or daughter-in-law of the public official;

(b) The parent, stepparent, child, sibling, stepsibling, son-in-law or daughter-in-law of the spouse of the public official;

(c) Any individual for whom the public official has a legal support obligation; or

(d) Any individual for whom the public official provides benefits arising from the public official's public employment or from whom the public official receives benefits arising from that individual's employment.

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NOTE: Definitions omit provisions not relevant to HERC.

Appendix B: Considerations for HERC members regarding personal interests and conflicts of interest

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The following is not legal advice, but is provided by OHA staff to assist members in complying with HERC bylaws and Oregon's conflict of interest law (ORS 244.120). For additional information, consult the Oregon Ethics Commission's Guide for Public Officials

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1. Use common sense: If someone might think your employment, financial interests or reputation might be affected by a vote, disclose it prior to the vote, or at the beginning where the matter is discussed. Do you provide the service you are voting on? Did you write a scientific or opinion paper related to the matter? Have you advocated before the legislature? Say so. For example: "I perform about 20 of these procedures per year." Or "I own stock in the manufacturer." Or "I am an author on an academic paper related to this service." Whether you vote after making a disclosure is your decision; make it considering the nature of the impact the decision would have on your employment, finances and reputation. Occasionally, the presiding officer may excuse you from voting or participating in discussion based on a disclosure.
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3. On the annual disclosure, make sure to disclose your employment and how it relates to HERC work in the biographical information posted on the HERC web site. With this disclosure, you effectively disclose to other members and the public how your employment relates to HERC work. Disclosing general things (e.g. I am an internist who works for XYZ clinic.) means you don't need to disclose things which may appear to meet the technical definition of a personal interest but are unlikely to influence your vote. (For example, 'My employer, XYZ health system provides this highly specialized service, which is completely unrelated to my professional responsibilities.')
4. Your appointment is based on requirements for membership. If you are a HERC member, the requirements appear in ORS 414.688; if you are a subcommittee member, the qualifications are a part of the bylaws. If a potential conflict would appear to arise based solely on a HERC member's qualification for membership, it is NOT a potential or actual conflict of interest in terms of ORS 244. However, HERC bylaws DO require that you disclose certain matters prior to voting if it meets a broader definition of "interest of the member that could interfere with the individual's ability to consider evidence with an open mind and to make unbiased recommendations."

5. Take cues from staff. Occasionally HERC staff will prompt members for disclosures that may not seem intuitive. This will happen when a vote might affect only a small number of providers in Oregon. This is the time to take a mental run through of your employer's business and your family tree.
6. Take special care to think about what you know about your relatives and their employers. Even if the relative isn't a health professional and especially if the employer is a large health system or health plan, this is worth thinking about. As you do:
    a. Consider the focus of a vote. If the vote is on a service provided by one of a handful of providers in the state (e.g. transplants, specialized radiology), you might want to disclose it even if it seems a stretch that it could be a conflict. If the service is provided by a large number of providers across the state (e.g. common surgeries or devices), or the conflict relates to health plans (of which there are more than a few), ORS 244.120(13)(b) contains an exception for conflicts which affect members of a class to the same degree.
    b. If it's a small class of impacted person or organizations, consider the following with respect to ORS 244, which requires disclosures of some things you wouldn't otherwise need to disclose according to HERC bylaws:
        i. ORS 244 and the HERC bylaws define relative broadly, including in-laws, parents and children and their employers. If you know you have relatives who work in the health care industry, and especially if they work in a narrow field where only a few businesses or persons would be impacted by a decision, consider disclosing this prior to voting on the matter. You don't need to name the relative but you do need to disclose. For example, you might say "I have a relative who works for XYZ health system, which is one of three providers of this service in Oregon."
        ii. Employment matters—even if the person's job function appears unrelated to health care.

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Section 3.0

VbBS Report

Tarsal Tunnel Syndrome Surgery

Question: Should additional surgical procedures be paired with tarsal tunnel syndrome?

Question source: HSD Hearings Division

Issue: Tarsal tunnel syndrome is a compression on the posterior tibial nerve that produces symptoms anywhere along the path of the nerve running from the inside of the ankle into the foot. It causes tingling, burning, numbness or pain, along the foot or ankle. Generally, treatment is non-surgical: rest, ice, NSAIDs, casting or splinting, PT, steroid injections or orthotic devices.

Tarsal tunnel syndrome (ICD10 G57.5 family) is on line 416 PERIPHERAL NERVE ENTRAPMENT; PALMAR FASCIAL FIBROMATOSIS. The only surgery paired on this line is CPT 28035 Release, tarsal tunnel (posterior tibial nerve decompression). This is the only surgery found in the literature that is recommended for this condition.

Recently, the HSD hearings division requested review of several procedures with this diagnosis.

CPT 28300 Osteotomy calcaneus (eg. Dwyer or Chambers type procedure), with or without internal fixation

CPT 28304 Osteotomy, tarsal bones, other than calcaneus or talus

CPT 27687 – Gastrocnemius recession (eg. Strayer procedure)

There was no reference to these procedures as treatment for tarsal tunnel syndrome found in the medical literature.

HERC staff recommendation:

1) Make no additional pairings for surgical treatment of tarsal tunnel syndrome.

VbBS Issue Summaries 5-2-2021

COVID-19 Related Codes -- Bamlanivimab
May 2021

Issues: The FDA has revoked the EUA on April 16, 2021 for bamlanivimab as a monotherapy for treatment of COVID-19. There are no other FDA approved indications for this medication. Bamlanivimab used a part of a combination of medications still has FDA EUA.

From the FDA:
On April 16, the FDA revoked the Emergency Use Authorization (EUA) for bamlanivimab, when administered alone, due to a sustained increase in COVID-19 viral variants in the U.S. that are resistant to this antibody therapy. The FDA determined that the known and potential benefits of bamlanivimab, when administered alone, no longer outweigh the known and potential risks.

The FDA indicates that alternative monoclonal antibody therapies remain appropriate to treat COVID-19 patients, and health care providers may continue using these authorized therapies when administered together:

- Casirivimab & imdevimab
- Bamlanivimab & etesevimab

Codes:

Code	Code Description	Current Placement	Recommended Placement
M0239	Intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring	399 INFLUENZA, COVID-19 AND OTHER NOVEL RESPIRATORY VIRAL ILLNESS	Never Covered File
M0245	Intravenous infusion, bamlanivimab and etesevimab, includes infusion and post administration monitoring	399	No change
Q0239	Injection, bamlanivimab-xxxx, 700 mg	Ancillary	Never Covered File
Q0245	Injection, bamlanivimab and etesevimab, 2100 mg	Ancillary	No change

The Health Systems Division has updated their COVID Coding Sheet to document that codes M0239 and Q0239 have expired EUAs as of April 16, 2021. Claims for these codes will be payable up through that date.

Medical Directors have been informed of these coding changes, which were presented by Dr. Ariel Smits to the Quality Health Outcomes Committee (QHOC) on May 10, 2021. The slide deck is available on the QHOC website.

HERC staff recommendations:

1) Remove HCPCS M0239 from line 399 and advise HSD to place on the Never Covered File
    a. Not available for line 662/GN173 as no longer FDA approved
2) Advise HSD to remove HCPCS Q0239 from the Ancillary File and place on the Never Covered File

VRS Issue Summaries 5-20-2021

COVID-19 Related Codes -- Novavax
May 2021

Issue: New codes were released Novavax COVID-19 vaccine administration.

Released on May 5, 2021, CPT codes effective upon FDA emergency use authorization of the Novavax COVID-19 vaccine

91304
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage, for intramuscular use

0041A
Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage; first dose

0042A
Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5mL dosage; second dose

Medical Directors have been informed of these coding changes, which were presented by Dr. Ariel Smits to the Quality Health Outcomes Committee (QHOC) on May 10, 2021. The slide deck is available on the QHOC website.

HERC staff recommendations:

1) Add CPT 91304, 0041A and 0042A to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
    a. Advise HSD to place these codes on the Ancillary List until the next published Prioritized List
    b. Codes will become effective upon the FDA issuing an Emergency Use Authorization (EUA) and ACIP issuing a recommendation for use per GN106

VbBS Issue Summaries 5-20-2021

Nebulizers for COVID-19

Question: Should nebulizers be covered for diagnoses of COVID-19?

Question source: HSD claims reconsideration

Issue: Nebulizers are devices that deliver mediations such as albuterol to the lungs. Currently, the CPT and HCPCS codes for nebulizer therapy are not on the COVID-19 line on the Prioritized List. Other methods of delivering these drugs are metered dose inhalers, which are Ancillary and thus covered for COVID-19 as well as any other diagnosis. COVID-19 causes breathing issues, which can be long term and can be helped by medications such as albuterol. Currently, the CPT code for nebulizer therapy is on 16 lines. The cost of nebulizer therapy is approximately $12.

The Health Systems Division has updated their COVID Coding Sheet to document that CPT 94640 and HCPCS E0570 are open and payable.

Medical Directors have been informed of these coding changes, which were presented by Dr. Ariel Smits to the Quality Health Outcomes Committee (QHOC) on May 10, 2021. The slide deck is available on the QHOC website.

Current Prioritized List status

CPT **94640** Pressurized or nonpressurized inhalation treatment for acute airway obstruction for therapeutic purposes and/or for diagnostic purposes such as sputum induction with an aerosol generator, nebulizer, metered dose inhaler or intermittent positive pressure breathing (IPPB) device: on 16 respiratory lines

HCPCS **E0570** Nebulizer, with compressor: Ancillary

HERC staff recommendation

1) Add CPT **94640** (Pressurized or nonpressurized inhalation treatment for acute airway obstruction for therapeutic purposes and/or for diagnostic purposes such as sputum induction with an aerosol generator, nebulizer, metered dose inhaler or intermittent positive pressure breathing (IPPB) device) to line 399 INFLUENZA, COVID-19 AND OTHER NOVEL RESPIRATORY VIRAL ILLNESS

VbBS Issue Summaries 5-20-2021

Breast Cancer Biomarkers

Question: Should Breast Cancer Index be added to the covered biomarkers for breast cancer?

