Health Evidence Review Commission

November 12, 2020

1:30 PM - 3:30 PM

Virtual Meeting

Join online meeting here

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Section 1.0

Call to Order

AGENDA

HEALTH EVIDENCE REVIEW COMMISSION

November 12, 2020 (revised 11/9/20)

1:30-3:30 pm

https://www.zoomgov.com/j/1606106579?pwd=b3N5N2R5OEtCTlhDaWdYdXY4OVQvZz09

(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 (10/1/2020	Kevin Olson	X
3	1:40 PM	Director's report	Jason Gingerich	
4	1:45 PM	Value-based Benefits Subcommittee report	Ariel Smits	X
5	3:00 PM	2022 Biennial Review Topics • Surgical repair of symptomatic inguinal hernias • Treatments for uterine polyps	Ariel Smits	X
6	3:25 PM	Next steps • Schedule next meeting –January 21, 2021 virtually	Kevin Olson	
7	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
Virtual Meeting
October 1, 2020

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, MBA, Vice-Chair; Leda Garside, RN, MBA; Gary Allen, DMD; Devan Kansagara, MD; Lynnea Lindsey, PhD; Adriane Irwin, PharmD, Michael Adler, MD (arrived at 1:40 pm); Kathryn Schabel, MD; Max Kaiser, DO; Mike Collins; Deborah Espesete, LAc, MAcOM, MPH, DiplOM.

Members Absent: Leslie Sutton.

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

Also Attending: Val King, MD, MPH, Bethany Godlewski, Erica Shaw, Aasta Thielke & Adam Obley, MD, (OHSU Center for Evidence-based Policy); Melissa Wood (Exact Sciences); Alyssa Hamilton; An Do; Brian Ridderbusch; Britt Redick; Hannah Mason; Koa Kai; Nadia Sanchez; Nicole (no last name given); Paulina Almaraz; Rebecca (no last name given); Renee Dolan; Savannah Vargas; Tim Bair; William (no last name given); Ridica (no last name given); LeRoy LeRoy Patton.

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 8/13/2020 meeting as presented. CARRIES 11-0. *(Absent: Adler)*

Director's Report

Jason Gingerich said he has no updates on the government ethics topic though he, staff and leadership are currently working through the topic.

Recruitment
Gingerich said staff are currently recruiting a public health nurse as Leda Garside is about to reach the end of her term with the Commission. He asked for members to email him with suggestions. Garside has expressed her willingness to continue to serve on a subcommittee.

Coverage guidance topic
He said a possible new topic, due to the recent decrease in compliance due to COVID-19, is how to increase childhood immunization. Hopefully, this topic will begin discussion at the December Evidence-

based Guidelines Subcommittee meeting. He asked any Commissioner who wanted to participate in the development process to please contact him. Adriane Irwin said she would like to participate, especially since there is a Department of Health & Human Services' (DHHS) proposal to allow pharmacists to immunize children as young as 3-years-old. Olson said it would be great to include any data on immunizations by non-traditional providers. He is interested as he is on the Governor's COVID-19 panel and they are looking at the best strategies to deliver the vaccines as quickly as possible once it is available. Allen said dentists now have legislative authorization to administer vaccines; there is still a question of how to incorporate that into their regular work practice. Irwin said that similar legislation is being considered at the national level.

Value-based Benefits Subcommittee (VbBS) Report on Prioritized List Changes
Meeting materials, pages 54-143

Ariel Smits reported the VbBS met earlier in the day, 10/1/2020. She summarized the subcommittee's recommendations.

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

- Place the majority of the 2021 CPT codes on the Prioritized Lists or other HSD files
- Add magnetoencephalography to the epilepsy surgery line with a new guideline
- Add the procedure codes for salpingo-oophorectomy and hysterectomy to the line for women at high risk of breast cancer
- Add various diagnosis codes related to allergies to various funded and unfunded lines on the Prioritized List

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

- Edit the preventive services guideline to show the latest U.S. Preventive Services Task Force (USPSTF) and Heath Resources and Services Administration (HRSA) references
- Delete several entries from the guideline note for ineffective procedures and place on Prioritized List lines or on the HSD Excluded File. Update several other entries with reason for placement and date of last review.
- Edit the SARS-CoV-2 testing guideline to include one additional antibody testing code
- Edit the guideline regarding preventive procedures covered for women who are BRCA positive to include salpingo-oophorectomy and to specify that hysterectomy is only included on the line for women who are BRCA1+ at the time of preventive salpingo-oophorectomy
- Edit the guideline regarding allergy treatment to include when allergy testing is covered and clarify when allergy treatment is covered
- Create a new guideline specifying the circumstances under which treatment of peanut allergies is covered.

MOTION: To accept the VbBS recommendations on *Prioritized List changes* not related to coverage guidances, as stated. See the VbBS minutes of 10/1/2020 for a full description. Carries: 12-0.

Reproductive Health Equity Act report

Meeting materials, pages 144-153

The legislature requires HERC to produce a report every other year for any changes that need to be made to the Reproductive Health Equity Act coverage. Gingerich said, after Commission approval, this report has additional approvals by the Oregon Health Authority (OHA) leadership then is submitted to the Legislature for their consideration.

There was no discussion.

MOTION: To approve the proposed report as presented. Carries 12-0.

Orientation Handbook
Meeting materials, pages 251-317

Liz Walker presented a draft orientation handbook which came from an interest in improving the Commission's onboarding process. Staff identified the needs for improved onboarding new Commissioners/committee members and transparency about our processes and norms. The preliminary areas of focus were the decision space, the population that this Commission affects with their decision-making, impacts of decisions on coverage and budget as well as evidence-based policy principles that guide decision-making. Staff sent a survey out in May 2020 to engage expectations to get an understanding before the work began. Response to the survey was sparse.

Walker reviewed the draft document (meeting materials, pages 251-317).

Suggestions:

- Abbreviations and acronyms should all be clearly defined
- Members requested some short videos to accompany the handbook. Several members gave suggestions about content for the videos.
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- Members requested that Commissioner/committee member contact information be removed from materials that are posted publicly

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Coverage Guidance Topic: Multicomponent Interventions to Improve Screening for Breast, Cervical or Colorectal Cancer Coverage Guidance
Meeting materials, pages 154-250

Obley and Gingerich presented an overview of the proposed multi-sector intervention from the Evidence-based Guidelines Subcommittee (EbGS). Obley summarized the GRADE table and box language. Gingerich said no written public comment was received on this topic during the official public comment period.

Appointed ad hoc expert Melinda Davis, PhD, a professor of Family Medicine and Public Health at Oregon Health Sciences University (OHSU), joined the meeting. She is also Associate Director of Research at the Oregon Rural Practice-based Research Network (ORPRN). Her research interests include

improving health and health care delivery in rural and vulnerable populations through dissemination and implementation research as well as use of participatory research, qualitative methods and practice-facilitation to improve cancer prevention and control and facilitate linkages between primary care and external partners (e.g., community resources, payers, specialists). She is currently a principal investigator on several studies related to this topic:

- Screening More Patients for CRC through Adapting and Refining Targeted Evidence-based Interventions in Rural Settings (SMARTER CRC), funded by the National Cancer Institute
- Using Context to Improve Implementation of Evidenced-based Interventions for Colorectal Cancer Screening in Rural Primary Care (PRECISE CRC)
- Evaluation of the Oregon Colorectal Cancer Screening Project (CRCCP), funded by the Oregon Health Authority

Dr. Davis said she liked the way the table was revised, and she liked the stated emphasis on multicomponent interventions. She said it is important to help community health workers (CHWs) engage in education and outreach. She thanked the Commission for doing this hard work.

Smits reviewed a summary document enumerating proposed changes to the Prioritized List (meeting materials, pages 181-186). She discussed adding CPT-4 codes 98960-98962 (Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes) to Line 3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS. Further, she proposed a new multisector intervention statement (MSI) for the Prioritized List.

Discussion

Lynnea Lindsay said there are billing codes traditionally used for credentialled and licensed entities or provider-types. She said she knows that CHWs are a provider-type, but they are not licensed; as such they bill as incident to or dependent to a licensed provider. She is wondering if CHWs can use these codes can nurses or other provider types (art therapists, for example) use these codes? Smits said that if the code is put on the List it is available to any provider who has OHP billing rights. CHWs must go through a process with OHA to become recognized as a provider. Gingerich said HERC does not get into scope of practice issues; that is a Health Systems Division (HSD) or Coordinated Care Organization (CCO) issue. Gingerich said that the codes would be available for use with any diagnosis on Line 3. Lindsey said this may be an issue for the Quality & Health Outcomes Committee (QHOC) and expressed concern that various types of unlicensed providers might provide these services independently, rather than under the supervision of a licensed provider. She sees CHWs as an essential part of healthcare systems, but the potential for misuse is potentially present with unlicensed providers operating independently. Leda Garside said that CHWs generally practice under the umbrella of a Federally Qualified Health Center (FQHC) or the provider's license; they can only order tests, etc., if the provider approves.

Olson said endorsing this MSI will provide a roadmap for entities to know where they could invest time and resources to improve cancer screening.

Public testimony

Melissa Wood, from Exact Sciences, the developer and marketer of Cologuard, provided testimony. She did not describe any other conflicts of interest. She said their patient adherence program, where they follow up with the patients, is included in the price of the test. She said they have a

complete database of who has been screened and can appropriately rescreen in three years, taking that work necessity away from the providers. She said there is a 20% delta between screening rates for Medicaid and Medicare patients, for many socioeconomic reasons.

Olson said that there are three buckets of services, getting the right people screened, who do we screen and what test do we use, and how do we make sure evidence-based treatments are used. He acknowledged that Cologuard is in the second group but that they also in the first bucket as well because they work at ensuring people are rescreened at appropriate intervals.

MOTION: To approve the proposed multisector interventions report as presented. Carries 12-0.

MOTION: To approve the proposed Multisector Intervention Statement: Multicomponent Interventions to Improve Screening Outcomes or Attendance for Breast, Cervical, or Colorectal Cancer guideline and coding changes for the Prioritized List as proposed. Carries 12-0.

Approved Multisector Intervention:

Multisector Interventions

To improve attendance at cancer screening for breast, cervical, and colorectal cancer, the evidence supports the following interventions across cancer types (ordered roughly according to effect size):

Across Cancer Types

Effective interventions

General population

- Combined approach including three interventions group (with objectives to increase community demand, community access, and provider delivery) (CPSTF, 2016)
- Patient navigation (Ali-Faisal et al, 2017)
- Combined approach including two interventions (with objectives to increase community demand and access) (CPSTF, 2016)
    - Increasing access is more effective than increasing demand
- Community health workers (Bellhouse et al, 2018)
- Narrative interventions (i.e. story-based; breast cancer and colorectal cancer) (Perrier et al, 2017)
- Clinician communication interventions (breast cancer and colorectal cancer) (Peterson et al, 2016)
    - Practice-facilitation workflow/communication skills training (breast cancer and colorectal cancer) (Peterson et al, 2016)

Subpopulations

- Limited English proficiency
    - Patient navigation (Genoff et al, 2016)

- Vulnerable populations
    - Community health workers (Kim et al, 2016)
- Hispanic/Latina populations
    - Educational interventions (*promotora*-delivered, one-on-one, group, combined, church or community-based settings) (Luque et al, 2018)

Interventions with unclear effectiveness

- Special events like health fairs, parties, special day (breast cancer, colorectal cancer and cervical cancer screening) (Escoffery et al, 2014)
- Clinician performance incentives (Mauro et al, 2019)

Breast Cancer Screening

Effective interventions

General population

- Two or more intervention approaches to increase community demand, community access and provider delivery (CPSTF, 2016)
- Two or more intervention approaches to reduce different structural barriers (CPSTF, 2016)

Subpopulations

- Multicomponent interventions to increase community demand or access in
    - African American populations (Copeland et al, 2018)
    - Rural areas (Rodriguez-Gomez et al, 2020)
- Multicomponent interventions that includes increasing provider delivery of screening services in rural areas (Rodriguez-Gomez et al, 2020)
- Individual-tailored educational interventions (provided by lay health workers) in American Indian/Alaska Native populations (Jerome D'Emilia et al, 2019)

Interventions with unclear effectiveness

- Health promotion programs (community-, home- or telephone-based) in ethnic minority women (Chan et al, 2015)
- Culturally tailored interventions (videos, individually tailored telephone counseling) in Chinese American women (Zhang et al, 2020)

Ineffective interventions

- Client reminders (calendar with health reminders) in American Indian/Alaska Native populations (Jerome D'Emilia et al, 2019)
- Small media in rural areas (Rodriguez-Gomez et al, 2020)

- One-on-one education in rural areas (Rodriguez-Gomez et al, 2020)

Cervical Cancer Screening

Effective interventions

General population

- Multicomponent interventions (two or more out of three categories) to increase community demand, access, or provider delivery (CPSTF, 2016)
- Two or more interventional approaches to reduce different structural barriers (CPSTF, 2016)

Subpopulations

- Rural populations (Rodriguez-Gomez et al, 2020)
    - Small media alone
    - Combination of small media, one-on-one education and client reminders
    - Combination of mass media, group education, and reducing structural barriers (e.g. HPV self-collection kit)
- Lower socioeconomic status populations
    - Client reminders (e.g. invitation) (Rees et al, 2018)
    - Lay health advisors (Rees et al, 2018)
    - Clinic-based strategies (Rees et al, 2018)
- Hispanic/Latina populations (Mann et al, 2015)
    - Lay health advisors
    - Clinic-based strategies
    - Church partnerships

Interventions with unclear effectiveness

- Health promotion programs alone in ethnic minority women (Chan et al, 2015)

Ineffective interventions

General population

- Provider assessment and feedback (CPSTF, 2016)

Subpopulations

- Rural areas (Rodriguez-Gomez et al, 2020)
    - Combination of group education and small media
    - Client reminders (e.g. invitation)
    - Small media (e.g. mailed video)

Colorectal Cancer Screening

Effective interventions

General population

- Multicomponent interventions (≥2 out of 3 categories) to increase community demand, access, or provider delivery (CPSTF, 2016; Dougherty et al, 2019)
- Two or more out of three intervention approaches to reduce different structural barriers (CPSTF, 2016)
- Distribution of fecal blood tests (in clinic or mailed outreach) (Dougherty et al, 2019; Issaka et al, 2019; Jager et al, 2019)
- Patient navigation (Dougherty et al, 2019)
- Multicomponent interventions (two or more out of three categories) to increase community demand, access, or provider delivery (CPSTF, 2016)
- Interventions focused on increasing community access
- Tailored communication interventions compared to control (Issaka et al, 2019)
- Clinician-directed interventions (Dougherty et al, 2019)
- Combination of FIT and influenza vaccination clinic (Issaka et al, 2019)
- Patient decision aids (Volk et al, 2016)
- Educational interventions (Dougherty et al, 2019; Issaka et al, 2019)
- Patient reminders (Dougherty et al, 2019)

Subpopulations

- Multicomponent interventions effective at increasing screening adherence in rural areas (Rodriguez-Gomez et al, 2020)
- Multicomponent interventions effective at increasing fecal testing in low-income and rural populations (Davis et al, 2018)
- First-degree relatives of individuals with colorectal cancer
    - Tailored communication interventions (Bai et al, 2020)
- Rural and low-income populations (Davis et al, 2018)
    - Multicomponent interventions to increase community demand, community access, and/or provider delivery
- Federally qualified health centers (Domingo et al, 2017)
    - Patient navigation
- Asian-Americans (Kim et al, 2020)
    - Culturally responsive interventions

Interventions with unclear effectiveness

- Interventions to increase community demand (Young et al, 2019)
- Tailored communication interventions based on family history and personal factors compared to mailed FIT kits (Issaka et al, 2019)

Ineffective interventions

General population

- Patient financial incentives (Dougherty et al, 2019)
- Small media (low literacy picture book, video mailed with FIT kit) (Issaka et al, 2019)

Subpopulations

- Rural areas (Rodriguez-Gomez, 2020)
    - Client reminders (e.g., telephone)
    - Clinician reminders (e.g., chart reminder)
    - Demonstrating how to use FIT kit

Changes for the Prioritized List of Health Services:

1) Add CPT 98960 (Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient) and 98961 (Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 2-4 patients) to :Line 3: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
2) Add a new multisector intervention statement:

Multisector Intervention Statement: Multicomponent Interventions to Improve Screening Outcomes or Attendance for Breast, Cervical, or Colorectal Cancer

To improve attendance at cancer screening for breast, cervical, and colorectal cancer, the evidence supports the following interventions across cancer types (ordered roughly according to effect size):

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    - Increasing access is more effective than increasing demand
- Community health workers (Bellhouse et al, 2018)
- Narrative interventions (i.e. story-based; breast cancer and colorectal cancer) (Perrier et al, 2017)
- Clinician communication interventions (breast cancer and colorectal cancer) (Peterson et al,

2016)

- Practice-facilitation workflow/communication skills training (breast cancer and colorectal cancer) (Peterson et al, 2016)

Subpopulations

- Limited English proficiency
  - Patient navigation (Genoff et al, 2016)
- Vulnerable populations
  - Community health workers (Kim et al, 2016)
- Hispanic/Latina populations
  - Educational interventions (*promotora*-delivered, one-on-one, group, combined, church or community-based settings) (Luque et al, 2018)

Interventions with unclear effectiveness

- Special events like health fairs, parties, special day (breast cancer, colorectal cancer and cervical cancer screening) (Escoffery et al, 2014)
- Clinician performance incentives (Mauro et al, 2019)

Breast Cancer Screening

Effective interventions

General population

- Two or more intervention approaches to increase community demand, community access and provider delivery (CPSTF, 2016)
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Subpopulations

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Interventions with unclear effectiveness

- Health promotion programs (community-, home- or telephone-based) in ethnic minority women (Chan et al, 2015)
- Culturally tailored interventions (videos, individually tailored telephone counseling) in Chinese

American women (Zhang et al, 2020)

Ineffective interventions

- Client reminders (calendar with health reminders) in American Indian/Alaska Native populations (Jerome D'Emilia et al, 2019)
- Small media in rural areas (Rodriguez-Gomez et al, 2020)
- One-on-one education in rural areas (Rodriguez-Gomez et al, 2020)

Cervical Cancer Screening

Effective interventions

General population

- Multicomponent interventions (two or more out of three categories) to increase community demand, access, or provider delivery (CPSTF, 2016)
- Two or more interventional approaches to reduce different structural barriers (CPSTF, 2016)

Subpopulations

- Rural populations (Rodriguez-Gomez et al, 2020)
    - Small media alone
    - Combination of small media, one-on-one education and client reminders
    - Combination of mass media, group education, and reducing structural barriers (e.g. HPV self-collection kit)
- Lower socioeconomic status populations
    - Client reminders (e.g. invitation) (Rees et al, 2018)
    - Lay health advisors (Rees et al, 2018)
    - Clinic-based strategies (Rees et al, 2018)
- Hispanic/Latina populations (Mann et al, 2015)
    - Lay health advisors
    - Clinic-based strategies
    - Church partnerships

Interventions with unclear effectiveness

- Health promotion programs alone in ethnic minority women (Chan et al, 2015)

Ineffective interventions

General population

- Provider assessment and feedback (CPSTF, 2016)

Subpopulations

- Rural areas (Rodriguez-Gomez et al, 2020)
    - Combination of group education and small media

- Client reminders (e.g. invitation)
- Small media (e.g. mailed video)

Colorectal Cancer Screening

Effective interventions

General population

- Multicomponent interventions (≥2 out of 3 categories) to increase community demand, access, or provider delivery (CPSTF, 2016; Dougherty et al, 2019)
- Two or more out of three intervention approaches to reduce different structural barriers (CPSTF, 2016)
- Distribution of fecal blood tests (in clinic or mailed outreach) (Dougherty et al, 2019; Issaka et al, 2019; Jager et al, 2019)
- Patient navigation (Dougherty et al, 2019)
- Multicomponent interventions (two or more out of three categories) to increase community demand, access, or provider delivery (CPSTF, 2016)
- Interventions focused on increasing community access
- Tailored communication interventions compared to control (Issaka et al, 2019)
- Clinician-directed interventions (Dougherty et al, 2019)
- Combination of FIT and influenza vaccination clinic (Issaka et al, 2019)
- Patient decision aids (Volk et al, 2016)
- Educational interventions (Dougherty et al, 2019; Issaka et al, 2019)
- Patient reminders (Dougherty et al, 2019)

Subpopulations

- Multicomponent interventions effective at increasing screening adherence in rural areas (Rodriguez-Gomez et al, 2020)
- Multicomponent interventions effective at increasing fecal testing in low-income and rural populations (Davis et al, 2018)
- First-degree relatives of individuals with colorectal cancer
    - Tailored communication interventions (Bai et al, 2020)
- Rural and low-income populations (Davis et al, 2018)
    - Multicomponent interventions to increase community demand, community access, and/or provider delivery
- Federally qualified health centers (Domingo et al, 2017)
    - Patient navigation
- Asian-Americans (Kim et al, 2020)
    - Culturally responsive interventions

Interventions with unclear effectiveness

- Interventions to increase community demand (Young et al, 2019)
- Tailored communication interventions based on family history and personal factors compared to mailed FIT kits (Issaka et al, 2019)

Ineffective interventions

General population

- Patient financial incentives (Dougherty et al, 2019)
- Small media (low literacy picture book, video mailed with FIT kit) (Issaka et al, 2019)

Subpopulations

- Rural areas (Rodriguez-Gomez, 2020)
    - Client reminders (e.g., telephone)
    - Clinician reminders (e.g., chart reminder)
    - Demonstrating how to use FIT kit

Obley said this would be his last HERC meeting working with the Center for Evidence-based Policy. Staff and commissioners expressed appreciation for Obley's work in simplifying complex issues so they can be well-understood.

Public Comment

Guideline Note 60 Opioids for Conditions of the Back and Spine

Koa Kai is a patient-ambassador for the Chronic Disease Coalition and stated she has no conflicts of interest. She said the most concerning part of Guideline Note 60, for patients, is the policy overreach from what the committee's given task was: from solely deciding coverage to making requirements that demand doctor's performance of treatments, often against the doctor's best clinical judgement. Kai said this policy interferes in the patient-doctor relationship to provide appropriate medical treatment and can cause patient harm and disability. She said the guideline is not scientifically supported. Although the clause "when clinically indicated" was added in the middle of aggressive taper language, the rest of the guideline note renders that statement moot.

OHA, to date, has not acquired any patient outcome data for this unprecedented policy so we are forced to rely on anecdotal evidence such as the 33% rise in deaths of Medicare/Medicaid patients in the last year alone in the Death with Dignity program due to lack of pain control. The OHA's Ombudsoffice was forced last year to seek emergency funding to add additional workers to deal with the increased number of concerns and complaints about the continuity of pain medication. She said doctors need to be able to use their best clinical judgement without fear of regulatory attention or retribution. Kai said patients are continuing to be harmed by this radical policy that needs to be revoked immediately.

Olson said this topic will be on a future agenda.

Other topics

With a COVID-19 vaccine potentially on the horizon, Garside said it is important for us to know which providers can provide vaccinations. Smits said the Centers for Disease Control (CDC) has been working with OHA on a plan; staff will update the Commission with any news.

Items for next meeting

- Guideline Note 60 discussion (potentially November or possibly January)

Adjournment

Meeting adjourned at 3:22 pm. The next meeting will be from 1:30-4:30 pm (time approximate) on Thursday, November 12, 2020, virtually.

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on October 1, 2020

For specific coding recommendations and guideline wording, please see the text of the 10/1/2020 VbBS minutes.

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

- Place the majority of the 2021 CPT codes on the Prioritized Lists or other HSD files
- Add magnetoencephalography to the epilepsy surgery line with a new guideline
- Add the procedure codes for salpingo-oophorectomy and hysterectomy to the line for women at high risk of breast cancer
- Add various diagnosis codes related to allergies to various funded and unfunded lines on the Prioritized List
- Add procedure codes for community health worker patient education to the funded preventive services line

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

- Edit the preventive services guideline to show the latest USPSTF and HRSA references
- Delete several entries from the guideline note for ineffective procedures and place on Prioritized List lines or on the HSD Excluded File. Update several other entries with reason for placement and date of last review.
- Edit the SARS-CoV-2 testing guideline to include one additional antibody testing code
- Edit the guideline regarding preventive procedures covered for women who are BRCA positive to include salpingo-oophorectomy and to specify that hysterectomy is only included on the line for women who are BRCA1+ at the time of preventive salpingo-oophorectomy
- Edit the guideline regarding allergy treatment to include when allergy testing is covered and clarify when allergy treatment is covered
- Create a new guideline specifying the circumstances under which treatment of peanut allergies is covered.
- Create a new guideline with the recommendations of the multi-sector interventions for screening for breast, cervical and colorectal cancer screening

VALUE-BASED BENEFITS SUBCOMMITTEE
Virtual Meeting
October 1, 2020
8:00 AM – 1:00 PM

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

Members Absent: Kathryn Schabel, MD.

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

Also Attending: Melissa Wood (Exact Sciences), Adam Obley MD, Val King MD MPH, Erica Shaw (OHSU Center for Evidence Based Policy); Koa Kai; and Zoom participants.