Question source: Biotheranostics

Issue: A 2018 coverage guidance recommended against coverage of Breast Cancer Index (weak recommendation) based on insufficient evidence that it aids in the decision for prolonged hormonal suppression therapy for patients with HR+, HER2- early stage breast cancer. That review only identified one study (a prospective case series with 153 patients). Newer studies have been published since the Coverage Guidance review, including a sub-analysis of a RCT.

At the time of the 2018 coverage guidance review, NCCN had not recommended its use due to lack of evidence that it predicted benefit of extended adjuvant endocrine therapy. The January 2021 NCCN Guideline for Treatment of Breast Cancer now recommends Breast Cancer Index as a new study by Noordhoek et al (2020) has shown that BCI predicted extended endocrine therapy (10 years rather than the standard 5 years) benefit for individuals with HR+, HER2-, node negative early stage breast cancer . NCCN notes that there is limited data on the role of BCI in node positive early stage breast cancer. NCCN lists BCI as a 2A recommendation, which is similar to other tests that are covered for specific breast cancer patients such as Mammaprint, Oncotype Dx, and Endopredict. These latter tests have prognostic information regarding adjuvant chemotherapy, whereas BCI provides prognostic information regarding prolonged endocrine therapy.

Breast Cancer Index (CPT 81518 Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy) is currently on line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

The American Society of Clinical Oncology (ASCO) in their 2016 recommendations for biomarkers gives a moderate strength recommendation to the use of BCI in patients with ER/PgR-positive, HER2-negative, node-negative breast cancer to guide decisions for adjuvant systemic therapy.

From Biotheranostics
We are writing to request an update to your Genome Expression Profiling for Breast Cancer Prognosis for Breast Cancer Index to be medically necessary when used in the extension of endocrine therapy based on new 2021 NCCN Society guidelines. We are also requesting this policy be updated to cover Breast Cancer Index as a chemo biomarker in line with the ASCO guidelines. With these policy updates, the Oregon State Medicaid medical policy would recommend Breast Cancer Index for extended endocrine therapy, node positive patients along with the chemo adjuvant indication recommended by ASCO…Inclusion of Breast Cancer Index™ into the NCCN Guidelines emphasizes the role of the biomarker as standard of care for extended endocrine therapy decision-making, with comprehensive validation supporting its routine use in HR+, early-stage breast cancer patients with node negative (N0) or node positive disease (N1).

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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 or HCPCS S3854) for breast tumors that are estrogen receptor or progesterone receptor positive, HER2 negative, lymph node negative, and only in those cases categorized as high clinical risk.

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

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

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

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

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

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

For prostate cancer, Oncotype DX Genomic Prostate Score, Prolaris Score Assay (CPT 81541), and Decipher Prostate RP (CPT 81542) are included on Line 662.

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

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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
81518	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy	Insufficient evidence of effectiveness	November 2018 Coverage Guidance May, 2018

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Evidence

1) **Bartlett 2019**, Breast Cancer Index and prediction of benefit from extended endocrine therapy in breast cancer patients treated in the Adjuvant Tamoxifen—To Offer More? (aTTom) trial
    a. Prospective-retrospective study of BCI
        i. N=583 HR+ node positive patients who were disease free after 4 years of adjuvant tamoxifen therapy
    b. BCI (H/I)-High derived a significant benefit in recurrence free survival from 10 versus 5 years of tamoxifen treatment [hazard ratio (HR): 0.35; 95% confidence interval (CI) 0.15–0.86; 10.2% absolute risk reduction based on RFI, P=0.027]. BCI (H/I)-low patients showed no significant benefit from extended endocrine therapy (HR: 1.07; 95% CI 0.69–1.65; -0.2% absolute risk reduction; P=0.768). Continuous BCI (H/I) levels predicted the magnitude of benefit from extended tamoxifen, whereas centralized ER and PR did not. Interaction between extended tamoxifen treatment and BCI (H/I) was statistically significant (P=0.012), adjusting for clinicopathological factors.
    c. Conclusion: BCI by high H/I expression was predictive of endocrine response and identified a subset of HR+, N+ patients with significant benefit from 10 versus 5 years of tamoxifen therapy.
    d. NOTE: several authors are employees and stockholders of Biotheranostics or are consultants for Biotheranostics
2) **Noordhoek 2021**, Breast Cancer Index Predicts Extended Endocrine Benefit to Individualize Selection of Patients with HR+ Early-stage Breast Cancer for 10 Years of Endocrine Therapy
    a. Subanalysis of the Investigation on the Duration of Extended Adjuvant Letrozole trial
        i. Patients randomized to 2.5 vs 5 years of letrozole
        ii. N=908 patients
    b. Significant differences in outcome from randomized treatment of an additional 5 versus 2.5 years of letrozole were dependent on classification by BCI [HOXB13/IL17BR (H/I)]. BCI (H/I)-high patients experienced a 58% and 66% reduction in relative risk of cancer recurrence in the overall cohort (N=908) and in the subset treated with primary adjuvant aromatase inhibitors (N = 794), respectively, whereas BCI (H/I)-low patients did not show benefit from EET.
    a. Conclusions: BCI (H/I) predicted preferential benefit from 5 versus 2.5 years of EET and identified patients with improved outcomes from completing 10 years of adjuvant endocrine therapy.
    b. NOTE: several authors are employees and stockholders of Biotheranostics

Expert guidelines

1) **NCCN 2021**, Breast Cancer
    a. In the table of recommended gene expression assays for consideration of adjuvant systemic therapy: Breast Cancer Index is listed as “predictive of benefit of extended adjuvant endocrine therapy” as a 2A recommendation
        i. For patients with T2 and T2 HR+ HER2- pN0 tumors, a BCI in the low-risk range (0-5), regardless of T size, places the tumor into the same prognostic category as T1a-T1b, N0, M0
        ii. Patients with BCI low demonstrated a lower risk of distant recurrence (compared to BCI high) and no significant improvement in DFS or OS compared to the control arm in terms of extending endocrine therapy duration

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   iii. For patients with T1 HR+ HER2- pN0 tumors, a BCI high (5.1-10) demonstrated significant rates of late distant recurrence
   iv. In secondary analysis of the MA17, Trans-a TTom, and IDEAL trials, patients with HR+, T1-T3, pN0 or pN+ who had a BCI high demonstrated significant improvements in DFS when adjuvant endocrine therapy was extended compared to the control arm
   v. In contrast BCI low patients derived no benefit from extended adjuvant therapy

b. In a secondary analysis of the ATAC trial [see Noordhoek 2021 above], BCI was prognostic in node negative breast cancer for both early (years 0-5) and late (years 5-10) distant recurrence. For patients with T1 and T2 HR+, HER2-, and lymph node negative tumors, a BCI in the low risk range, regardless of T size, places the tumor into the same prognostic category as a T1a-T1b, N0, M0.
c. There are limited data as to the role of BCI in HR+, HER2-, and lymph node positive breast cancer

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HERC staff summary

New evidence has been published since the coverage guidance review of Breast Cancer Index. Based on new secondary trial analysis, NCCN has determined that Breast Cancer Index was found to determine whether a patient would achieve disease free survival benefit from prolonged adjuvant endocrine therapy to prevent cancer recurrence if they have HR+, HER2-, node negative breast cancer. Therefore this test has clinical utility in determining which patients should be offered prolonged adjuvant endocrine therapy. This test would only be helpful in the population of women with this type of cancer who are willing to take prolonged adjuvant endocrine therapy, given its known side effects. NCCN has changed their recommendations to include use of BCI in this population. NCCN stated that there was not enough clinical data to determine utility in node positive patients. The American Society of Clinical Oncology (ASCO) recommendations agree with NCCN, with a moderate strength recommendation to the use of BCI in patients with ER/PgR-positive, HER2-negative, node-negative breast cancer to guide decisions for adjuvant systemic therapy.

HERC staff recommendations:

1) Modify GN 148 as shown below
2) Remove the entry for Breast Cancer Index from GN173 as shown below

GUIDELINE NOTE 148, BIOMARKER TESTS OF CANCER TISSUE

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

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

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

- Oncotype DX Breast Recurrence Score (CPT 81519) for breast tumors that are estrogen receptor positive, HER2 negative, and either lymph node negative, or lymph node positive with 1-3 involved nodes.
- EndoPredict (CPT 81522) and Prosigna (CPT 81520 or PLA 0008M) for breast tumors that are estrogen receptor positive, HER2 negative, and lymph node negative.
- MammaPrint (using CPT 81521 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 lymph node negative, 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.

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

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

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

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

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

For prostate cancer, Oncotype DX Genomic Prostate Score, Prolaris Score Assay (CPT 81541), and Decipher Prostate RP (CPT 81542) are included on Line 662.

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
~~81518~~	~~Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy~~	~~Insufficient evidence of effectiveness~~	~~November 2018~~ ~~Coverage Guidance May, 2018~~

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PET Re-scans for Hodgkin's Lymphoma

Question: Should interim PET scans be covered during treatment for Hodgkin's lymphoma?

Question source: Alison Little, CCO medical director

Issue: Currently, the PET scan guideline allows PET scans for initial staging of Hodgkin's lymphoma, but does not allow re-scanning during treatment. NCCN guidelines have PET scans as decision points for changing therapy for classic Hodgkin's lymphoma at various points of treatment for all stages of disease. Not allowing PET scans during therapy would hamper the most effective care for this condition. In fact, without PET scans, the NCCN guideline cannot be followed at all as PET scans drive all of the clinical decision points.

Current Prioritized List status:

DIAGNOSTIC GUIDELINE D22, PET SCAN GUIDELINES

PET Scans are covered for diagnosis of the following cancers only:

- Solitary pulmonary nodules and non-small cell lung cancer
- Evaluation of cervical lymph node metastases when CT or MRI do not demonstrate an obvious primary tumor.

For diagnosis, PET is covered only when it will avoid an invasive diagnostic procedure, or will assist in determining the optimal anatomic location to perform an invasive diagnostic procedure.