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

  The meeting was called to order at 8:05 am and roll was called. A quorum of members was present at the meeting. Minutes from the August 13, 2020 VbBS meeting were reviewed and approved.

  Smits mentioned the errata document was in the meeting packet. She polled subcommittee members about their preferences for breaks and lunch break for virtual meetings. The members requested that the current meeting schedule, with a very short lunch break (5 min) be continued so that members can get to afternoon work obligations or have a break prior to the Health Evidence Review Commission (HERC) afternoon meeting.

- **Topic: Straightforward/Consent Agenda**

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

  Recommended Actions:
  1) GN106 was updated as shown in Appendix A

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

- **Topic: 2021 CPT code placement**

  Discussion: Smits reviewed all of the CPT code suggested placements. There was no discussion on any recommended placements except for the following:

  1) **76145** Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report
     a. Dehen suggested that this type of evaluation is for employees whose radiation monitor indicated that they have received radiation exposure beyond an accepted limit. The evaluation would be done by the radiation safety or employee safety department. The decision was to have HERC staff reach out to a radiation or employee safety expert to consult about recommended placement and bring back for further discussion at the November meeting.
  2) **55880** Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance
     a. Duty noted that HIFU was used as salvage therapy after failed radiation therapy. This procedure is not being used in the urology community due to lack of clinical efficacy and high side effect profile. He had discussed this therapy with the Oregon Urology Society and that group agreed with non-coverage.
     b. Gingerich noted that the coverage guidance on HIFU for benign prostatic hypertrophy should be included in the GN173 entry. Staff was given permission to make that change by the Subcommittee
  3) **99072** Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency, as defined by law, due to respiratory-transmitted infectious disease
     a. Hodges noted that HSD and CCOs need to be aware that 99072 will no longer be a billable/reimbursable code once the COVID Public Health Emergency is declared over, until a future public health emergency.

  Recommended Actions:
  1) 2021 CPT code placements as shown in Appendix B
  2) GN173 was modified as shown in Appendix A

3) Remove HCPCS C9745 (Nasal endoscopy, surgical; balloon dilation of eustachian tube) from line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS/GN173
    a. Add HCPCS C9745 to line 654 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
4) Modify GN148 BIOMARKER TESTS OF CANCER TISSUE as shown in Appendix A
5) Add CPT 99072 (Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency, as defined by law, due to respiratory-transmitted infectious disease) to line 399 INFLUENZA, NOVEL RESPIRATORY VIRUSES
6) Advise HSD to add CPT 86413 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative) to the Diagnostic Procedures File
7) Modify DIAGNOSTIC GUIDELINE D27 SARS-COV-2 (COVID-19) TESTING as shown in Appendix A

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

- **Topic: Completion/re-review of GN173 entries**

Discussion: There was no discussion about these agenda items.

Recommended Actions:
1) Add CPT 69740-69745 (Suture facial nerve) to line 228 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES
2) Add CPT 41821 (Operculectomy, excision pericoronal tissue) to line 344 DENTAL CONDITIONS (E.G., SEVERE CARIES, INFECTION)
3) Add CPT 92354-92355 (Fitting of spectacle mounted low vision aid) to line 654 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
4) Remove the following code entries from GN173 and advise HSD to add to the Excluded File
    a. 43647-43648, 43881-43882 Laparoscopy, surgical; implantation or replacement or revision of gastric neurostimulator electrodes, antrum
    b. 55300 Vasotomy for vasograms, seminal vesiculograms, or epididymogram
    c. 82757 Fructose, semen
    d. 92559 Audiometric testing of groups
    e. 92640 Diagnostic analysis with programming of auditory brainstem implant
    f. 94452-94453 High altitude simulation test (HAST)
5) Modify GN173 entries as shown in Appendix A

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

- **Topic**: **Magnetoencephalography**

Discussion: Smits reviewed the summary document. Hodges raised the concern that the staff recommendation placed a procedure on the Prioritized List that was only available out of state. Gingerich responded that proton beam therapy is also on the Prioritized List and available only out of state. Hodges noted that this requires CCOs to pay for transportation and housing for a patient

approved to get this test. Dehen asked staff if there was any easily available data on the number of OHP patients who require epilepsy surgery. Staff responded that the exact number was not known but it was not thought to be large. Duty asked if the epilepsy surgery would be done at UCSF, or only the magnetoencephalography. Smits replied that the surgery would be in state. Olson expressed concern that if OHP does not cover this test, then OHP may end up covering the cost of an epilepsy surgery that might not be as effective as it would have been with the test. Olson wondered if this test could be approved at the CCOs discretion. The subcommittee members felt that the staff recommendation should be approved. Dehen requested that HERC staff monitor this code for utilization and readdress coverage if a large increase in utilization is seen. Gingerich responded that he had added a reminder to review code utilization in a year.

Recommended Actions:

1) Add magnetoencephalography (CPT 95965- 95967) to line 174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS Treatment: SINGLE FOCAL SURGERY
2) Add a new guideline note to line 174 as shown in Appendix C

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

- **Topic: Nerve allographs**

Discussion: Smits reviewed the summary document. Hodges requested that the proposed coding specification be changed to a guideline, as guidelines are easier to find and administer for a CCO. Smits replied that staff would work on changing the recommendation to a guideline and bring back to the November meeting as a consent agenda item.

Recommended Actions:

1) Tabled to November 2020 VBBS meeting

- **Topic: Combined kidney liver transplants**

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

Recommended Actions:

1) Delete the coding specification from line 307 CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR MALFORMATIONS; CAROLI'S DISEASE
    a. ~~Liver-kidney transplant only included on this line for a documented diagnosis of Q44.6 (cystic disease of the liver).~~

MOTION: To recommend the coding specification as presented. CARRIES 7-0.

- **Topic: Hysterectomy at time of salpingo-oophorectomy for BRCA1+ women**

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

  Recommended Actions:
  1) Add CPT 58720 (Salpingo-oophorectomy, complete or partial, unilateral or bilateral) to line 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
  2) Add hysterectomy to line 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER and GN3 PROPHYLACTIC TREATMENT FOR PREVENTION OF BREAST CANCER IN HIGH-RISK WOMEN
     a. CPT 58150-58180,58260-58263,58290-58292,58541-58554,58570-58573
  3) Modify GN3 as shown in Appendix A

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

- **Topic: Peanut allergies and allergy testing and treatment**

  Discussion: Smits reviewed the summary document. Dehen had questions about the availability of the double-blind, placebo-controlled food challenge (DBPCFC) test. Smits responded that this test was a requirement to entry in all the peanut allergy medication trials. The testing will likely become available if not already once the new peanut allergy medications come to market. HERC staff will monitor and bring back to the HERC if they determine there is an issue with access to DBPCFC testing.

  Recommended Actions:
  1) Remove the ICD-10 T78.0 family of codes (Anaphylactic reaction due to food) from the dysfunction lines
     a. 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
     b. 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
     c. 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS
     d. 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
  2) Add ICD-10 Z01.82 (Encounter for allergy testing) to lines 9,102,123,222,313,532,533,552, 561,568
     a. Advise HSD to remove Z01.82 from the DIAGNOSTIC WORKUP FILE (DWF)
  2) Modify GN 156 as shown below to include coverage of allergy testing
  3) Add ICD-10 Z91.010 (Allergy to peanuts) to lines 123 ANAPHYLACTIC SHOCK; EDEMA OF LARYNX, 545 SYMPTOMATIC URTICARIA and 552 OTHER NONINFECTIOUS GASTROENTERITIS AND COLITIS
     a. Advise HSD to remove Z91.010 from the INFORMATIONAL DIAGNOSES list
  4) Add a new guideline for peanut allergy treatment to lines 123, 545 and 552 as shown in Appendix C

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

- **Topic: Coverage Guidance— Multi-Sector Intervention (MSI) for cancer screening**

Discussion: Obley and Gingerich presented the evidence review. Gingerich reviewed the screening rates for various CCOs for these cancer types. Smits reviewed the summary of Prioritized List changes required for implementation of this MSI report. Hodges requested additional information on the codes allowed for billing by community health workers; Smits sent her the OHA statement on this topic.

Melissa Wood offered public comment. She represents Exact Sciences, the company that makes Cologuard, a stool DNA screening test for colorectal cancer. Exact Sciences shared written testimony earlier to subcommittee members regarding Cologuard. Oregon is head and shoulder above other states on increasing screening for Medicaid populations. She emphasized that in person interventions are less available during the COVID pandemic.

Recommended Actions:

1) Add CPT 98960 (Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient) and 98961 (Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 2-4 patients) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
2) Adopt a new multisector intervention statement as shown in Appendix C

MOTION: To approve the recommended changes to the Prioritized List based on the draft MSI for cancer screening coverage guidance scheduled for review by HERC at their October 1, 2020 meeting. CARRIES 7-0.

- **Public Comment:**

Koa Kai commented regarding GN60 Opioids for Conditions of the Back and Spine. She is a national patient ambassador for patients with chronic conditions. She said that this guideline is an overreach. GN60 instructs and requires doctors to treat patients in a manner that might go against their clinical judgement. She believes the GN60 should be revoked. It is scientifically unsupported. It is based on the opinions of the Chronic Pain Taskforce, and several had conflicts of interest. The phrase "when clinically indicated" is found in between some aggressive tapering language. She requests an independent review with patient and advocates as stakeholders. This guideline has caused patient suffering and harm, including suicide. In severe, progressive and incurable disease, the only option is to manage symptoms. Patients need individualized care and as many treatment options as possible. Providers need to be able to treat patients without fear of retribution. She said that the OHA ombudsperson office had to employ six new full-time employees due to increased call volume due to issues related to the continuity of pain medication.

- **Issues for next meeting:**
  - 2021 CPT Code Review Medical Physics Evaluation
  - Nerve allografts

- **Next meeting:**

  November 12, 2020; virtual meeting

- **Adjournment:**

  The meeting adjourned at 12:55 PM.

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DIAGNOSTIC GUIDELINE D27, SARS-COV-2 (COVID-19) TESTING

Testing for SARS-CoV-2 (COVID-19) virus RNA or viral antigen is a covered diagnostic service.

Antibody testing for SARS-CoV-2 (COVID-19; CPT 86413, 86328 or 86769) is covered as diagnostic only when such testing meets the following criteria:

A) Testing is done using tests that have FDA Emergency Use Authorization (EUA) or FDA approval; AND
B) Testing is used as part of the diagnostic work up of multisystem inflammatory syndrome in children (MIS-C) for hospitalized persons under the age of 21.

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

Line 191

Bilateral prophylactic breast removal and/or salpingo-oophorectomy are included on Line 191 for women without a personal history of invasive breast cancer who meet the criteria in the NCCN Clinical Practice Guidelines in Oncology. Breast Cancer Risk Reduction. ~~V.1.2016 (2/23/16).~~ V.1.2020 (12/4/19) www.nccn.org. Prior to surgery, women without a personal history of breast cancer must have a genetics consultation as defined in section A2 of the DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE.

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

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

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, ~~2019~~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 ~~on December 20, 2016~~. Available at https://www.hrsa.gov/womens-guidelines-2019 ~~https://www.hrsa.gov/womens-guidelines-2016/index.html~~ as of ~~11/5/2019~~ September 14, 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

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.

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.

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.

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- 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, 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 156, ENCOUNTER FOR TESTING AND DESENSITIZATION TO ALLERGENS

Lines 9,102,123,222,313,532,533,552,561,568

ICD-10 CM Z01.82 (Encounter for allergy testing) is only included on these lines when

1) used to diagnose an allergy that affects a diagnosis appearing on a line above the current funding line (e.g. asthma, severe eczema); AND
2) symptoms are not adequately controlled by empiric conservative therapy; AND
3) testing must correlate specifically to the member's history, risk of exposure and physical findings; AND

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4) test technique and/or allergens tested must have proven efficacy demonstrated through scientifically valid medical studies published in the peer-reviewed literature.

ICD-10-CM Z51.6 (Encounter for desensitization to allergens) is only included on these lines when

1) used to treat a diagnosis appearing on ~~a line above the current funding line (i.e.~~ Lines 9, 102, 123, 222 and 313~~)~~, AND
2) The patient has a properly performed skin test and/or serologic evidence of IgE-mediated antibody to a potent extract of the allergen, *AND*
3) Hypersensitivity to allergen cannot be adequately managed by appropriate medication therapy or allergen avoidance.

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
~~C9745~~	~~Nasal endoscopy, surgical; balloon dilation of Eustachian tube~~	~~Insufficient evidence of effectiveness~~	~~May, 2018~~
C9747, 55880	Ablation of prostate/ablation of malignant prostate tissue, transrectal, high-intensity focused ultrasound (hifu), including imaging guidance	Insufficient evidence of effectiveness	~~May, 2018~~ October, 2020 Add link to CG
32998	Radiofrequency ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s)	Insufficient evidence of effectiveness	October, 2020
~~41821~~	~~Operculectomy, excision pericoronal tissue~~		
~~43647-43648 43881-43882~~	~~Laparoscopy, surgical; implantation or replacement or revision of gastric neurostimulator electrodes, antrum~~		
~~55300~~	~~Vasotomy for vasograms, seminal vesiculograms, or epididymogram~~		
55873	Cryosurgical ablation of the prostate	Insufficient evidence of effectiveness	October, 2020

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Procedure Code	Intervention Description	Rationale	Last Review
57465	Computer-aided mapping of cervix uteri during colposcopy, including optical dynamic spectral imaging and algorithmic quantification of the acetowhitening effect	Insufficient evidence of effectiveness	October, 2020
~~69740-69745~~	~~Suture facial nerve~~		
69955	Total facial nerve decompression and/or repair	Insufficient evidence of effectiveness	October, 2020
77084	Magnetic resonance (eg, proton) imaging, bone marrow blood supply	Insufficient evidence of effectiveness	October, 2020
81529	Oncology (cutaneous melanoma), mRNA, gene expression profiling by real-time RT-PCR of 31 genes (28 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk, including likelihood of sentinel lymph node metastasis	Insufficient evidence of effectiveness	October, 2020
81546	Oncology (thyroid), mRNA, gene expression analysis of 10,196 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)	Insufficient evidence of effectiveness	October, 2020
81554	Pulmonary disease (idiopathic pulmonary fibrosis [IPF]), mRNA, gene expression analysis of 190 genes, utilizing transbronchial biopsies, diagnostic algorithm reported as categorical result (eg, positive or negative for high probability of usual interstitial pneumonia [UIP])	Insufficient evidence of effectiveness	October, 2020
82107	Alpha-fetoprotein (AFP); AFP-L3 fraction isoform and total AFP	Insufficient evidence of effectiveness	October, 2020
82610	Cystatin	Insufficient evidence of effectiveness	October, 2020
~~82757~~	~~Fructose, semen~~		
92229	Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral	Insufficient evidence of effectiveness	October, 2020

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69720-69725	Decompression facial nerve	Insufficient evidence of effectiveness	October, 2020
~~92354-92355~~	~~Fitting of spectacle mounted low vision aid~~		
~~92559~~	~~Audiometric testing of groups~~		
~~92640~~	~~Diagnostic analysis with programming of auditory brainstem implant~~		
~~94452-94453~~	~~High altitude simulation test (HAST)~~		

Procedure Code	Intervention Description	Rationale	Last Review
92517-92519	Vestibular evoked myogenic potential (VEMP) testing	Insufficient evidence of effectiveness	October 2020

Code	Code description	Placement Recommendation
30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)	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
32408	Core needle biopsy, lung or mediastinum, percutaneous, including imaging guidance, when performed	DIAGNOSTIC PROCEDURES
33741	Transcatheter atrial septostomy (TAS) for congenital cardiac anomalies to create effective atrial flow, including all imaging guidance by the proceduralist, when performed, any method (eg, Rashkind, Sang-Park, balloon, cutting balloon, blade)	Any line which currently has 92992-92998
33745	Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, including all imaging guidance by the proceduralist, when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (eg, atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); initial intracardiac shunt	All congential heart disease lines
33746	Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, including all imaging guidance by the proceduralist, when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (eg, atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); each additional intracardiac shunt location (List separately in addition to code for primary procedure)	All congential heart disease lines
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only	69 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION

33997	Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion	69 CUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 81 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS 97 HEART FAILURE 264 CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE
55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
57465	Computer-aided mapping of cervix uteri during colposcopy, including optical dynamic spectral imaging and algorithmic quantification of the acetowhitening effect (List separately in addition to code for primary procedure)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral	652 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral	652 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
71271	Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
76145	Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report	Tabled to November 2020
80143	Acetaminophen	DIAGNOSTIC PROCEDURES
80151	Amiodarone	DIAGNOSTIC PROCEDURES
80161	Carbamazepine; -10,11-epoxide	DIAGNOSTIC PROCEDURES
80167	Felbamate	DIAGNOSTIC PROCEDURES
80179	Salicylate	DIAGNOSTIC PROCEDURES
80181	Flecainide	DIAGNOSTIC PROCEDURES
80189	Itraconazole	DIAGNOSTIC PROCEDURES
80193	Leflunomide	DIAGNOSTIC PROCEDURES
80204	Methotrexate	DIAGNOSTIC PROCEDURES
80210	Rufinamide	DIAGNOSTIC PROCEDURES
81168	CCND1/IGH (t(11;14)) (eg, mantle cell lymphoma) translocation analysis, major breakpoint, qualitative and quantitative, if performed	DIAGNOSTIC PROCEDURES

81191	NTRK1 (neurotrophic receptor tyrosine kinase 1) (eg, solid tumors) translocation analysis	DIAGNOSTIC PROCEDURES
81192	NTRK2 (neurotrophic receptor tyrosine kinase 2) (eg, solid tumors) translocation analysis	DIAGNOSTIC PROCEDURES
81193	NTRK3 (neurotrophic receptor tyrosine kinase 3) (eg, solid tumors) translocation analysis	DIAGNOSTIC PROCEDURES
81194	NTRK (neurotrophic-tropomyosin receptor tyrosine kinase 1, 2, and 3) (eg, solid tumors) translocation analysis	DIAGNOSTIC PROCEDURES
81278	IGH@/BCL2 (t(14;18)) (eg, follicular lymphoma) translocation analysis, major breakpoint region (MBR) and minor cluster region (mcr) breakpoints, qualitative or quantitative	DIAGNOSTIC PROCEDURES
81279	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) targeted sequence analysis (eg, exons 12 and 13)	DIAGNOSTIC PROCEDURES
81338	MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; common variants (eg, W515A, W515K, W515L, W515R)	DIAGNOSTIC PROCEDURES
81339	MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; sequence analysis, exon 10	DIAGNOSTIC PROCEDURES
81347	SF3B1 (splicing factor [3b] subunit B1) (eg, myelodysplastic syndrome/acute myeloid leukemia) gene analysis, common variants (eg, A672T, E622D, L833F, R625C, R625L)	DIAGNOSTIC PROCEDURES
81348	SRSF2 (serine and arginine-rich splicing factor 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, P95H, P95L)	DIAGNOSTIC PROCEDURES
81351	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; full gene sequence	To be reviewed by GAP and will be discussed at the November VBBS meeting
81352	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; targeted sequence analysis (eg, 4 oncology)	To be reviewed by GAP and will be discussed at the November VBBS meeting
81353	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; known familial variant	To be reviewed by GAP and will be discussed at the November VBBS meeting
81357	U2AF1 (U2 small nuclear RNA auxiliary factor 1) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, S34F, S34Y, Q157R, Q157P)	DIAGNOSTIC PROCEDURES

81360	ZRSR2 (zinc finger CCCH-type, RNA binding motif and serine/arginine-rich 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variant(s) (eg, E65fs, E122fs, R448fs)	DIAGNOSTIC PROCEDURES
81419	Epilepsy genomic sequence analysis panel, must include analyses for ALDH7A1, CACNA1A, CDKL5, CHD2, GABRG2, GRIN2A, KCNQ2, MECP2, PCDH19, POLG, PRRT2, SCN1A, SCN1B, SCN2A, SCN8A, SLC2A1, SLC9A6, STXBP1, SYNGAP1, TCF4, TPP1, TSC1, TSC2, and ZEB2	To be reviewed by GAP and will be discussed at the November VBBS meeting
81513	Infectious disease, bacterial vaginosis, quantitative real-time amplification of RNA markers for Atopobium vaginae, Gardnerella vaginalis, and Lactobacillus species, utilizing vaginal-fluid specimens, algorithm reported as a positive or negative result for bacterial vaginosis	DIAGNOSTIC PROCEDURES
81514	Infectious disease, bacterial vaginosis and vaginitis, quantitative real-time amplification of DNA markers for Gardnerella vaginalis, Atopobium vaginae, Megasphaera type 1, Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), and Lactobacillus species (L. crispatus and L. jensenii), utilizing vaginal-fluid specimens, algorithm reported as a positive or negative for high likelihood of bacterial vaginosis, includes separate detection of Trichomonas vaginalis and/or Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata, Candida krusei, when reported	DIAGNOSTIC PROCEDURES
81529	Oncology (cutaneous melanoma), mRNA, gene expression profiling by real-time RT-PCR of 31 genes (28 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk, including likelihood of sentinel lymph node metastasis	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81546	Oncology (thyroid), mRNA, gene expression analysis of 10,196 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

81554	Pulmonary disease (idiopathic pulmonary fibrosis [IPF]), mRNA, gene expression analysis of 190 genes, utilizing transbronchial biopsies, diagnostic algorithm reported as categorical result (eg, positive or negative for high probability of usual interstitial pneumonia [UIP])	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
82077	Alcohol (ethanol); any specimen except urine and breath, immunoassay (eg, IA, EIA, ELISA, RIA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)	DIAGNOSTIC PROCEDURES
82681	Estradiol; free, direct measurement (eg, equilibrium dialysis)	DIAGNOSTIC PROCEDURES
86408	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); screen	EXCLUDED
86409	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); titer	EXCLUDED
90377	Rabies immune globulin, heat- and solvent/detergent-treated (RIg-HT S/D), human, for intramuscular and/or subcutaneous use	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
92229	Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
92517	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report; cervical (cVEMP)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
92518	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report; ocular (oVEMP)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
92519	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report; cervical (cVEMP) and ocular (oVEMP)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
92650	Auditory evoked potentials; screening of auditory potential with broadband stimuli, automated analysis	DIAGNOSTIC PROCEDURES
92651	Auditory evoked potentials; for hearing status determination, broadband stimuli, with interpretation and report	DIAGNOSTIC PROCEDURES

92652	Auditory evoked potentials; for threshold estimation at multiple frequencies, with interpretation and report	DIAGNOSTIC PROCEDURES
92653	Auditory evoked potentials; neurodiagnostic, with interpretation and report	DIAGNOSTIC PROCEDURES
93241	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation	DIAGNOSTIC PROCEDURES
93242	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)	DIAGNOSTIC PROCEDURES
93243	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report	DIAGNOSTIC PROCEDURES
93244	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation	DIAGNOSTIC PROCEDURES
93245	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation	DIAGNOSTIC PROCEDURES
93246	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)	DIAGNOSTIC PROCEDURES
93247	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report	DIAGNOSTIC PROCEDURES
93248	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation	DIAGNOSTIC PROCEDURES
94619	Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry; without electrocardiographic recording(s)	DIAGNOSTIC PROCEDURES

99417	Prolonged office or other outpatient evaluation and management service(s) beyond the minimum required time of the primary procedure which has been selected using total time, requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service, each 15 minutes of total time (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services)	All lines with E&M codes
99439	Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)	All lines with E&M codes

Appendix C

New Guideline Notes

GUIDELINE NOTE XXX MAGNETOENCEPHALOGRAPHY

Line 174
Magnetoencephalography (MEG) is included on this line only for pre-surgical evaluation in persons with intractable focal epilepsy to identify and localize areas of epileptiform activity, when discordance or continuing questions arise from among other techniques designed to localize a focus.

GUIDELINE NOTE XXX PEANUT ALLERGY TREATMENT

Lines 123,545,552
ICD-10 Z91.010 (Allergy to peanuts) and T78.01X (Anaphylactic reaction due to peanuts) are included on line 123 for

1) Office visit, specialist consultation, ER evaluation/treatment, and hospital care; and
2) Symptomatic treatment with medications such as antihistamines or epinephrine; and
3) Pharmaceutical treatment with medications intended to reduce the severity of the peanut allergy only when ALL of the following criteria are met:
    a. The patient has a clinical history of serious peanut allergy with anaphylaxis, AND
    b. The diagnosis of peanut allergy has been confirmed with an IgE or skin-prick test, AND
    c. The patient has a baseline eliciting dose of allergy symptoms on double-blind, placebo-controlled food challenge (DBPCFC) test, AND
    d. The pharmaceutical treatment is prescribed by, or in consultation with, an allergist or immunologist.