PET scans are covered for the initial staging of the following cancers:

- Cervical cancer only when initial MRI or CT is negative for extra-pelvic metastasis
- Head and neck cancer when initial MRI or CT is equivocal
- Colon cancer
- Esophageal cancer
- Solitary pulmonary nodule
- Non-small cell lung cancer
- Lymphoma
- Melanoma

For staging, PET is covered when clinical management of the patient will differ depending on the stage of the cancer identified and either:

A) the stage of the cancer remains in doubt after standard diagnostic work up, OR
B) PET replaces one or more conventional imaging studies when they are insufficient for clinical management of the patient.

Restaging is covered only for cancers for which staging is covered and for thyroid cancer if recurrence is suspected and L131 scintography is negative. For restaging, PET is covered after completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence or to determine the extent of a known recurrence. PET is not covered to monitor tumor response during the planned course of therapy. PET scans are NOT indicated for routine follow up of cancer treatment or routine surveillance in asymptomatic patients.

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PET scans are also indicated for preoperative evaluation of the brain in patients who have intractable seizures and are candidates for focal surgery. PET scans are NOT indicated for cardiac evaluation.

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HERC staff recommendation:

1) Modify Diagnostic Guideline D22 as shown below

DIAGNOSTIC GUIDELINE D22, PET SCAN GUIDELINES

PET Scans are covered for diagnosis of the following cancers only:

- Solitary pulmonary nodules and non-small cell lung cancer
- Evaluation of cervical lymph node metastases when CT or MRI do not demonstrate an obvious primary tumor.

For diagnosis, PET is covered only when it will avoid an invasive diagnostic procedure, or will assist in determining the optimal anatomic location to perform an invasive diagnostic procedure.

PET scans are covered for the initial staging of the following cancers:

- Cervical cancer only when initial MRI or CT is negative for extra-pelvic metastasis
- Head and neck cancer when initial MRI or CT is equivocal
- Colon cancer
- Esophageal cancer
- Solitary pulmonary nodule
- Non-small cell lung cancer
- Lymphoma
- Melanoma

For staging, PET is covered when clinical management of the patient will differ depending on the stage of the cancer identified and either:

C) the stage of the cancer remains in doubt after standard diagnostic work up, OR
D) PET replaces one or more conventional imaging studies when they are insufficient for clinical management of the patient.

Restaging is covered only for cancers for which staging is covered and for thyroid cancer if recurrence is suspected and l131 scintography is negative. For restaging, PET is covered after completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence or to determine the extent of a known recurrence. PET is not covered to monitor tumor response during the planned course of therapy, except for classic Hodgkin's lymphoma treatment. PET scans are NOT indicated for routine follow up of cancer treatment or routine surveillance in asymptomatic patients.

PET scans are also indicated for preoperative evaluation of the brain in patients who have intractable seizures and are candidates for focal surgery. PET scans are NOT indicated for cardiac evaluation.

VbBS Issue Summaries 5-20-2021

Treatment of Chronic Patellar Subluxation
2021 Re-Review

Question: What procedures should be covered for the treatment of chronic patellar subluxation?

Question source: Dr. Holly Jo Hodges, OHP Medical Director; Dr. Jacqueline Brady, OHSU orthopedics

Issue: Treatments for patellar subluxation were last reviewed in 2011. At that time, anterior tibial tubercleplasty (Maquet procedure) was reviewed and found to not have evidence to support its use. It was placed on line 662/GN173 as having more efficacious procedures available. This was based on a 2008 review by Colvin et al and a 2007 review by Muford et al.

Dr. Hodges has had two recent cases in which a surgeon requested approval for use of CPT 27418 (Anterior tibial tubercleplasty (eg, Maquet type procedure)), which Dr. Hodges judged to be appropriate. Dr. Hodges has requested that the HERC reconsider non-coverage of this procedure.

Patellar subluxation is a partial dislocation of the patella. It is also known as patellar instability or kneecap instability. First line treatment for patellar subluxation is conservative care with physical therapy along with bracing or taping. If a patient does not respond to conservative treatment, then several surgical options exist for repair.

Current Prioritized List placements

CPT code	Code Description	Line(s)
27418	Anterior tibial tubercleplasty (eg, Maquet type procedure) [used for Maquet procedure, Fulkerson osteotomy]	**662** CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
27420	Reconstruction of dislocating patella (eg, Hauser type procedure) [used for Fulkerson osteotomy]	**359** DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS **431** INTERNAL DERANGEMENT OF KNEE AND LIGAMENTOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT **598** CONGENITAL DEFORMITIES OF KNEE
27422	Reconstruction of dislocating patella with extensor realignment and/or muscle advancement or release (eg Campbell, Goldwaite type procedure) [used for Elmslie-Trillat procedure]	**359, 431, 598**
24724	Reconstruction of dislocating patella with patellectomy	**355** CLOSED FRACTURE OF EXTREMITIES (EXCEPT MINOR TOES) **359,431,598**

VbBS Issue Summaries 5-20-2021

Treatment of Chronic Patellar Subluxation
2021 Re-Review

CPT code	Code Description	Line(s)
27425	Lateral retinacular release, open [used for Elmslie-Trillat procedure]	**359,431,598**
27455	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); before epiphyseal closure [used for Fulkerson osteotomy]	**359,505,527**
27457	After epiphyseal closure	**356** RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS O BONE **359**
27560	Closed treatment of patellar dislocation, without anesthesia	**132** OPEN FRACTURE/DISLOCATION O EXTREMITIES **359**
27562	Closed treatment of patellar dislocation, with anesthesia	**132,359**

ICD-10 Code	Code description	Line(s)
S83.00	Unspecified dislocation of unspecified patella	**359** DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
S83.01	Lateral subluxation of patella	**359**
S93.091	Other subluxation of patella	**359**
S83.094	Other dislocation of patella	**359**
S83.1	Subluxation of knee	**359**
M25.36	Other instability, unspecified knee	**527** DEFORMITIES OF UPPER BODY AND ALL LIMBS

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
27418	Anterior tibial tubercleplasty (eg, Maquet type procedure)	Harms outweigh benefits, more efficacious procedures exist	May, 2011

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Treatment of Chronic Patellar Subluxation
2021 Re-Review

Evidence

1) **Smith et al 2015**, Cochrane review "Surgical vs Non-Surgical Interventions for Treating Patellar Subluxation"
    a. N=5 RCTs and 1 quasi-randomized study (N=344 patients)
        i. Adolescents and young adults with primary patellar dislocation
        ii. Quality of evidence rated as very low (high risk of performance and detection bias, lack of blinding)
    b. Surgeries evaluated:
        i. Proximal patellar realignment soft tissue procedures, designed to repair or tighten the capsular soft tissues and tendinous soft tissues on the medial side of the knee (repair or medial plication) or reconstruct the ligamentous structures, particularly the medial patellofemoral ligament (MPFL) to resist lateral displacement of the patella (Conlan 1993;Hautamaa 1998). If the lateral capsular soft tissues appear too tight, they may be incised (lateral release).
        ii. Osseous (bony) procedures specifically for trochlear dysplasia (abnormal anatomy). This includes a trochleoplasty where the surgeon constructs a groove in the femur for the patella to move within (Dejour 1994; Donell 2006b). This may also include femoral or tibial osteotomy or abnormal or excessive rotation of the tibia or femur or tubercle transfer where, most commonly, the patella's attachment is medialised (moved more centrally) and distalised (moved downwards) to correct abnormal patellar tracking in the distal femur (Cosgarea 2002; Dath 2006; Dejour 1994).
        iii. Distal patellar realignment procedures. This can include a Roux-Goldthwaite procedure in which the surgeon alters where the patella attaches onto the tibia (Donell 2006a).
    c. There was very low quality but consistent evidence that participants managed surgically had a significantly lower risk of recurrent dislocation following primary patellar dislocation at two to five years follow-up (21/162 versus 32/136; RR 0.53 favoring surgery, 95% confidence interval (CI) 0.33 to 0.87; five studies, 294 participants). Based on an illustrative risk of recurrent dislocation in 222 people per 1000 in the non-surgical group, these data equate to 104 fewer (95% CI 149 fewer to 28 fewer) people per 1000 having recurrent dislocation after surgery.
    a. The very low quality evidence available from single trials only for four validated patient-rated knee and physical function scores (the Tegner activity scale, KOOS, Lysholm and Hughston VAS (visual analogue scale) score) did not show significant differences between the two treatment groups.
    b. Although there is some evidence to support surgical over non-surgical management of primary patellar dislocation in the short term, the quality of this evidence is very low because of the high risk of bias and the imprecision in the effect estimates. We are therefore very uncertain about the estimate of effect. No trials examined people with recurrent patellar dislocation. Adequately powered, multicentre, randomised controlled trials, conducted and reported to contemporary standards, are needed
2) **Grimm et al 2018**, Tibial Tubercle Osteotomies: a Review of a Treatment for Recurrent Patellar Instability
    a. Options include the Maquent procedure, Elmslie-Trillat procedure, and the Fulkerson osteotomy

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b. The Maquet technique, which has largely been abandoned for less morbid transfers, was plagued by high complication rates, most notable for skin necrosis, compartment syndrome, and nonunion

Expert guidelines

1) **Post and Fithian 2018**; Patellofemoral Instability, A Consensus Statement From the AOSSM/PFF Patellofemoral Instability Workshop
    a. Surgical treatment can be recommended after failure of nonoperative treatment, when history and physical examination findings are clearly consistent with diagnosis and examination under anesthesia of pathologic laxity in full extension and 30 degrees of flexion.
    b. Isolated lateral retinacular release or lengthening is not recommended to treat patellar instability
    c. Medial reconstruction with or without lateral release or lengthening is indicated when there is no more than mild trochlear dysplasia and there is clear evidence on history, physical examination, and examination under anesthesia that pathologic laxity is present. Some patients with no trochlear dysplasia, no patella alta, and no systemic hypermobility may be candidates for medial repair or imbrication of the medial retinacular tissues.
    d. Lateral release or lengthening is indicated in addition to medial patellofemoral ligament reconstruction when there is pathologic lateral retinacular tightness. Tilt on imaging alone does not confirm lateral retinacular tightness. When manual correction of a laterally tilted patella to neutral is not possible on physical examination, then suspect lateral tightness. Progressive tilt with knee flexion on CT scan suggests lateral retinacular tightness. Similarly, a patella that does not center in the trochlea with flexion presumably has fixed shortening of the lateral tissues that must be corrected to allow the patella to reduce fully.
    e. Tibial tuberosity medialization is not commonly included in surgery for instability.
    f. Many participants were cautious not to want to necessarily address alta surgically owing to perceived morbidity associated with distalization. Start to consider surgical correction of patella alta when Caton- Deschamps ratio is ≥1.2 and the patellotrochlear index (PTI) is <15% to 20%. The morphology (degree of concavity and proximal extent) of the proximal trochlea is also an important consideration when understanding engagement of the patella into the proximal trochlea.
    g. Trochleoplasty is not often indicated. Deepening trochleoplasty is considered when all of the following are present: a J-sign, a boss or supratrochlear spur ≥5 mm, and a convex proximal trochlea. Participants may undergo trochleoplasty as part of primary or revision surgery based on these guidelines.
    h. Tibial tuberosity medialization is not commonly included in surgery for patellar instability. There is no evidence to indicate medialization as a necessary part of instability surgery

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Treatment of Chronic Patellar Subluxation
2021 Re-Review

HERC staff summary:
Based on an updated literature review, it appears that the Maquet procedure is not currently the standard of care as it has higher morbidity that other available and covered surgeries.