Otherwise, ICD-10 Z91.010 is included on lines 545 or 552

Multisector Intervention Statement: Multicomponent Interventions to Improve Screening Outcomes or Attendance for Breast, Cervical, or Colorectal Cancer

To improve attendance at cancer screening for breast, cervical, and colorectal cancer, the evidence supports the following interventions across cancer types (ordered roughly according to effect size):

Across Cancer Types

<u>Effective interventions</u>

<u>General population</u>

- Combined approach including three interventions group (with objectives to increase community demand, community access, and provider delivery) (CPSTF, 2016)
- Patient navigation (Ali-Faisal et al, 2017)
- Combined approach including two interventions (with objectives to increase community demand and access) (CPSTF, 2016)
    - Increasing access is more effective than increasing demand
- Community health workers (Bellhouse et al, 2018)
- Narrative interventions (i.e. story-based; breast cancer and colorectal cancer) (Perrier et al, 2017)

- Clinician communication interventions (breast cancer and colorectal cancer) (Peterson et al, 2016)
    - Practice-facilitation workflow/communication skills training (breast cancer and colorectal cancer) (Peterson et al, 2016)

Subpopulations

- Limited English proficiency
    - Patient navigation (Genoff et al, 2016)
- Vulnerable populations
    - Community health workers (Kim et al, 2016)
- Hispanic/Latina populations
    - Educational interventions (*promotora*-delivered, one-on-one, group, combined, church or community-based settings) (Luque et al, 2018)

Interventions with unclear effectiveness

- Special events like health fairs, parties, special day (breast cancer, colorectal cancer and cervical cancer screening) (Escoffery et al, 2014)
- Clinician performance incentives (Mauro et al, 2019)

Breast Cancer Screening

Effective interventions

General population

- Two or more intervention approaches to increase community demand, community access and provider delivery (CPSTF, 2016)
- Two or more intervention approaches to reduce different structural barriers (CPSTF, 2016)

Subpopulations

- Multicomponent interventions to increase community demand or access in
    - African American populations (Copeland et al, 2018)
    - Rural areas (Rodriguez-Gomez et al, 2020)
- Multicomponent interventions that includes increasing provider delivery of screening services in rural areas (Rodriguez-Gomez et al, 2020)
- Individual-tailored educational interventions (provided by lay health workers) in American Indian/Alaska Native populations (Jerome D'Emilia et al, 2019)

Interventions with unclear effectiveness

- Health promotion programs (community-, home- or telephone-based) in ethnic minority women (Chan et al, 2015)
- Culturally tailored interventions (videos, individually tailored telephone counseling) in Chinese

American women (Zhang et al, 2020)

Ineffective interventions

- Client reminders (calendar with health reminders) in American Indian/Alaska Native populations (Jerome D'Emilia et al, 2019)
- Small media in rural areas (Rodriguez-Gomez et al, 2020)
- One-on-one education in rural areas (Rodriguez-Gomez et al, 2020)

Cervical Cancer Screening

Effective interventions

General population

- Multicomponent interventions (two or more out of three categories) to increase community demand, access, or provider delivery (CPSTF, 2016)
- Two or more interventional approaches to reduce different structural barriers (CPSTF, 2016)

Subpopulations

- Rural populations (Rodriguez-Gomez et al, 2020)
    - Small media alone
    - Combination of small media, one-on-one education and client reminders
    - Combination of mass media, group education, and reducing structural barriers (e.g. HPV self-collection kit)
- Lower socioeconomic status populations
    - Client reminders (e.g. invitation) (Rees et al, 2018)
    - Lay health advisors (Rees et al, 2018)
    - Clinic-based strategies (Rees et al, 2018)
- Hispanic/Latina populations (Mann et al, 2015)
    - Lay health advisors
    - Clinic-based strategies
    - Church partnerships

Interventions with unclear effectiveness

- Health promotion programs alone in ethnic minority women (Chan et al, 2015)

Ineffective interventions

General population

- Provider assessment and feedback (CPSTF, 2016)

Subpopulations

- Rural areas (Rodriguez-Gomez et al, 2020)
    - Combination of group education and small media

- Client reminders (e.g. invitation)
- Small media (e.g. mailed video)

Colorectal Cancer Screening

Effective interventions

General population

- Multicomponent interventions (≥2 out of 3 categories) to increase community demand, access, or provider delivery (CPSTF, 2016; Dougherty et al, 2019)
- Two or more out of three intervention approaches to reduce different structural barriers (CPSTF, 2016)
- Distribution of fecal blood tests (in clinic or mailed outreach) (Dougherty et al, 2019; Issaka et al, 2019; Jager et al, 2019)
- Patient navigation (Dougherty et al, 2019)
- Multicomponent interventions (two or more out of three categories) to increase community demand, access, or provider delivery (CPSTF, 2016)
- Interventions focused on increasing community access
- Tailored communication interventions compared to control (Issaka et al, 2019)
- Clinician-directed interventions (Dougherty et al, 2019)
- Combination of FIT and influenza vaccination clinic (Issaka et al, 2019)
- Patient decision aids (Volk et al, 2016)
- Educational interventions (Dougherty et al, 2019; Issaka et al, 2019)
- Patient reminders (Dougherty et al, 2019)

Subpopulations

- Multicomponent interventions effective at increasing screening adherence in rural areas (Rodriguez-Gomez et al, 2020)
- Multicomponent interventions effective at increasing fecal testing in low-income and rural populations (Davis et al, 2018)
- First-degree relatives of individuals with colorectal cancer
    - Tailored communication interventions (Bai et al, 2020)
- Rural and low-income populations (Davis et al, 2018)
    - Multicomponent interventions to increase community demand, community access, and/or provider delivery
- Federally qualified health centers (Domingo et al, 2017)
    - Patient navigation
- Asian-Americans (Kim et al, 2020)
    - Culturally responsive interventions

Appendix C

Interventions with unclear effectiveness

- Interventions to increase community demand (Young et al, 2019)
- Tailored communication interventions based on family history and personal factors compared to mailed FIT kits (Issaka et al, 2019)

Ineffective interventions

General population

- Patient financial incentives (Dougherty et al, 2019)
- Small media (low literacy picture book, video mailed with FIT kit) (Issaka et al, 2019)

Subpopulations

- Rural areas (Rodriguez-Gomez, 2020)
    - Client reminders (e.g., telephone)
    - Clinician reminders (e.g., chart reminder)
    - Demonstrating how to use FIT kit

HIghlights

Behavioral Health Advisory Panel
Virtual meeting
October 21, 2020
1:00 pm--3:00 pm

Members Present: Lynnea Lindsey, PhD Chair; Kathy Savicki, LCSW; Gary Cobb; Sheldon Levy, PhD; John Bischof, MD; Sondra Marshal MD.

Members Absent: Eric Davis, MSW, CADC III, PSS; MSCP.

Staff Present: Jason Gingerich; Ariel Smits, MD, MPH.

Also Attending: Laurie Theodorou, LCSW (OHA); Jodie Nokoa; Athena Goldberg; Chris Wig; Chris Bouneff; Craig Chan; DeAnn (no last name given); Hannah Proffitt-Allee, Jacek/Jack Haciak, PsD, Jeanne McLaws; Jen (no last name given); Libbie Rascon; Lisa Hanson; Liz Schwarz; Tamara McNatt; Tami S; Terri Watkins; Trent Taylor; Tyler Duffield, PhD; Wendy (no last name given); Amanda Parish; BJ Lynch; Karen (no last name given); Barbara Scaturro; Shari (no last name given); Mellony (no last name given); Gordon Clay; other unidentified participants

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1. CALL TO ORDER

Lynnea Lindsey called the meeting to order at 1:00 PM

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2. STAFF REPORT

1) Smits made panel members aware of the OHA document "Community Health Workers as OHP Providers." This was purely informational.
2) Smits noted that HERC staff had been asked about coverage of acupuncture for treatment of substance use disorder. The CPT codes for acupuncuture are on the Substance Use Disorder (SUD) line, but this line is not included in the acupuncture guideline, which is confusing for providers and CCOs. Smits noted that the evidence for acupuncture for SUD is for treatment of withdrawal symptoms and cravings rather than as monotherapy for the SUD itself. Lindsey agreed that acupuncture should be part of a larger package. Cobb noted that acpuncture is also used for anxiety and post-treatment support. Lindsey felt that even post treatment, most patients are still in therapy or in other supportive programs. HERC staff will draft up guideline wording for the acupuncture guideline indicating that acupuncture is included for treatment of SUD only as part of a larger treatment program. Lindsey and Gary Cobb want to look at guideline changes for HERC staff.

3. PRIORITIZED LIST ISSUES

1) Straightforward code change recommendations
    a. Smits reviewed the codes recommended for change. The panel members did not feel that ICD-10 F43.9 (Reaction to severe stress, unspecified) should be added to the Prioritized List. There are much better, more specific diagnosis codes that can be used. Theodorou noted that ICD-10 F43.9 might be useful in children in which a more specific diagnosis can't be made, but she agreed that other codes such as ICD-10 F43.8 could be used in this situation
    b. There was no discussion about adding HCPCS H2014 to the substance use line. The panel agreed unanimously with this change
    c. Smits reviewed a question that had come up since the BHAP packet had been sent out. A stakeholder had requested clarification on whether health and behavior assessment codes (CPT 96156-96159) could be used for substance use disorder diagnoses, as these codes are on line 4 SUBSTANCE USE DISORDER. CMS rules do not allow use of the CPT codes with BH/SUD diagnoses. The panel agreed that that was correct and recommended removal of these codes from line 4.
2) Neurobehavioral status exam and neuropsychological testing guideline
    a. Smits reviewed the summary document. The panel generally felt that the guideline changes as recommended by staff were reasonable. There was discussion about CPT 96132 and 96133 being "thinking codes" that have a higher RVU that the general testing codes, and therefore they are being used more frequently. The panel unanimously agreed with adding coverage for these services after epilepsy surgery.
3) Cognitive rehabilitation guideline:
    a. Panelists said that the staff changes were appropriate and that the cognitive rehabilitation procedure codes were mispairings on the lines recommended for removal.
4) Repetitive transcranial magnetic stimulation guideline
    a. BHAP members were concerned about the use of rTMS in children and adolescents and requested that HERC staff research the evidence and FDA regulations around rTMS use in children. HERC staff have determined that the FDA approval of rTMS is limited to adults and private insurers require patients to be 18 year of age or older. Studies reviewed found only adult patients included. There was some discussion about the use of rTMS for indications other than depression, particularly OCD. HERC staff reviewed the literature included in this review and found that experts do not feel that there is sufficient evidence to support the use of rTMS for any indication other than major depression. There was also discussion about an upper limit of sessions. BHAP members were concerned about possible adverse effects of multiple sessions. Dr. Bischof noted that CareOregon reviews cases after approximately 30 sessions to determine if a change in therapy is indicated.
5) Biofeedback
    a. Smits reviewed the summary document. Lindsey noted that it is hard to define what is actually being done when biofeedback is billed. She has seen that it can be effective for anxious chronic pain patients with catastrophizing. Biofeedback is frequently done as part of psychotherapy, but therapists don't bill the code because its not being paid. It was noted by panel members that there is not a lot of research around biofeedback for chronic pain treatment. This topic will be further discussed at the VBBS meeting in January, 2021.

6) HCPCS Code H0031
    a. Smits asked about whether HCPCS H0031 should be removed from the Diagnostic File. The panel felt that this code was widely used for substance abuse treatment programs, intakes for mental health programs, etc. No changes were recommended.
7) Telehealth as it relates to MH/SUD
    a. HERC staff requested BHAP feedback on telehealth services as they relate to BH/SUD. The panel discussed the tension between ensuring access to care/equity and ensuring quality of care. Telehealth, including telephone only visits, allows access for many people without the means to afford a device capable of audiovisual visits (smart phone, tablet, etc.). Its an equity issue to keep telephone visits available. However, members did feel that a visual evaluation of patients and seeing patient nonverbal expression is an important part of a behavioral health evaluation. Some members noted that clinics are starting to have devices available in the clinic that can be used for a virtual visit with a provider off-site, which can help with the equity/access issue.
    b. There was discussion about requiring HIPAA compliant platforms. Currently, the Office of Civil Rights has waived encryption requirements, but the panel felt that ensuring secure, private communication was very important once the public health emergency is over.
    c. There was discussion about whether the large increase in telehealth visits for BH seen in OHP is a sign of increase in access to patients. It was noted that studies have found many more people in the US meet mental health diagnosis criteria since the start of the COVID epidemic; therefore, telehealth visit increases may be appropriate access to care. It was also noted that some of the increase in telehealth visits may be driven by situations such as parents with kids doing home-schooling who can't come in for visits in person.
    d. Public testimony:
        i. Chris Wig testified that he was the director of a program in Eugene that serves SUD patients, many of whom have co-occurring mental health diagnoses. COVID has drastically reduced his program's ability to see patients in person and do drug tests. Virtual visits have allowed his program to continue to do counseling and group therapy. BH providers have finally achieved the motivation to give services via telehealth. He highlighted that services just delivered over telephone can also really benefit patients. Patients work with peer support via telephone to get resources to use smart phone. Clients have been able to work more hours, because they can do sessions over the phone during work breaks. Telephone visits helps patients with severe anxiety who are not comfortable with audiovisual visits or groups.

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4. OTHER BUSINESS/PUBLIC COMMENT

There was no other business or public comment

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5. ADJOURNMENT

The meeting was adjourned at 2:50 PM

HIGHLIGHTS

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

Virtual Meeting
October 5, 2020
9:00-11:00 a.m.

Members Present: Gary Allen, DMD, Chair; Eli Schwarz, DDS, MPH, PhD; Dayna Steringer; Laura McKeane; Alison Noble.

Members Absent: Karen Nolon; Deborah Loy; Mary Robinson.

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

Also Attending: Kellie Skenandore, Teri McClain (Oregon Health Authority); Manu Chaudhry, MS, DDS (Capital Dental); Dr. Kyle Ash (Pacificsource Dental).

Roll Call/Minutes Approval/Staff Report

The meeting was called to order at 9:00 am and roll was called. Minutes from October 11, 2018 were reviewed and approved.

Smits announced that Kellie Skenandore was retiring at the end of December and wished her well. Teri McClain will be taking over her position.

Dr. Allen suggested adding Dr. Manu Chaudhry from Capital Dental to the OHAP group. Smits suggested that Dr. Chaudhry send his information to HERC staff for consideration.

- **Topic:** New Codes--2021 CDT code placement

No discussion

- **Topic:** Straightforward CDT code changes

No discussion

- **Topic:** Guideline for dental implant removal

There was minimal discussion on this topic.

- **Topic:** Cone beam computed tomography (CBCT)

Smits reviewed the evidence summary. Dr. Allen noted that oral surgeons and endodontists feel that CBCT is standard of care for certain cases. He agreed that other than for exceptions, having CBCT only on the craniofacial anomalies line was appropriate.

Dr. Chaudhry uses CBCT for impacted teeth and for evaluation of root canals. CBCT is helpful for endodontists but is not required. He agreed with HERC staff recommendation.

Dr. Schwarz was concerned that CBCT is not useful for vertical root fractures. This is one of the areas that he feels that CBCT is most useful. He points out that the systematic review only includes four studies because of lack of research in this area. The sensitivity and specificity were relatively high for detection of vertical root fractures. Aging teeth with crowns are more likely to have issues like vertical root fractures, and more likely to be difficult to diagnose. He suggests consideration of adding of CBCT for diagnosis of vertical root fracture.

Dr. Ash stated that CBCT is overused; physical exam and x-ray can give a lot of the required information.

Dr. Allen noted that he has made exceptions in certain cases. He felt that vertical root fractures might be a use of CBCT. Dr. Chaudhry did not agree with the use of CBCT with vertical root fractures; the detection depends on the resolution of the CBCT.

Dr. Schwarz asked about the number of claims to expect and the reimbursement that would be available. Skenandore stated that there was no reimbursement rate determined yet. Dr. Allen noted that the number of claims he has evaluated for CBCT for vertical root fracture is not very large. Dr. Allen noted that if vertical root fracture is diagnosed, generally the tooth is extracted. This is the same outcome that would occur if vertical root fracture was not actually diagnosed and the patient was symptomatic. Therefore, CBCT does not affect the treatment or outcome for vertical root fractures.

Dr. Chaudhry felt that mandibular impacted molars evaluation is a good use of CBCT. His practice found several cases that required in hospital care rather than office care due to root location. Smits reviewed that the evidence review did not find evidence to support the use of CBCT for mandibular impacted molars. Dr. Allen did note that supernumerary tooth evaluation was another common exception he made. Dr. Ash agreed that CBCT can be useful in several cases as exception; he reiterated his concern for overutilization and high radiation exposure.

The group agreed to leaving the current coverage of CBCT and having the dental directors evaluate cases on a case by case basis for determination of exceptions. Specifically, evaluation of vertical root fracture should be considered as a possible exception.

- **Topic:** Mercury amalgam fillings

Smits reviewed the summary document. Allen noted that payment for composite is currently at the amalgam rate. Skenandore noted that this issue was brought forward by public health due to concerns for adverse health effects. She noted that OHA/HSD has considered any change in rates for composite. She felt that perhaps HSD would need to consider changing the rates in the future. Smits noted that if the rates needed to be changed, this change could be held. Skenandore noted that the rates for DCOs has already been done for the next biennium, but felt that the proposed guideline note change would be acceptable.

Dr. Chaudhry stated that he wanted to wait for the ADA to endorse the FDAs statement. This would be a significant change in dental practice. He offered to reach out to the ADA to see if they are going to come out with new guidelines. Allen noted that the ADA put out a statement after the FDA announcement that was lukewarm in their support.

Gingerich asked what risk OHA might take by not calling this out since the FDA has put out this statement. Allen noted that there is not universal agreement with the FDA statement. Allen stressed that HERC should be evidence based, and any change should reflect the evidence. Dr. Chaudhry suggested having the HERC do an evidence-based review of this topic. Dr. Schwarz agreed with looking at the underlying evidence. He noted that the concern with amalgam has been going on since the 1980s. Dr. Ash noted that the evidence supports that amalgam is a very safe product. He noted that this is the ADA's position.

Skenandore noted that OHA needs supporting evidence for whatever position is taken. Sarah Kowalski in public health might be a resource for HERC staff in further evidence review.

Dr. Allen noted that OHP has already given dentists the option of using composite. It comes down to a reimbursement issue.

Dr. Schwarz offered to connect HERC staff to the Center for Evidence Based Dentistry at the ADA.

The decision was to have HERC staff do an evidence review on the risks of mercury containing amalgam. Smits will engage with public health on this topic as well. Smits will circulate the evidence review to OHAP for comments and input, but no formal approval will be needed to advance this topic to VBBS. Gingerich will work with OHA leadership regarding possible rate issues.

- **Public Comment:**

No public comment was received.

- **Issues for next meeting:**

- **Next meeting:**
  - TBD

Highlights

Genetic Advisory Panel (GAP)
Virtual Meeting
October 7, 2020
9:00 AM-12:00 PM

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

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

Also Attending: Alyssa Hamilton; Ashley Svenson (Myriad Genetics); Beverly Skram; Cori Feist; Devki Nagar (Myriad Genetics); Hannah Mason; Jamie Dunphy, ACS CAN; Jeanne McLaws, Katy McDowell; Kim Martin MD; Kimberlynn Heller, DO; Laytont (no last name given); Madison Strickland; Dana Morris; Nadia Sanchez; Patrick Hardyman; Peggy Tighe; Rebecca (no last name given); Rick Frees; Scott (no last name given); Taryn Couture; Tracy Futch; Vanessa Nitibhon (Integrated Genetics); Karen Heller; Rashelle Kukuk; Hannah Baer (Coalition for Access to Prenatal Screening); Nathan (no last name given).

The meeting was called to order at 9 AM. Roll was called. This is an advisory panel to the Health Evidence Review Commission (HERC) Medical Director in preparing meeting materials for deliberation by the Value-based Benefits Subcommittee at its 11/12/20 meeting and a quorum is not necessary as no votes are taken. The highlights from the 2019 GAP meeting were reviewed and no changes were suggested.

1) 2020 genetic CPT codes
    a. There was extensive discussion regarding the 4 new genetic related CPT codes.
        i. For Li-Fraumeni testing: Stevens noted that different labs may offer different testing at very different pricing. Voian noted that these tests are done usually as panels, which usually include TP53. She would just do these single tests in very limited situations. She felt this testing would not be cost effective, except in the case of familial variant. It was noted that the panels generally cost less than the single gene testing. There was some concern that if the panel does not contain this test, then the individual tests should be covered. Some insurance requires a list of all gene codes on the panel If a patient is positive for this mutation, it changes screening recommendations for various cancers for the patient.

Stevens noted that there is language in the genetic testing guideline requiring the least expensive test. The panelists recommended covering this test as a Diagnostic Procedure

ii. For epilepsy panel testing: There was discussion about whether this specific test of genes are a proprietary panel. Members noted that there are multiple panels for epilepsy evaluation. Many of these panels include more genes than this test. Harding noted that there are different epilepsy panels depending on age of onset. However, these panels have been replaced by whole exome sequencing in his practice. Smits noted that the code lists these codes as the minimum list for billing this test; more genes can be included. Stevens wondered about limiting to tests only after consultation with a geneticist. Others thought there might not be enough bandwidth among geneticists; also, neurologists may be more knowledgeable about this testing. Harding noted that this panel is most useful for medication management, which would be most appropriately ordered by a neurologist. The GAP recommendation was to include on the epilepsy line.

2) Whole exome sequencing:
    a. There was minimal discussion. GAP members agreed with continuing the current coverage as it is.
3) Coding changes to the prenatal genetic testing guideline
    a. There was no discussion. GAP members agreed with staff recommendations
4) Non-invasive prenatal genetic screening (NIPS) also known as cell-free DNA testing (cfDNA)
    a. There was extensive GAP discussion in favor of covering this testing for all-risk women, advocating coverage of lower risk as well as high-risk women. This is in line with ACOG recommendations, and in line with what is occurring in practice in Oregon. Stevens noted that his CCO is finding an equity issue with this testing—it is being ordered and covered by the majority of the patients in the OB-Gyn practice in their network for privately insured patients, but not for OHP patients. NIPS has a lower false positive rate, which lowers the rate of invasive confirmatory testing (amniocentesis and CVS). There was also discussion that NIPS can be used as a second-tier test, for example, after an abnormal quad screen. In this situation, the higher negative and positive predictive value of the NIPS test is helpful in determining if the first screening test was a false positive and therefore reducing the need for invasive testing like amniocentesis.
    b. Public Testimony:
        i. Hannah Baer: representing CAPS, a collaborative alliance of genetic testing companies. 14 state Medicaid programs cover cell free fetal DNA testing (cfDNA) for all singleton pregnancies. 29 state Medicaid programs cover cf DNA for high risk women only. Many states have moved from no coverage to high risk or from high risk to low risk screening in the past few years. All commercial payers cover cfDNA for high risk women, and many for all risk pregnancies.
        ii. Kimberly Martin: OB-Gyn, clinical geneticist. She noted in her conflict of interest statement that she has worked for genetic testing companies, but is now retired and not being paid for this testimony. Dr. Martin brought up that lack of coverage for NIPS for OHP women of average risk is an equity issue as commercially covered women frequently are covered for this testing. She noted that fetal nuchal translucency testing requires a certified provider, which many OB-Gyn practices do not have; this requires the patient to set up a separate appointment for this testing and pay costs for

travel and childcare, etc. cfDNA is the most sensitive and specific prenatal screening test available. The NEXT study in 2015 in NEJM (Norton et al), was a head to head comparison of cfDNA to other screening modalities. This study clearly showed increased PPV of cfDNA versus other modalities. ACOG 226 released a guideline around 9/1/2020 which noted this type of testing was acceptable in twin pregnancies.

iii. Vanessa Nitibhan: certified genetic counselor, testified on behalf of Insight Genetics. She said that cfDNA provides the most equitable care. ACOG's new practice bulletin supports cfDNA for all pregnant women. cfDNA is the most sensitive and specific screening test for aneuploidies in both low and high-risk women. With fewer false positive tests, there are fewer amniocenteses required and thus fewer complications like miscarriage. cfDNA has 100 times lower rate of false positives than some of the other screening modalities. This testing allows less stress for patients.

iv. Nathan [unclear last name]: geneticist in private practice in Nevada. Will be joining a medical lab next month as a medical director. The higher positive predictive value argument is profound. The negative predictive value is so great that a negative test result as less than a 1:10,000 change that its wrong. Issue of justice in access to better testing.

5) Expanded carrier screening.

a. GAP members were unanimously in favor of adding expanded carrier screening for pre-pregnancy and prenatal genetic screening. GAP members felt unanimously that relying on a patient's reported race or ethnicity was problematic, as many patients do not fully know their ancestry.

There was discussion that the staff proposed requirement for pre-testing genetic counseling was not feasible. However, positive tests would require genetic counseling regarding the results. There was discussion about the fact that several of the labs offering these tests provide free genetic counseling to patients regarding results; however, the quality of this counseling cannot be verified. It was also noted that the labs vary widely in the information they send back to providers and patients; some just send the test result while others send a page or two of interpretive information.

GAP members had concerns about the fact that the commercially available tests vary dramatically in the number and types of genes tested. The larger the number of genes in the panel, the higher the likelihood for finding a positive result. The number of women with positive results could overwhelm the capacity of genetic counselors in the state, although it was noted that virtual visits could help with this.