HERC staff recommendation

1) Make no change is the current placement of the Maquet procedure on line 662/GN173
2) Update the GN173 entry to reflect the most recent review date

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
27418	Anterior tibial tubercleplasty (eg, Maquet type procedure)	Harms outweigh benefits, more efficacious procedures exist	May, 2021 ~~May, 2011~~

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Tethered Cord

Question: When should release of a tethered cord be covered?

Question source: OHA hearing division; Alison Little, CCO medical director

Issue: The surgery for release of tethered cord (CPT 63200) is on the covered and uncovered back surgery lines with no clear indications for when it is a covered service. Tethered cord release has never been specifically discussed by HSC or HERC.

Tethered cord syndrome is a stretch-induced functional disorder associated with the fixation (tethering) effect of inelastic tissue on the caudal spinal cord, limiting its movement. This abnormal attachment is associated with progressive stretching and increased tension of the spinal cord as a patient ages, potentially resulting in a variety of neurological and other symptoms. The specific symptoms, severity and progression of tethered cord syndrome vary from one individual to another. In most cases, individuals experience symptoms during childhood. In some cases, symptoms are stabilized in childhood, but become apparent only in adulthood. A high percentage of pediatric cases, with tethered cord syndrome show cutaneous tufts of hair, skin tags, dimples, benign fatty tumors, skin discoloration or hemangiomas. Additional symptoms include lower back pain that worsens with activity and improves with rest (although rarely complained by young children, because of inability to express pain), leg pain or numbness, difficulty walking (gait disturbances), foot and spinal deformities, such as abnormal side-to-side curvature of the spine (scoliosis) or hollow lowback (exaggerated lordosis), high-arched feet and hammertoes, and less commonly difference in leg strength. Tethered cord syndrome can also cause difficulties with bladder and bowel control. Affected children may experience involuntary urination or defecation (incontinence) and repeated urinary tract infections. Symptoms in children may be slowly progressive. Adult onset of tethered cord syndrome was considered to be rare for many years, but an increasing number of cases have been reported in recent years. This trend is due to improvement in neurological examinations and in the interpretation of imaging studies. Symptoms common to adult tethered cord syndrome include constant, often severe back and leg pain, which may extend to the rectum and genital area in some cases. Progressive sensory and motor deficits may affect the legs potentially resulting in numbness, weakness or muscle wasting (atrophy) in the affected areas. More than 50 percent of the affected individuals experience bladder and bowel dysfunction, manifested by increased frequency or urgency of urination or constipation.

Treatment in children is surgery to release "untether" the spinal cord to prevent or reverse progressive neurological symptoms. Treatment for adult patients with tethered cord syndrome is controversial However, it is clear that in both pediatric and adult patients who have firm evidence of tethered cord syndrome, prompt surgical intervention results in reversal, or at least stabilization, of symptoms in many cases.

Tethered cord is represented by ICD-10 Q06.8 (Other specified congenital malformations of spinal cord) when congenital and G96.89 (Other specified diseases of spinal cord) when acquired.

HSD hearings and the CCOs are requesting clarification regarding if GN37 SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS applies to tethered cord, and if so, whether imaging must show pathology.

Current Prioritized List status

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Code	Code description	Current line(s)
G96.89	Other specified diseases of spinal cord	71,292,345,377 (dysfunction lines)
Q06.8	Other specified congenital malformations of spinal cord	71,292,345,377 346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS 402 CONDITIONS OF THE BACK AND SPINE 529 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
63200	Laminectomy, with release of tethered spinal cord, lumbar	346,529

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

Lines 346,529

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

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

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

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

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

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

- local injections (including ozone therapy injections)

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- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- percutaneous laser disc decompression
- radiofrequency denervation
- corticosteroid injections for cervical pain

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

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

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Evidence

Pediatric

1) **Tuite 2017**, review of tethered cord in children
    a. No published level I data exists
    b. Recommendations based on the International Children's Continence Society (ICCS) recommendations for diagnosis and treatment of OSD (Occult spinal dysraphism)
    c. Diagnosis
        i. Imaging
            1. Ultrasound is ideal for screening neonates and infants up to 3 months due to its ease of performance, no radiation exposure and low cost
            2. MRI is the modality of choice for evaluating patients with OSD. Because sedation is often required for optimal imaging in infants, MRI is delayed till 3 months of age
            3. Most clinicians consider conus termination below the L2 vertebral body abnormal
        ii. Symptoms
            1. Affected infants and young children are recognized by cutaneous markers or orthopedic deformities; older children present with bladder and bowel dysfunction, pain or sensorimotor lower extremity deficits; adolescents with scoliosis and/or urinary incontinence
2) **Tu and Steinbok 2013**, Occult tethered cord syndrome: a review
    a. Symptoms may be classified into four main categories: neurologic (i.e., motor or sensory dysfunction), urologic, neurocutaneous, and neuro-orthopedic. The most common in occult tethered cord syndrome (OTCS) is urinary dysfunction, which is seen in 68–100 % of patients
    b. Diagnosis
        i. Imaging
            1. Supine MR, in the absence of any other features of spinal dysraphism or abnormally positioned conus has not been found to be particularly sensitive for OTCS but does a have reasonable negative predictive value reaching 90% in some series
            2. prone MRI has a sensitivity reported to be as low as 62%
    c. Management
        i. In uncontrolled case series, intervention in appropriately selected patients can generate substantial meaningful improvement. The longevity of these benefits in the long term remains to be determined. Because management of these patients remains controversial, a randomized controlled trial is underway to compare outcomes after section of the filum with best medical management in children over the age of 5 years and possible OTCS, but accrual of patients has been slow, and the study is not expected to be completed for another 2 years.
            1. **Steinbok 2016**, RCT of surgery vs medical management of occult tethered cord syndrome in children with urinary incontinence
                a. After 8 years we accrued 21 patients. The bowel and bladder dysfunction score improved in the surgical and medical arms (20% and 24%) and the urodynamic score improved slightly (6% and 4%, respectively). The PEMQOL Child and Family Impact Scales improved modestly in both groups. All differences were nonsignificant. Interim analysis indicated that more than 700

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patients in each arm would be required to demonstrate a statistical difference with respect to urodynamic score based on our preliminary data.

b. Conclusions: There appears to be no objective difference in urological outcome between medical management plus or minus filum section for patients with occult tethered cord syndrome

Adults

1) **O'Connor 2020,** Surgical Treatment of Tethered Cord Syndrome in Adults: A Systematic Review and Meta-Analysis
    a. N=49 articles; N=708 adults with tethered cord syndrome treated with surgical de-tethering
    b. Magnetic resonance imaging (MRI) is the imaging modality of choice for aiding in the diagnosis of TCS
    c. The most common preoperative sign or symptom was pain (81%), followed by motor deficits (63%), sensory deficits (61%), bladder dysfunction (56%), and bowel dysfunction (15%).
        i. Pain was the symptom that was most responsive to surgery, with 81% of patients reporting that their pain improved after detethering. Of those patients with motor deficits, 61% improved postoperatively. For sensory deficits, 45% of patients improved. For bladder dysfunction, 45% of patients improved. For bowel dysfunction, 32% of patients showed improvement.
    d. Physical examination findings included cutaneous or subcutaneous stigmata in 42% of patients, scoliosis in 34% of patients, and foot deformities in 35% of patients. Spina bifida was seen in 56%.
    e. A thick and/or fatty filum terminale was the most common radiographic finding, affecting 37% of patients, followed by intradural or extradural lipoma in 29%, lipomeningocele or lipomyelomeningocele in 21%, fibrous adhesions in 8%, split cord malformation in 17%, and previous myelomeningocele repaired in 13%.
    f. Complications occurred in 7% of patients. These complications included 55 cases of cerebrospinal fluid leaks (8%), 14 cases of difficult wound healing (2%), 1 case of meningitis, 1 case of abscess, 1 case of draining cyst, 2 cases of postoperative bleeding, and 1 death.

<u>Other payer policies:</u>

1) Aetna 2021

a. Aetna considers cervical, lumbar, or thoracic laminectomy medically necessary for *any* of the following:
    i. Repair of open spinal dysraphism, or radiographically demonstrated closed spinal dysraphism (including tethered cord) with significant signs or symptoms of lumbosacral spinal dysfunction or in asymptomatic young children who are not yet toilet trained or have not yet begun to walk. Surgery for asymptomatic closed spinal dysraphism in older individuals or clinical tethered cord syndrome without radiographic abnormalities will be considered upon individual case review

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No other commercial or Medicaid policies identified.