There was discussion about adding restrictions on the type of testing offered, such as limiting the included number of genes or only clinically meaningful variants. Other members stated that testing has moved to only include meaningful variants. There was other discussion that the number of genes is a moving target and would not be advisable to add. There was discussion about putting in wording requiring the tests to follow national guidelines like ACOG or ACGME. However, there was concern that if a panel had a gene in addition to the ones in these guidelines, that the entire test might be non-covered.

GAP discussed whether pre-conception expanded carrier screening should be included in the non-prenatal genetic testing guideline. The restriction proposed by staff to limit to once in a lifetime was felt to be too restrictive, as the tests are constantly changing and, in the future, different conditions might be included. The staff proposal to require pre- and post-testing counseling was felt to be useful.

b. Public Testimony
    i. Kimberlynn Heller: Heller is an ObGyn at the Oregon Clinic, and stated no conflicts of interest. She supports expanded carrier screening. This is about disparities in health care, and the difficulty in determining ethnicity. Pre-pregnancy counseling involves offering these tests prior to pregnancy. Carrier screening is very effective at letting women determine what risks they have. The tests included on expanded carrier screening focuses on non-European disease like sickle-cell disease, making lack of coverage an equity issue. ACOG recommends pre-pregnancy counseling and pre-pregnancy screening.
    ii. Devki Nagaris a genetic counselor who works for Myriad Genetics. Access to expanded carrier screening can help address inequities that are part of ethnic based screening. 81443 is the appropriate CPT code. Many labs are doing sequencing, labs don't report results of uncertain significance. She expressed support for pretest education, but feels that tests should be ordered by multiple types of providers
    iii. Kimberly Martin said that Access is critical. There are not enough genetic counselors to meet the pre- and post- test requirements. Genetic counseling is also a requirement for spinal muscular atrophy (SMA) screening in the current guideline—she recommends taking that out. ACOG is a great place to refer to for types of tests. At a minimum, genes should include those examined in all the ethnicity-based tests. X linked recessive disorders have been overlooked in this discussion. Both fragile X and Duchenne muscular dystrophy should be included in the expanded carrier panel.

6) Cancer genetic testing guideline
    a. Voian noted that the NCCN guideline for high risk genetic testing for breast and ovarian cancer screening had been updated since the staff summary was developed. Smits said she will find the updated NCCN guideline and adjust the reference update accordingly.
    b. Public testimony:
        i. Ashley Svenson is a genetic counselor and employee of Myriad Genetics. She requested change to the provision that counseling must be provided by a genetic specialist. She also suggested adding four additional provider types: OB/GYNs, FP, surgeons, oncologists. She said that the current requirement is out of line with recommendations from NCCN, USPSTF, breast surgeons, ACOG, etc. and that non-geneticists are increasingly ordering genetic testing to manage their patients. She added that the current guideline is also out of line with commercial payers and state Medicaid programs. This requirement is burdensome to patients, particularly rural Oregonians.

Section 2.0

VbBS Report

Scope for Potential 2021 Biennial Review Topics

1) Coverage of hernias
    a. Consider new guideline allowing coverage of inguinal hernias that prohibit work, interfere or ADLs or require daily pain medication
    b. Outcomes include quality of life, progression to strangulation/incarceration, surgical complications, pain medication requirements, ability to return/keep work.
    c. No data on a policy where patients are not offered surgery when hernias cause pain.
2) Uterine polyps
    a. Separate uterine polyps from uterine fibroids; consider creating a new line for uterine polyps without hysterectomy
3) Other suggestions?

Consent Agenda Issues—November 2020

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
11981 11982 11983	Insertion, non-biodegradable drug delivery implant Removal, non-biodegradable drug delivery implant Removal with reinsertion, non-biodegradable drug delivery implant	312 GENDER DYSPHORIA/TRANSEXUALISM	HSD claims reconsideration requested review of pairing of 11981 with gender dysphoria. These codes are used for implantable puberty suppression medications. Puberty suppression medication is covered in the gender dysphoria guidelines	Add 11981-11983 to line 312
26480 26483	Transfer or transplant of tendon, carpometacarpal area or dorsum of hand; without/with free graft, each tendon	356 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE	A CCO requested that CPT 26480 and 26483 pair with ICD10 M18.12 Unilateral primary osteoarthritis of first carpometacarpal joint, left hand pairs. This diagnosis appears on line 356. Coding resources indicate that this is an appropriate pairing.	Add 26480 and 26483 to line 356

Nerve Allografts

Question: Should nerve allografts be moved to a covered line on the Prioritized List?

Question source: Holly Jo Hodges, CCO medical director

Issue: Nerve allografts were discussed at the October, 2020 VBBS meeting. VBBS members were in agreement that this procedure should only be covered for digital nerve injuries. However, the staff recommendation to add a coding specification to the line with digital nerve injuries was thought to not be the preferred solution. Staff were directed to create a guideline note regarding this and bring back as a consent item.

HERC staff recommendations:

1) Add CPT 64912-64913 (Nerve repair; with nerve allograft) to line 536 PERIPHERAL NERVE DISORDERS Treatment SURGICAL TREATMENT
    a. Will pair with ICD10 S64.4 category (Injury of digital nerve of finger)
    b. Consistent with our trusted source (NICE) and prioritization of relevant conditions
2) Remove the GN173 entry for CPT 64912-64913 as shown below
3) Add the following new guideline to line 536

GUIDELINE NOTE XXX NERVE ALLOGRAFTS
Line 536
Nerve allografts (CPT 64912-64913) are only on this line for repair of digital nerve injury (ICD-10-CM S64.4 code category).

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

The following treatments are prioritized on Line 662, CONDITIONS FOR WHICH CERTAIN TREATMENTS HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS; UNPROVEN TREATMENTS for the conditions listed here:

CPT/HCPCS code	INTERVENTION	Rationale	Date of last Review
~~64912-64913~~	~~Nerve repair; with nerve allograft~~	~~Unproven treatment~~	~~November, 2017~~

COVID Updates
November 2020

Question: Should the COVID testing guideline be modified to include multisystem inflammatory syndrome in adults (MIS-A)?

Question source: HERC staff

Issue: The CDC recently released a case series of adult patients with multisystem inflammatory syndrome (MIS-A) after COVID infection. Currently, the Prioritized List COVID testing guideline limits COVID antibody testing to multisystem inflammatory syndrome in children (MIS-C) under age 21. The Health Systems Division has already issued guidance allowing antibody testing for patients with suspected MIS-A.

Evidence

1) **MMWR 2020**, Case Series of Multisystem Inflammatory Syndrome in Adults Associated with SARS-CoV-2 Infection — United Kingdom and United States, March–August 2020
    a. N=27 patients
    b. Findings indicate that adult patients of all ages with current or previous SARS-CoV-2 infection can develop a hyperinflammatory syndrome resembling MIS-C.
    c. Patients had cardiovascular, gastrointestinal, dermatologic, and neurologic symptoms without severe respiratory illness and concurrently received positive test results for SARS-CoV-2, the virus that causes COVID-19, by polymerase chain reaction (PCR) or antibody assays indicating recent infection
    d. Antibody testing was required to identify SARS-CoV-2 infection in approximately one third of 27 cases.
    e. All but one of the patients with MIS-A described in this report belonged to racial or ethnic minority groups
    f. 3 of 27 patients died
    g. Clinicians and health departments should consider MIS-A in adults with compatible signs and symptoms. These patients might not have positive SARS-CoV-2 PCR or antigen test results, and antibody testing might be needed to confirm previous SARS-CoV-2 infection

HERC staff recommendation

1) Modify Diagnostic Guideline D27 as shown below *effective January 1, 2021*
    a. Allows workup of MIS-A

DIAGNOSTIC GUIDELINE D27, SARS-COV-2 (COVID-19) TESTING
Testing for SARS-CoV-2 (COVID-19) virus RNA or viral antigen is a covered diagnostic service.

Antibody testing for SARS-CoV-2 (COVID-19; CPT 86413, 86328 or 86769) is covered as diagnostic only when such testing meets the following criteria:

A) Testing is done using tests that have FDA Emergency Use Authorization (EUA) or FDA approval; AND
B) Testing is used as part of the diagnostic work up of multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A) for hospitalized persons ~~under the age of 21~~.

COVID-19 Related Codes

Issue: Multiple new CPT codes related to COVID-19 have been released on October 7, 2020. These codes were effective immediately.

New codes released October 7, 2020:
87636 Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) and influenza virus types A and B, multiplex amplified probe technique
87637 Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique
87811 Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])

Currently, COVID RNA and antigen testing is on the Diagnostic Procedures File, as is testing for influenza and RSV. Diagnostic Guideline D27 includes a statement that COVID virus RNA or antigen tests are covered.

HERC staff recommendations:
1) Advise HSD to place 87636, 87637 and 87811 to the DIAGNOSTIC PROCEDURES file

Straightforward CDT Code Changes

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
D0320	Temporomandibular joint arthrogram, including injection	643 TMJ DISORDERS	TMJ conditions are only included on an uncovered line. D0320 is currently on the Diagnostic Procedures File	Add D0320 to line 643 Advise HSD to remove D0320 from the DIAGNOSTIC PROCEDURES file
D0321	Other temporomandibular joint radiographic images, by report	643 TMJ DISORDERS	See above	Add D0321 to line 643 Advise HSD to remove D0321 from the DIAGNOSTIC PROCEDURES file

Dental Implant Removal

Question: Should a guideline be added to the Prioritized List regarding dental implant removal?

Question source: Gary Allen, DMD; DCOs

Issue: As part of the 2018 Biennial Review, dental implant removal (CDT D6100) was added to a covered line and kept on an uncovered line. The intent was to cover for situations in which the implant is infected or otherwise impacting the health of the patient. HERC staff was directed to work with Dr. Allen to devise a guideline regarding D6100. However, for reasons unclear in the minutes, such a guideline was never put forward. Dr. Allen and dental directors of the DCOs feel that such a guideline should be added to the Prioritized List.

Current Prioritized List status
D6100 (Implant removal, by report) is on lines 344 DENTAL CONDITIONS (E.G., SEVERE CARIES, INFECTION) and 619 DENTAL CONDITIONS (E.G., MISSING TEETH)

HERC staff recommendation:

1) Adopt the following new guideline note

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

Mercury Dental Amalgam

Question: Should the dental amalgam guideline be modified to reflect new FDA warnings regarding use of mercury in certain risk groups?

Question source: OHA dental program, HERC staff

Issue: The FDA released new recommendations on September 24, 2020 regarding the use of mercury containing amalgam in certain high risk groups: pregnant women or women who plan to become pregnant, nursing women, children especially under the age of 6, people with pre-existing neurological disease or impaired kidney function, and people with known mercury allergies. Currently, the Prioritized List has one guideline that recommends the use of mercury amalgam in posterior tooth restoration.

Dental amalgam is a type of dental restorative material that is a mixture of elemental mercury and an alloy primarily composed of silver, tin, and copper, and is used to restore the missing structure and surfaces of a decayed tooth. It releases small amounts of mercury in the form of a vapor (gas), depending on the number and age of existing fillings as well as some dietary and chewing habits. Inhaling mercury vapors may be harmful, especially at doses considered higher than those typically seen from use of dental amalgam. Mercury vapor release is highest when placement or removal of the filling occurs. The levels of mercury vapors may also temporarily increase when chewing, brushing, or teeth grinding over the tooth with the amalgam filling. The mercury vapors are primarily absorbed by the body through inhalation to the lungs. The body eliminates some of the absorbed mercury, but small amounts distributed through the bloodstream may collect in certain tissues, including the brain and kidneys, or in the case of pregnant women, in the blood going to the fetus through the umbilical cord.

Dental amalgam has advantages over resin-based composites in certain limited clinical situations. This includes use in high caries risk patients, for large fillings in posterior (back) teeth where biting forces are high, and where moisture can present a problem for certain placement such as near the gumline. Other filling materials such as resin-based composites and glass ionomers have become more widely used. The durability of these resin-based materials has improved, although its longevity does not equal that of amalgam, especially for large restorations with higher biting forces, wear, or stress.

From the FDA 9/24/20:
The U.S. Food and Drug Administration (FDA) is providing recommendations about the use of dental amalgam in certain groups of people who may be at greater risk to the potential adverse health effects of mercury exposure, to include:

- Pregnant women and their developing fetuses;
- Women who are planning to become pregnant;
- Nursing women and their newborns and infants;
- Children, especially those younger than six years of age;
- People with pre-existing neurological disease;
- People with impaired kidney function; and
- People with known heightened sensitivity (allergy) to mercury or other components of dental amalgam

The FDA is not recommending anyone remove or replace existing amalgam fillings in good condition unless it is considered medically necessary because removing intact amalgam fillings can cause a

temporary increase in exposure to mercury vapor and the potential loss of healthy tooth structure, potentially resulting in more risks than benefits.