Expert input:

Dr. Nathan Selden, OHSU neurosurgery

> … the syndrome is well known in adults, is responsive to surgery in appropriately selected patients, and suffers a natural history without intervention in these patients of severe and inexorable neurological decline (leading to incontinence and wheel chair bound weakness in many cases – this is generally not a pain driven patient selection and in fact we avoid pain only patients).
>
> The traditional approach, and most proven, is untethering, although rarely for refractory patients with recurrence after a primary and a re-do untethering, spinal column shortening has been a newer and functionally saving definitive intervention.
>
> Pediatric untethering (again, in appropriately selected patients, something I have studied and written extensively about in the literature myself) is – as you have surmised – well established and standard care. Although much rarer, adult untethering is also important but should be limited to functionally symptomatic patients.

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HERC staff summary

The literature on tethered cord is extremely limited. Infants and children with significant neurologic symptoms and evidence of tethered cord on ultrasound or MRI have surgery recommended as standard of care. Surgical management of older children and adolescents with tethered cord with significant neurologic or urologic symptoms is also recommended for surgery by expert groups. Children and adults with occult tethered cord syndrome do not appear to benefit from surgery, based on one extremely underpowered RCT.

HERC staff recommendation:

1) Adopt a new guideline for tethered cord as shown below
    a. 346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS
    b. 529 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
    c. Wording in purple was suggested by Dr. Selden and colleagues but not recommended by CCO medical directors—these sections require discussion

GUIDELINE NOTE XXX TETHERED CORD

Lines 346,529

Surgical repair of tethered cord is included on line 346 for patient when the following conditions are met:

1) Symptoms:
    a. Infants and pre-walking/toilet trained children with cutaneous markers or orthopedic deformities; OR
    b. Children and adults with bladder and bowel incontinence of neurologic origin or constipation unresponsive to medications AND/OR sensorimotor lower extremity deficits; AND
2) Imaging:
    a. Ultrasound findings consistent with tethered cord for infants up to 3 months; OR
    b. MRI findings consistent with tethered cord (i.e. conus termination below the L2 vertebral body, intradural or extradural lipoma, lipomeningocele, lipomyelomeningocele, split cord malformation, low conus termination at the L2 vertebral body with thickened non-fatty filum in a symptomatic patient, or previous myelomeningocele repair or other spinal surgery resulting in fibrous adhesions).

Surgery for tethered cord in patients not meeting the above criteria are included on line 529.

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Rhinoplasty and Septoplasty Coverage Clarification

Question: How can coverage of rhinoplasty and septoplasty on the Prioritized List be clarified, particularly as part of sinus surgery?

Question source: Medical Management Committee (MMC) of HSD

Issue: Rhinoplasty and septoplasty appear on several covered and multiple uncovered lines on the Prioritized List. It is unclear particularly how coverage of these procedures is intended as it relates to chronic sinusitis. There is a guideline which outlines when surgery for chronic sinusitis is covered, but that guideline does not explicitly indicate whether rhinoplasty and septoplasty are included in the guideline requirements. Per MMC, nasal septoplasty and/or rhinoplasty are frequently requested when sinus surgery is planned and reviewers need guidance on when these procedures should be covered. It is unclear if the nasal surgery is cosmetic or necessary for the sinus surgery. Also, there is a question from reviewers about whether rhinoplasty would be covered if a patient has a diagnosis of chronic sinusitis as a stand alone procedure as these codes pair and do not appear to be addressed in the currently guideline; this has been interpreted by some reviewers as a possible way to have an aesthetic surgery done.

HSC/HERC history

Nasal surgery was last discussed in October, 2015, when the VBBS/HERC clarified coverage for congenital nasal anomalies. However, coverage of nasal surgery for chronic sinusitis was not discussed at that time. No previous discussion was found in HSC or VBBS minutes.

Current Prioritized List status

Code	Code Description	Current Placement
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip	465 CHRONIC SINUSITIS 506 NASAL POLYPS, OTHER DISORDERS OF NASAL CAVITY AND SINUSES 576 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip	465,506,576
30420	Rhinoplasty, primary; including major septal repair	228 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES 465, 506 561 ALLERGIC RHINITIS AND CONJUNCTIVITIS, CHRONIC RHINITIS 576
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)	Excluded
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)	465,506
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)	228,465,506

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Code	Code Description	Current Placement
30460-30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate	300 CLEFT PALATE AND/OR CLEFT LIP
30465	Repair of nasal vestibular stenosis (eg, spreader grafting, lateral nasal wall reconstruction)	465,506,576
30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)	465,506,576
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft	42 CLEFT PALATE WITH AIRWAY OBSTRUCTION 119 CHOANAL ATRESIA 202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER 246 LIFE-THREATENING EPISTAXIS 287 CANCER OF ORAL CAVITY, PHARYNX, NOSE AND LARYNX 465 CHRONIC SINUSITIS 506 NASAL POLYPS, OTHER DISORDERS OF NASAL CAVITY AND SINUSES 525 BENIGN NEOPLASM OF NASAL CAVITIES, MIDDLE EAR AND ACCESSORY SINUSES

GUIDELINE NOTE 35, SINUS SURGERY

Lines 287,465,506

Sinus surgery (other than adenoidectomy) is indicated when at least one of the following circumstances occur (A-G):

A) Recurrent acute rhinosinusitis, defined as 4 or more episodes of acute bacterial rhinosinusitis in one year without signs or symptoms of rhinosinusitis between episodes and have failed optimal medical management defined as nasal steroid therapy and nasal saline therapy, in patients who are compliant with oral antibiotics and/or oral corticosteroids for management of acute episodes of rhinosinusitis

OR

B) Chronic sinusitis defined as 12 weeks of continuous symptoms without improvement with one of the following (1-3):
1) Symptomatic mucocele OR
2) Negative CT scan but significant disease found on nasal endoscopy
AND
Failure of medical therapy defined as (1-2)
3) Two or more courses of antibiotics with adequate doses AND
4) Trial of inhaled and/or oral steroids (2 or more courses of adequate doses of one or both)

OR

C) Nasal polyposis causing or contributing to sinusitis

OR

D) Complications of sinusitis including subperiosteal or orbital abscess, Pott's puffy tumor, brain abscess or meningitis

OR

E) Invasive or allergic fungal sinusitis

OR

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F) Tumor of nasal cavity or sinuses

OR

G) CSF rhinorrhea

Adenoidectomy (CPT 42830, 42835) is included on Line 465 only for treatment of children with chronic sinusitis who fail appropriate medical therapy.

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HERC staff recommendation

1) Clarify coverage of rhinoplasty and septoplasty when these procedures are proposed to be done as part of larger sinus surgery
    a. See proposed modifications to GN35 below

GUIDELINE NOTE 35, SINUS SURGERY

Lines 287,465,506

Sinus surgery (other than adenoidectomy), including rhinoplasty and/or septoplasty if medical necessary , is ~~indicated~~ included on these lines only when at least one of the following circumstances occur (A-G):

A) Recurrent acute rhinosinusitis, defined as 4 or more episodes of acute bacterial rhinosinusitis in one year without signs or symptoms of rhinosinusitis between episodes and have failed optimal medical management defined as nasal steroid therapy and nasal saline therapy, in patients who are compliant with oral antibiotics and/or oral corticosteroids for management of acute episodes of rhinosinusitis

OR

B) Chronic sinusitis defined as 12 weeks of continuous symptoms without improvement with one of the following (1-3):
    5) Symptomatic mucocele OR
    6) Negative CT scan but significant disease found on nasal endoscopy

    AND

    Failure of medical therapy defined as (1-2)
    7) Two or more courses of antibiotics with adequate doses AND
    8) Trial of inhaled and/or oral steroids (2 or more courses of adequate doses of one or both)

OR

C) Nasal polyposis causing or contributing to sinusitis

OR

D) Complications of sinusitis including subperiosteal or orbital abscess, Pott's puffy tumor, brain abscess or meningitis

OR

E) Invasive or allergic fungal sinusitis

OR

F) Tumor of nasal cavity or sinuses

OR

G) CSF rhinorrhea

Adenoidectomy (CPT 42830, 42835) is included on Line 465 only for treatment of children with chronic sinusitis who fail appropriate medical therapy.

Rhinoplasty and/or septoplasty are not included on these lines except as part of surgery for sinus issues meeting the criteria above.

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Platelet Rich Plasma for Non-healing Diabetic Lower Extremity Wounds

Question: Should platelet rich plasma (PRP) be paired with non-healing diabetic lower extremity wounds on the Prioritized List?

Question source: several CCOs

Issue: Until December 2020, PRP was considered experimental for all indications by CMS. The HCPCS code for PRP use for chronic wounds is on the Excluded File due to the previous lack of allowed coverage by CMS. On April 13, 2021 CMS issued a national coverage determination (NCD) which allowed use of PRPs for treatment of lower extremity non-healing diabetic wounds, and allowed local coverage determinations for use of PRP for other types of non-healing wounds such as pressure ulcers.

Autologous platelet-derived growth factors (APDGF) also referred to as platelet-rich plasma (PRP), platelet gel, platelet-rich concentrate, autogenous platelet gel, plasma rich in growth factors (PRGF) or platelet releasate, have been proposed for the treatment of multiple conditions to enhance healing. PRP is derived from autologous blood, with platelets being the main constituent. A collection and preparation system is used to collect a small sample of the patient's blood to be used to produce PRP. The plasma is combined with other substances to form a platelet-rich gel that can be applied to the wound. The mechanism of action is not well-understood, but is proposed to provide a high concentration of growth factors including tissue growth factor and platelet-derived growth factors, which can mediate the proliferation of mesenchymal stem cells and increase matrix synthesis and collagen formation. APDGF has been proposed for numerous indications including wound care, orthopedic conditions, abdominal surgery and oral/dental procedures.

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Current Prioritized List placement:

HCPCS code	**Code description**	**Current Placement**	**Notes**
G0460	Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment	EXCLUDED FILE (TRAVEL VACCINES ETC.)	CMS approved code for use when PRP used for treatment of wound
P9020	Platelet rich plasma, each unit	EXCLUDED FILE	Per CMS, only to be used for transfused PRP for coagulopathy or similar indication
S9055	Procuren or other growth factor preparation to promote wound healing	NEVER REVIEWED	
CPT code	**Code description**	**Current Placement**	
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed	NEVER REVIEWED	Per CMS, only to be used for non-cutaneous injections (e.g. joint injections)

ICD10 Code	**Code Description**	**Current Placement**
E08.621	Diabetes mellitus due to underlying condition with foot ulcer	27 TYPE 2 DIABETES MELLITUS 165 PREVENTIVE FOOT CARE IN HIGH-RISK PATIENTS 332 CONDITIONS REQUIRING HYPERBARIC OXYGEN THERAPY 379 CHRONIC ULCER OF SKIN; VARICOSE VEINS WITH MAJOR COMPLICATIONS
E08.622	Diabetes mellitus due to underlying condition with other skin ulcer	27,332,379
E10.621	Type 1 diabetes mellitus with foot ulcer	8 TYPE 1 DIABETES MELLITUS 165,332,379
E10.622	Type 1 diabetes mellitus with other skin ulcer	8,332,379
E11.621	Type 2 diabetes mellitus with foot ulcer	27,165,332,379
E11.622	Type 2 diabetes mellitus with other skin ulcer	27,332,379
E13.621	Other specified diabetes mellitus with foot ulcer	27,165,332,379
E13.622	Other specified diabetes mellitus with other skin ulcer	27,332,379

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Evidence:

1) **AHRQ 2020**: Platelet-Rich Plasma for Wound Care in the Medicare Population
    a. N=27 studies (22 randomized, 5 comparative observational studies, total of 1,796 patients).
        i. 15 studies enrolled patients with lower extremity diabetic ulcers, 11 enrolled patients with lower extremity venous ulcers, and 2 enrolled patients with pressure ulcers in any location.
            1. Lower extremity diabetic ulcers: 14 RCTs and 1 comparative observational trial (N= 1,096 patients)
                a. RCTs: Li 2015, Driver 2006, Gude 2019, Ahmed 2017, Saad Setta 2011, Yang 2017, Saldalamacchia 2014, Serra 2014, Karimi 2016, Kakagia 2007, Singh 2018, Elsaid 2020, Xie 2020, Game 2018,
                b. Observational trial: Milek 2017
            2. The risk of bias was judged to be high in 8 RCTs (57.14%), moderate in 6 RCTs (42.86%) and high in the one observational study (100%).
        ii. Follow-up after intervention ranged from no follow-up to 11 months.
        iii. Control group treatment included simple saline dressings (3 studies), proprietary saline gel (1 study), hydrocolloid dressing (1 study), polyurethane foam dressings, hydrogels, alginates along with water-solubility hydrocolloids-kolloidnye bandage (2 studies), saline and Vaseline gauze dressing (1 study) and skin graft (1 study). The use of systemic antibiotics was reported in 3 studies. Offloading was explicitly described in one study. Four studies did not clearly define what they referred to as “usual care” or “standard care”.
        iv. Eleven studies used a gel formulation for PRP application. One study mixed PRP with thrombin and calcium gluconate and applied PRP to the wound bed via pipette, others prepared PRP for application via dressing, another applied PRP via injection to the wound bed, and one study delivered gel prepared with a proprietary gravitational separation system.
        v. In terms of frequency, most studies provided biweekly treatments (once or twice weekly) (5 studies), or weekly treatments (5 studies), every 10 days (1 study), every two days (1 study), or every three days (1 study). Total treatment duration varied as well, with many studies reporting treatment of 12 weeks (3 studies) 3 months (1 study), one month (3 studies), up to 20 weeks (3 studies), 8 weeks 1 study), 5 weeks (1 study), or 3 weeks (1 study).
        vi. Types of wounds: There was some consensus that in general, wounds should not have exposed ligament, tendon or bone in order to be considered eligible for treatment with PRP or platelet products. Recommendations regarding ulcer size varied widely, from as small as 0.5 to as great as 50 cm^2.
        vii. The available studies suffered from important limitations, such as inadequate description of offloading and wound care procedures, wound characteristics, platelet-rich plasma formulation techniques, concentration and volume; inadequate length of follow-up; and lack of stratification by comorbidities and other patient characteristics including older adults.
    b. Compared with management without PRP, autologous PRP demonstrated a statistically significant increase in complete wound closure or healing (Relative risk [RR]: 1.20; 95% CI: 1.09 to 1.32; Moderate strength of evidence [SOE]). SOE was lowered from high to moderate because of risk of bias, and because of not having concerns about other domains of SOE. PRP also shortened time to complete wound closure (range: -40 to -

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4.90 days; Low SOE), and reduced wound area and depth (Low SOE). Evidence was insufficient to estimate an effect on important outcomes such as pain, hospitalization, amputations and wound recurrence.

c. In patients with lower extremity venous ulcers, the SOE was insufficient to estimate an effect on critical outcomes, such as complete wound closure or time to complete wound closure. Similarly, evidence was insufficient to estimate an effect on any outcome in pressure ulcers.
d. There was no statistically significant difference in death, total adverse events or serious adverse events between PRP and management without PRP.
e. We identified 22 ongoing trials from trial registries. Six trials are being conducted investigating PRP therapy in lower extremity venous ulcers, 12 studies in lower extremity diabetic ulcers, and 3 studies in pressure ulcers at any location. One study plans to investigate PRP treatment for a mixed variety of ulcers at any location.
f. Conclusions:
    i. We are moderately confident that autologous platelet-rich plasma increases complete wound closure or healing (moderate strength of evidence [SOE]) in individuals with lower extremity diabetic ulcers. We have low confidence that autologous platelet-rich plasma may shorten time to wound closure (low SOE) and reduce wound size (low SOE). Evidence is insufficient to make conclusions about other important outcomes such as hospitalization, amputations and wound recurrence.
    ii. Evidence is insufficient to make conclusions about the effect of autologous platelet-rich plasma on wound healing in individuals with lower extremity venous ulcers.
    iii. Evidence is insufficient to make conclusions about the effect of autologous platelet-rich plasma on wound healing in individuals with pressure ulcers.
    iv. The available literature suffers from important limitations, such as inadequate description of offloading and wound care procedures, wound characteristics, platelet-rich plasma formulation techniques, concentration and volume; inadequate length of follow-up and lack of stratification by comorbidities and other patient characteristics such as diabetes control, vascular perfusion and under representation of older adults.

2) **Martinez-Zapata 2016**, Cochrane review of autologous platelet-rich plasma for treating chronic wounds
    a. N=10 RCTs (442 patients)
        i. N=2 RCTs (189 patients) for diabetic wounds
    b. It is unclear whether autologous PRP improves the healing of chronic wounds generally compared with standard treatment (with or without placebo) (risk ratio (RR) 1.19, 95% confidence interval (CI) 0.95 to 1.50; I2 = 27%, low quality evidence, 8 RCTs, 391 participants).
    c. Autologous PRP may increase the healing of foot ulcers in people with diabetes compared with standard care (with or without placebo) (RR 1.22, 95% CI 1.01 to 1.49; I2 = 0%, low quality evidence, 2 RCTs, 189 participants).
    d. It is unclear if autologous PRP affects the healing of venous leg ulcers (RR 1.02, 95% CI 0.81 to 1.27; I2 = 0%). It is unclear if there is a difference in the risk of adverse events in people treated with PRP or standard care (RR 1.05, 95% CI 0.29 to 3.88; I2 = 0%, low quality evidence from 3 trials, 102 participants).

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e. Conclusions: PRP may improve the healing of foot ulcers associated with diabetes, but this conclusion is based on low quality evidence from two small RCTs. It is unclear whether PRP influences the healing of other chronic wounds. The overall quality of evidence of autologous PRP for treating chronic wounds is low. There are very few RCTs evaluating PRP, they are underpowered to detect treatment effects, if they exist, and are generally at high or unclear risk of bias. Well designed and adequately powered clinical trials are needed.

3) **Del Pino-Sedena 2019**, systematic review and meta-analysis of platelet-rich plasma for the treatment of diabetic foot ulcers
    a. N=8 RCTs and 2 prospective observational studies with control groups
        i. Included 7 studies from the AHRQ review
            1. RCTs: Li 2015, Driver 2006, Ahmed 2017, Saad Setta 2011, Saldalamacchia 2014, Karimi 2016, Kakagia 2007
        ii. Additional studies not included in AHRQ review:
            1. RCT: Steed 1992
            2. Observational: Jeong 2010, Steed 1996
    b. Platelet-rich plasma treatment increased the likelihood of chronic wound healing (RR = 1.32; 95% CI: 1.11, 1.57, I2 = 15%) while the volume of the ulcer (MD = 0.12 cm2; 95% CI: 0.08, 0.16; p < 0.01; I2 = 0%) and time to complete wound healing (MD = −11.18 days; 95% CI: −20.69, −1.68; I2 = 53%) decreased.
    c. Regarding safety profile, platelet-rich plasma did not differ from standard treatment in terms of probability of occurrence of wound complications (RR = 0.57; 95% CI: 0.25, 1.28; I2 = 0%) or recurrences (RR = 2.76; 95% CI: 0.23, 33.36; p = 0.43; I2 = 82%) but it decreased the rate of adverse events (RR = 0.80; 95% CI: 0.66, 0.96; p = 0.02; I2 = 0%).
    d. Cumulative meta-analysis revealed that there is enough evidence to demonstrate a statistically significant benefit. However, studies included presented serious methodologic flaws. According to the results, platelet-rich plasma could be considered a candidate treatment for nonhealing of diabetic foot ulcers.
4) **Li 2018**, meta-analysis of autologous platelet rich gel treatment for diabetic chronic cutaneous ulcers
    a. N=15 RCTS (829 patients)
        i. Included 8 studies from the AHRQ review
            1. RCTs: Li 2015, Driver 2006, Ahmed 2017, Saad Setta 2011, Saldalamacchia 2014, Karimi 2016, Kakagia 2007, Serra 2014
        ii. Additional studies not included in AHRQ review:
            1. RCT: Friese 2007, Zhang 2016, Zhou 2015, Chen 2008, Ma 2014, Zhu 2012, Liu 2016, Qi 2014
    b. Compared with standard care or conventional treatment, APG significantly improved the healing rate (RR 1.39; 95% CI 1.29, 1.50; P < 0.00001) [15 trials included in meta-analysis, all ulcer types]
        i. Diabetic subgroup analysis (all 15 trials): The results showed that compared with standard care or conventional treatment, APG significantly improved the healing rate in patients with diabetic foot ulcers (RR 1.41; 95% CI 1.29, 1.54; P < 0.00001)
    c. Compared with standard care or conventional treatment, APG significantly shortened the healing time (MD -9.18; 95% CI −11.32, −7.05; P < 0.00001) [6 trials used in random effects model]
    d. Conflicting results on length of hospital stay

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   e. Meta-analysis of 6 trials showed that compared with standard care or conventional treatment, APG significantly lowered the incidence of infection (OR 0.34; 95% CI 0.15, 0.77; P = 0.009)
   a. Conclusions: Current evidence suggests that APG is effective and safe, and is feasible for use as an adjuvant treatment for diabetic ulcers, especially chronic refractory ulcers. However, more RCTs with a good design and of a high quality are needed before the use of APG can be implemented widely.
5) **Washington HTA 2016**: Autologous blood or platelet-rich plasma injections: final evidence report https://www.hca.wa.gov/assets/prp_final_rpt_041516.pdf
   a. Reviewed 13 indications (mostly joint and soft tissue injury/inflammation)
      i. Wound healing for any type of wound not included in report

Other evidence-based guidelines

1) **NICE 2015** (updated 2019): Diabetic foot problems https://www.nice.org.uk/guidance/ng19/resources/diabetic-foot-problems-prevention-and-management-pdf-1837279828933
   a. Do not offer the following to treat diabetic foot ulcers, unless as part of a clinical trial: Electrical stimulation therapy, autologous platelet-rich plasma gel, regenerative wound matrices and dalteparin
   b. Note: no evidence review identified underlying this recommendation; website evidence review found Cochrane review above

Other payer policies:

Both Aetna (2020) and Cigna (2020) find PRP use to be experimental for all indications including wound healing

CMS 2021

The Centers for Medicare & Medicaid Services (CMS) will cover autologous platelet-rich plasma (PRP) for the treatment of chronic non-healing diabetic wounds…for a duration of 20 weeks, when prepared by devices whose FDA cleared indications include the management of exuding cutaneous wounds, such as diabetic ulcers. Coverage of autologous PRP for the treatment of chronic non-healing diabetic wounds beyond 20 weeks will be determined by local Medicare Administrative Contractors (MACs).

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HERC staff summary

Platelet rich plasma has moderate evidence of effectiveness for increasing the healing rate and reducing the healing time for chronic lower extremity diabetic ulcers. Evidence is insufficient to estimate the effect of PRP on important outcomes such as pain, hospitalization, amputations and wound recurrence for diabetic ulcers. There is also insufficient evidence for the use of platelet rich plasma for non-diabetic chronic wounds. One highly regarded evidence-based source (AHRQ) found moderate SOE for use of PRP for diabetic lower extremity ulcers; however, another highly regarded evidence based source (NICE) does not recommend PRP for this indication. Currently, no private insurer surveyed is covering PRP for any indication, although this may change in the future based on the 2021 CMS decision.

HERC staff recommendations:

1) Add HCPCS G0460 (Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment) to line 379 CHRONIC ULCER OF SKIN; VARICOSE VEINS WITH MAJOR COMPLICATIONS
    a. Advise HSD to remove HCPCS G0460 from the Excluded File
2) Adopt a new guideline for line 379 as shown below

GUIDELINE NOTE XXX PLATELET RICH PLASMA THERAPY

Line 379

Platelet rich plasma therapy (HCPCS G0460) is only included on this line for pairing with chronic diabetic lower extremity wounds and only when

1) there is failure of a 3 month trial of conventional wound care; AND
2) the wound(s) do(es) not have exposed ligament, tendon or bone; AND
3) therapy is no more than 1-2 times per week; AND
4) therapy has a maximum treatment duration of 20 weeks, AND
5) when therapy is prepared by devices whose FDA cleared indications include the management of exuding cutaneous wounds, such as diabetic ulcers.

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Treatment of Port Wine Stains

Question: Should port wine stains be moved to a covered line on the Prioritized List?

Question source: Dr. Tracy Funk, OHSU Pediatric Dermatology

Issue: Port wine stains/capillary malformations are current on an uncovered line on the Prioritized List. On review of old versions of the Prioritized List, the ICD-9 and ICD-10 code for this condition have always been on an unfunded line. A search of old minutes found no discussion of this prioritization at any past meeting. In the past, there was no effective treatment for port wine stains, which likely was the rationale for the low prioritization of the condition. The currently recommended ICD10 code to use for these lesions is Q82.5 (Congenital non-neoplastic nevus).

During the 2012 ICD-10 dermatology review, a similar condition, hemangiomas, had a new line created to allow treatment for complicated lesions (ulcerated, infected, bleeding or function threatening).

Port-wine stains, also called capillary malformations, are congenital malformation made up of excess capillary vessels and are caused by an inherited somatic mutations. They present as pink, red or purplish macules or patches on the skin and are present at birth. Port-wine stains occur most often on the face but can appear anywhere on the body. Port-wine stains may be part of a syndrome such as Sturge–Weber syndrome or Klippel–Trénaunay–Weber syndrome. Port wine stains are not static birthmarks. They have the propensity to darken and thicken over time, often also developing intermittently bleeding papules and nodules akin to pyogenic granulomas. Thickening of a port wine stain can cause tissue hypertrophy that leads to disfigurement and possible functional impairment, especially when involving tissues around the eyes or mouth.

Many treatments have been tried for port-wine stains including freezing, surgery, radiation, and tattooing; port-wine stains can also be covered with cosmetics. The accepted standard of care for treatment of port-wine stains is pulsed dye laser therapy, which has the ability to both lighten the discoloration and prevent some of the tissue thickening. In the absence of successful treatment, hypertrophy (increased tissue mass) of the stains may cause problems later in life, such as loss of function (especially if the stain is near the eye or mouth), bleeding, and increasing disfigurement. Lesions on or near the eyelid can be associated with glaucoma. When port-wine stains are present on the face or other highly visible parts of the body, they can lead to substantial disfigurement, stigmatization, emotional and social impairment for the affected patient.

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Current Prioritized List status

ICD10 Code	Code Description	Current Placement
D18.01	Hemangioma of skin and subcutaneous tissue	321 DERMATOLOGIC HEMANGIOMAS, COMPLICATED 627 BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES
Q82.5	Congenital non-neoplastic nevus	656 DERMATOLOGICAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
17106-17108	Destruction of cutaneous vascular proliferative lesions (eg, laser technique);	242 DERMATOLOGICAL PREMALIGNANT LESIONS AND CARCINOMA IN SITU 276 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA 321 DERMATOLOGIC HEMANGIOMAS, COMPLICATED 401 BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS 558 BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE INCLUDING OSTEOID OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE 625 SEBORRHEIC KERATOSIS, DYSCHROMIA, AND VASCULAR DISORDERS, SCAR CONDITIONS, AND FIBROSIS OF SKIN 627 BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES

GUIDELINE NOTE 13, HEMANGIOMAS, COMPLICATED

Lines 321,627

Dermatologic hemangiomas (ICD-10-CM D18.01 Hemangioma and Lymphangioma of skin and subcutaneous tissue) are included on Line 321 when they are ulcerated, infected, recurrently hemorrhaging, or function-threatening (e.g. eyelid hemangioma). Otherwise, they are included on Line 627.

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Evidence

1) **Faurschou 2011**, Cochrane review of lasers for treating port wine stains
    a. N=5 RCTs (N=103 patients)
    b. All trials examined short-term efficacy of less than six months after treatments with the pulsed dye laser, intense pulsed light, and Nd: YAG laser. The pulsed dye laser was evaluated in all five trials. Depending upon the setting of the pulsed dye laser, this resulted in more than 25% reduction in redness. This was after 1 to 3 treatments for up to 4 to 6 months postoperatively in 50% to 100% of the participants. There was only one study each of intense pulsed light and Nd:YAG laser. Two trials had no occurrence of long-term adverse effects, i.e. six months after treatment. Three trials reported pigmentary alterations in 3% to 24% of the participants, with the highest percentage occurring in Chinese participants with darker skin types. In one study one participant experienced scarring of the skin caused by a too-high dose of the laser used. Short-term side-effects included pain, crusting, and blistering in the first two weeks after treatment.
    c. Authors' conclusions: The pulsed dye laser leads to clinically relevant clearance of port-wine stains. A limited number of RCTs evaluated the efficacy from intense pulsed light and other laser types. High-quality RCTs are needed to assess individual efficacy from different lasers and light sources, as well as participant satisfaction.
2) **CADTH 2007,** Technology Report on Pulsed Dye Laser Therapy for Port Wine Stains
    a. Commonly reported sequelae of PWS are stigmatization, sadness, stress, and low self esteem. The negative effects can have repercussions for parents and for affected children and adolescents, particularly those aged 10 to 20 years. As a result, treatment is not just cosmetic, but reconstructive as well
    b. N= 40 articles (27 clinical studies, 10 reviews, two quasi-systematic reviews, and one quality of life analysis)
        i. The evidence on which this review is based was methodologically weak.
        ii. The studies in this review reported three to seven treatments at intervals of six- to 12-weeks
    a. Quasi systematic reviews
        i. De Borgie *et al*
            1. 10 studies that were reviewed were published between 1989 and 1998, with sample sizes ranging from 12 to 134 children
            2. Overall clearance rates of >50% were reported for 73% to 100% of the children in the study.
            3. The burden of illness was found to be significant (particularly the psychosocial impact). The authors concluded that PDL treatment of facial PWS in children is justifiable for two reasons: prevention of psychological morbidity and improvements in health status. They observed that children should be treated as young as possible to avoid the disturbances observed between ages 10 and 20 years.
        ii. Smit *et al*.
            4. 71 studies reported on PDL for the management of PWS. Among the 71 trials, 54% were prospective, 34% were based on objective measurements, and 24% were controlled.
            5. The location of a PWS was predictive for outcome (lesions on the forehead, lateral face, and neck responded more favourably than those on the central face, lip, chin, dermatome V2 of the face, and the extremities). Although complete clearance was rare (data were not

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provided), most patients were satisfied with the outcomes. Although the age at treatment did not influence the degree of lesion lightening, early treatment maximized the psychological benefit.

b. Case series
    iii. In the five non-comparative case series that examined efficacy, good or excellent results were obtained in 56% to 90% of patients, whereas poor results occurred in 1% to 20% (1% to 7% in studies where the PWS was limited to the face or neck, versus lesions of the trunk that are more resistant).
    iv. 8 of the studies reported adverse effects. Most were mild. Purpura was common as was swelling, crusting, and weeping of the lesion. Permanent AEs such as scarring or hyper- or hypo-pigmentation (side effects of earlier types of technologies) were not reported in any of the studies
c. Conclusions: …the literature suggests that PDL therapy is beneficial, particularly when compared with the alternatives (including no treatment). Success is greater when patients are treated during childhood or adolescence, and when visible PWS are targeted to limit stigmatization, particularly when related to school attendance.

Evidence regarding impact on quality of life

a. **Nguyen 2018**, Vascular Malformations and Health-Related Quality of Life: A Systematic Review and Meta-analysis
    i. N=11 studies (692 patients)
        1. Variety of vascular malformations, including PWS
    ii. Those with VAMs had lower 36-Item Short-Form Health Survey scores in bodily pain (mean difference, −11.87; 95% CI, −21.45 to −2.29; I 2 = 92%; P = .02) and mental health (mean difference, −6.04; 95% CI, −11.55 to −0.52; I 2 = 83%; P = .03) compared with the US general population.
    iii. Patients with facial PWSs had lower HRQoL scores across all domains of the Skindex-29 compared with the population without skin disease. The emotions domain is influenced the most, followed by the functioning and the symptoms domain. The emotional influence of facial PWSs is similar to that of vitiligo, rosacea, epidermolysis bullosa, and psoriasis

<u>Expert guidelines</u>

1) **Sabeti 2020,** consensus statement on treatment of PWS in Sturge-Weber Syndrome
    a. Panel of 12 experts
    b. Sturge-Weber Syndrome is a syndrome in which the child has port wine stain(s) and in addition has vascular anomalies in the brain
    c. Treatment of PWBs is indicated to minimize the psychosocial impact and diminish nodularity and potentially tissue hypertrophy. Better outcomes may be attained if treatments are started at an earlier age. In the US, pulsed dye laser is the standard for all PWBs regardless of the lesion size, location, or color

2) AAP 2015

a. Early treatment of vascular anomalies should be considered medically necessary for benefit plan coverage and payment due to the high risk of serious medical and psychological issues. Therefore, we call upon public and private payers, including health plans, to provide comprehensive benefits coverage and appropriate payment for

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evaluation and treatment of vascular anomalies. In the long run, it will be more cost effective for carriers to cover early intervention and treatment of these disorders. Children who are not treated properly at the earliest possible stage may not only require more reconstructive procedures down the road, but often require psychological counseling to address living with these debilitating and disfiguring lesions.

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Other payer policies:

1) **Health Partners 2020**: covers laser therapy destruction of port wine stain
2) **Aetna 2020**: Aetna considers pulsed dye laser treatment medically necessary for any of the following conditions:
    a. Port wine stains and other hemangiomas when lesions are located on the face and neck
3) **Regence 2020**: Laser treatment may be considered medically necessary for port wine stains
4) **Anthem BCBS 2020**:
    a. Treatment of cutaneous hemangioma, port wine stain, or other vascular lesions is considered **medically necessary** when there is documented evidence of significant physical functional impairment (for example, bleeding or a lesion which interferes with vision) and the procedure can be reasonably expected to improve the physical functional impairment.
    b. Treatment of cutaneous hemangioma, port wine stain, or other vascular lesions using lasers or other methods to restore appearance is considered **reconstructive** when intended to address a significant variation from normal related to a congenital defect.
    c. Treatment of cutaneous hemangioma, port wine stain, or other vascular lesions is considered **cosmetic and not medically necessary** when performed in the absence of a significant physical functional impairment, are not reconstructive, and are intended to change a physical appearance that would be considered within normal human anatomic variation.
5) **Cigna 2020**: Laser destruction (CPT codes 17106, 17107, 17108) of cutaneous vascular lesions is considered medically necessary for ANY of the following:
    a. port wine stain on the face and/or neck
    b. port wine stain on the trunk or extremities associated with recurrent bleeding or painful nodules

Expert Input

Julie Dhossche, OHSU Dermatology

PDL [pulsed dye laser] treatment of port wine stains, especially ones on the head and neck, is standard of care now. This is a congenital malformation and PDL is considered a reconstructive/restorative procedure, not a cosmetic one. Laser treatments are usually started in childhood to prevent complications of hypertrophy and bleeding down the road, which is a common complication of facial PWS. There is thought that the earlier laser treatment can start, the better, to reduce social stigma when starting to learn interactions with others, and while skin is still thinner to allow better penetration of the laser. Once hypertrophy starts it is harder to treat.

HERC staff summary:
Port wine stains can cause significant functional and psychological effects on patients. Treatment with pulsed dye laser is standard of care, with all surveyed insurers covering this therapy. The evidence supports the efficacy of pulsed dye laser therapy for improvement of lesion appearance and reduction in psychosocial impacts; in some cases, there is also a reduction in functional impact.

HERC staff recommendations:

1) Add ICD-10 Q82.5 (Congenital non-neoplastic nevus) to line 321 DERMATOLOGIC HEMANGIOMAS, COMPLICATED
    a. Change the line title of line 321 to DERMATOLOGIC HEMANGIOMAS, COMPLICATED; PORT WINE STAINS
2) Modify GN 13 as shown below
    a. Add GN 13 to line 656 DERMATOLOGICAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

GUIDELINE NOTE 13, HEMANGIOMAS, COMPLICATED; PORT WINE STAINS
Lines 321,627,656
Dermatologic hemangiomas (ICD-10-CM D18.01 Hemangioma and Lymphangioma of skin and subcutaneous tissue) are included on Line 321 when they are ulcerated, infected, recurrently hemorrhaging, or function-threatening (e.g. eyelid hemangioma). Otherwise, they are included on Line 627.

ICD-10 Q82.5 (Congenital non-neoplastic nevus) is included on line 321 only when representing port wine stains. For all other diagnoses, it is included on line 656. Treatment of port wine stains is only included on line 321 when treatment is with pulsed dye lasers and:

1) When lesions are located on the face and neck; OR
2) When lesions are located on the trunk or extremities AND are associated with recurrent bleeding or painful nodules.

Otherwise treatment of port wine stains is included on line 656.

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Section 4.0

Coverage Guidances-EbGS

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections, Pediatric Acute-onset Neuropsychiatric Syndrome, Autoimmune Encephalitis (PANDAS/PANS/AE)

Population description	Children diagnosed with: - Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS), - Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS), or - Autoimmune Encephalitis (AE) ~~Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS): Children with acute onset of severe obsessive-compulsive disorder (OCD) and/or tics associated with infection of streptococci group A whose symptoms are not explained by another neurological disorder.~~ ~~Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS): Children with abrupt, dramatic onset of OCD or severely restricted food intake, as well as additional neuropsychiatric symptoms (≥2 of the following: anxiety; emotional lability and/or depression; irritability, aggression and/or severely oppositional behavior; behavioral regression; deterioration in school performance; sensory or motor abnormalities; somatic symptoms including sleep disturbances, enuresis or urinary frequency) whose symptoms are not better explained by another neurological or medical disorder.~~ ~~Autoimmune Encephalitis (AE): Children with all three of the following criteria:~~ ~~1. Subacute onset (rapid progression within <3 months) of working memory deficits (short-term memory loss), altered mental status, or psychiatric symptoms~~ ~~2. At least one of the following:~~ ~~• New focal central nervous system (CNS) findings~~ ~~• Seizures not explained by a previously known seizure disorder~~ ~~• Cerebrospinal fluid (CSF) pleocytosis (white blood cell count of more than five cells per mm3)~~ ~~• MRI features suggestive of encephalitis~~ ~~3. Reasonable exclusion of alternative causes~~ *Population scoping notes: Patients without any of the above conditions are excluded*

DRAFT

Intervention(s)	Therapeutic plasma exchange; intravenous immunoglobulin (IVIG); cognitive behavioral therapy (CBT) or other behavioral interventions; selective serotonin reuptake inhibitors (SSRIs); antibiotics; tonsillectomy and/or adenoidectomy; corticosteroids *Intervention exclusions: None*
Comparator(s)	Usual care or other interventions
Outcome(s) (up to five)	Critical: Change in psychiatric symptom scores (e.g., Children's Yale-Brown Obsessive Compulsive Scale, Clinical Global Impressions-Improvement, Yale Global Tic Severity scale); Hospitalizations, including institutionalization or emergency visits Important: Harms; Standardized measures of function or quality of life for patients and caregivers *Considered but not selected for GRADE Table: None*
Key questions	1. What is the effectiveness of treatments for PANDAS/PANS/AE as compared to the named comparators? 2. Does the comparative effectiveness of treatments for PANDAS/PANS/AE differ by: a. Patient characteristics b. Condition characteristics c. Intervention d. Provider characteristics (e.g., Center of Excellence 3. What are the harms of interventions for PANDAS/PANS/AE in children?
Contextual questions	What are the evidence-based criteria available for the diagnosis of PANDAS/PANS/AE, and what are the diagnostic accuracy of available criteria or tests?

CHANGE LOG

Date	Change	Rationale
4/8/2021	Added adenoidectomy (Intervention), institutionalization and emergency visits (Critical Outcome), caregiver quality of life (Important Outcome), and condition/provider characteristics (Key Question 2).	Public comment and EbGS discussion

Date	Change	Rationale
5/20/2021	Replaced the Population Description with the following: “Children diagnosed with Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS), Pediatric Acute-Onset Neuropsychiatric Syndrome (PANS), or Autoimmune Encephalitis (AE).”	Public comment