Current Prioritized List status

CDT code	Code description	Current placement
D2140	Amalgam-one surface, primary or permanent	343 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH)
D2150	Amalgam-two surfaces, primary or permanent	343
D2160	Amalgam-three surfaces, primary or permanent	343
D2161	Amalgam-four or more surfaces, primary or permanent	343
D2330-D2335	Resin-one surface, anterior, 1 to 4 surfaces	343
D2391-D2394	Resin-based composite – posterior, 1 to 4 surfaces	343
D2410-D2544	Inlay or onlay, metallic or gold foil or noble metal	591 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH)
D2610-D2664	Inlay or onlay, ceramic or resin-based composite	645 DENTAL CONDITIONS WHERE TREATMENT IS CHOSEN PRIMARILY FOR AESTHETIC CONSIDERATIONS

GUIDELINE NOTE 123, DENTAL FILLINGS FOR POSTERIOR TEETH

Line 343

For dental fillings in posterior teeth, amalgam is preferred for extensive restorations. If amalgam is unavailable or contraindicated, composite is acceptable.

Evidence

1) **FDA 2019**, Systematic review of the health effects related to mercury from dental amalgam https://www.fda.gov/media/131151/download
    a. N=185 publications
    b. Amalgam associated with increased mercury urine concentration
        i. Most of the reviewed studies reported elevated mercury levels, when assessing urine samples from dental professionals, or adult and pediatric bearers of dental amalgams. Most studies on *adult populations with non-occupational exposure* reported positive correlation between mercury levels in biospecimens and the number of dental amalgam fillings or surfaces. Similarly, mercury increases in biospecimens positively correlating with the number of amalgam fillings/surfaces were reported in many studies on *pediatric population.* Thus, slightly increased mercury levels (at or below the WHO reference level) constituted one of the outcomes most frequently reported in relation to dental amalgam; however, despite the consistency of this subclinical outcome, its translation into clinically manifested adverse outcomes remained unclear throughout the reviews
    c. Health outcomes
        i. Evidence linking possible mercury toxicity from dental amalgam to self-assessed health complaints and other health-related measures such as hospital discharges remains inconsistent
        ii. Overall, evidence linking mercury toxicity from dental amalgam to possible systemic inflammatory/immune responses was inconsistent and did not originate from robust clinical studies with appropriate control groups and study endpoints.
        iii. Overall, evidence regarding possible mercury neurotoxicity due to dental amalgam remains inconclusive with regards to both occupational and non-occupational exposure.
            1. Neurotoxic conditions evaluated: Multiple sclerosis, Alzheimer's disease, children diagnosed with motor and mental developmental disabilities, epilepsy, attention deficit/hyperactivity disorder and autism
        iv. The overall evidence was found by the study authors to be inconsistent for linking prenatal exposure to mercury from dental amalgam to adverse birth outcomes.
        v. there was no consistent evidence from the reviewed publications that would link adverse pregnancy- and physical development-related outcomes to mercury exposure due to maternal dental amalgam.
        vi. Although perinatal outcomes related to vulnerable populations such as pregnant women and their developing fetuses as well as neurodevelopmental outcomes in children have been the focus of many studies, no conclusive and reproducible evidence with regards to potential mercury toxicity due to exposure to maternal or personal dental amalgams was found throughout the reviews
        vii. the evidence on cardiovascular outcomes was very limited and not supportive in terms of their relevance to mercury from dental amalgam.
        viii. no conclusive and reproducible evidence was presented on potential links between dental amalgam and clinically detectable signs of nephrotoxicity, including subclinical markers of renal function.

d. Conclusions
    i. there is insufficient evidence to support that exposure to mercury from dental amalgam causes adverse health effects in the general population or in vulnerable populations.

Oral Health Advisory Panel (OHAP) input:
OHAP members had concerns about making any change to the current policy to preferentially cover amalgam for dental fillings due to the large cost difference between amalgam and composite fillings. It was noted that the Prioritized List already includes the option of composite fillings, but that these fillings are reimbursed at the amalgam rate. Such a change would like trigger the need to reconsider DCO rates. The members also noted that the ADA has not endorsed the FDA statement, and continues to hold the position that amalgam is a safe product. Members requested that HERC staff do an evidence review (see above) into the health risks of mercury amalgam and base any change in coverage on the evidence, rather than just an FDA statement.

HERC staff summary:
The FDA recently released guidance regarding reducing the use of mercury containing amalgam in certain high risk populations. However, the underlying extensive evidence review conducted by the FDA found no evidence of increased risk of any clinical outcomes in any population.

HERC staff discussed this topic with OHAP and HSD leadership and determined the best strategy would be to remove any reference to preferred restoration from the Prioritized List.

HERC staff recommendation:
1) Delete GN123
    a. Allow patients and dentists to discuss the restoration material to use

~~**GUIDELINE NOTE 123, DENTAL FILLINGS FOR POSTERIOR TEETH**~~

~~*Line 343*~~

~~For dental fillings in posterior teeth, amalgam is preferred for extensive restorations. If amalgam is unavailable or contraindicated, composite is acceptable.~~

2021 CPT Code Review
Genetics Codes

1) **81351-81353** TP53 genetic analysis
    a. Codes
        i. **81351** TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; full gene sequence
        ii. **81352** targeted sequence analysis (eg, 4 oncology)
        iii. **81353** known familial variant
    b. Definition: The *TP53* gene provides instructions for making a protein called tumor protein p53 (or p53). This protein acts as a tumor suppressor. Although somatic mutations in the *TP53* gene are found in many types of cancer, Li-Fraumeni syndrome appears to be the only cancer syndrome associated with inherited mutations in this gene. This condition greatly increases the risk of developing several types of cancer, including breast cancer; bone cancer; and cancers of soft tissues (such as muscle) called soft tissue sarcomas, particularly in children and young adults. At least 140 different mutations in the *TP53* gene have been identified in individuals with Li-Fraumeni syndrome.
    c. Classic LFS is diagnosed when a person has all of the following criteria:
        i. A sarcoma diagnosed before age 45
        ii. A first-degree relative, meaning a parent, sibling or child, with any cancer before age 45
        iii. A first-degree relative or second-degree relative, meaning a grandparent, aunt/uncle, niece/nephew, or grandchild, with any cancer before age 45 or a sarcoma at any age
    d. Genetics Advisory Panel (GAP) discussion: Stevens noted that different labs may offer different testing at very different pricing. Voian noted that these tests are done usually as panels, which usually include TP53. She would just do these single tests in very limited situations. She felt this testing would not be cost effective, except in the case of familial variant. It was noted that the panels generally cost less than the single gene testing. There was some concern that if the panel does not contain this test, then the individual tests should be covered. Some insurance requires a list of all gene codes on the panel If a patient is positive for this mutation, it changes screening recommendations for various cancers for the patient. Stevens noted that there is language in the genetic testing guideline requiring the least expensive test. The GAP decision was to cover as a Diagnostic Procedure
    e. <u>GAP/HERC staff recommendation</u>:
        i. Add CPT **81351-81353** to the Diagnostic Procedures File

2) **81419** Epilepsy genomic sequence analysis panel
    a. Code
        i. **81419** Epilepsy genomic sequence analysis panel, must include analyses for ALDH7A1, CACNA1A, CDKL5, CHD2, GABRG2, GRIN2A, KCNQ2, MECP2, PCDH19, POLG, PRRT2, SCN1A, SCN1B, SCN2A, SCN8A, SLC2A1, SLC9A6, STXBP1, SYNGAP1, TCF4, TPP1, TSC1, TSC2, and ZEB2
    b. A panel of multiple genes to aid in the diagnosis of the underlying cause of epilepsy. Various types of testing are used, including microarray testing, gene panels, and whole exome sequencing.

c. **Thodeson 2019**, review of genetic testing in epilepsy
    i. In children with epilepsy of early onset or without specific dysmorphic features, targeted NGS panels are the most cost-effective initial test after electroencephalogram and neuroimaging.
    ii. Various studies have shown diagnostic yield of gene panel testing to be between 15.4% and 37.8%.
        1. The most common implicated genes were SCN1A, GABRB3, CKNQ2, SCN2A, SCN8A, GABRA1, GABRB3, KCNQ2, SCN2A, SCN8A, SLC2A1, and STXBP1
        2. Identification of certain genes can lead to medication recommendations (medications to use or avoid)
    iii. Whole exome sequencing resulting in a diagnostic yield of 33.4%-48% in the epilepsy group
d. GAP discussion: There was discussion about whether this specific test of genes are a proprietary panel. Members noted that there are multiple panels for epilepsy evaluation. Many of these panels include more genes that this test. Harding noted that there are different epilepsy panels depending on age of onset. However, these panels have been replaced by whole exome sequencing in his practice. Smits noted that the code lists these codes as the minimum list for billing this test; more genes can be included. Stevens wondered about limiting to tests only after consultation with a geneticist. Others thought there might not be enough bandwidth among geneticists; also, neurologists may be more knowledgeable about this testing. Harding noted that this panel is most useful for medication management, which would be most appropriately ordered by a neurologist.
e. <u>GAP/HERC staff recommendation</u>:
    i. Add CPT **81419** to line 30 EPILEPSY AND FEBRILE CONVULSIONS
        1. Can change medication therapy choice if certain genes are identified

Prenatal Genetic Testing Guideline
VBBS 2020

Genetics Advisory Panel (GAP)/HERC staff recommendations:

1) Modify the CPT codes in section "E" as shown below
    a. Removes inappropriate code: 81509 $1041.16 (PAPP-A, hCG [any form], DIA)
        i. No claims for this code in past year for FFS or CCOs
    b. Adds missing code
        i. 84163 Pregnancy-associated plasma protein-A (PAPP-A) $10.54
2) Expand cell free fetal DNA testing to all risk women; see separate issue document
3) Add coverage for expanded carrier screening; see separate issue document

DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

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

A) Genetic counseling (CPT 96040, HPCPS S0265) for high-risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect.
B) Genetic counseling (CPT 96040, HPCPS S0265) prior to consideration of chorionic villus sampling (CVS), amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening
C) Validated questionnaire to assess genetic risk in all pregnant women
D) Screening high-risk ethnic groups for hemoglobinopathies (CPT 83020, 83021)
E) Screening for aneuploidy with any of ~~five~~ six screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, ~~and~~ contingency, and cell free fetal DNA testing] (CPT 76813, 76814, 81508, ~~-~~81510, 81511, 81420, 81507, 81512, 82105, 82677,84163)
F) ~~Cell free fetal DNA testing (CPT 81420, 81507) for evaluation of aneuploidy in women who have an elevated risk of a fetus with aneuploidy (maternal age >34, family history or elevated risk based on screening).~~
G) Ultrasound for structural anomalies between 18 and 20 weeks gestation (CPT 76811, 76812)
H) 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.
I) 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.
J) 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)
K) 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
L) Screening for cystic fibrosis carrier status once in a lifetime (CPT 81220-81224)
M) Screening for fragile X status (CPT 81243, 81244, 81171. 81172) 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

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

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

P) Expanded carrier screening only ~~for those genetic conditions identified above~~ with pre- and posttest genetic counseling. Expanded carrier testing is only covered when the panel would replace and would be similar or lower cost than individual gene testing or targeted panel testing.

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.

Cell Free Fetal DNA Non-Invasive Prenatal Screening

Question: Should cell free fetal DNA non-invasive prenatal screening coverage be broadened to include average risk women?

Question source: Genetics Advisory Panel (GAP), HERC staff, Coalition for Access to Prenatal Screening (CAPS)

Issue: Cell free fetal DNA non-invasive prenatal screening (NIPS) is a test to determine a woman's risk of having an infant affected by various chromosomal aneuploidies. If a screening test is positive, a woman should be offered definitive testing such as amniocentesis. Cell free fetal DNA testing involves taking a maternal blood sample and isolating fetal DNA for testing. It does not carry any risk to the fetus. The cfDNA in a maternal blood sample can be screened for T21 (Down syndrome), T18 (Edwards syndrome), T13 (Patau syndrome), and aneuploidies involving the number of sex chromosomes, such as Klinefelter syndrome (47,XXY) and Turner syndrome (45,X).

Currently, according to the HERC guideline note, cell free fetal DNA screening is only available to high risk women (maternal age >34, family history or elevated risk based on screening) in the prenatal genetic testing guideline on the Prioritized List. This topic was reviewed in 2018 at the request of the Coalition for Access to Prenatal Screening (CAPS) and no change was made to this coverage. The current new review is due to a new Washington HTA report supporting NIPS for all risk women.

During the 2018 GAP review, a 2017 Cochrane review, a 2017 meta-analysis and a 2014 TEC review were all reviewed in detail. ACOG recommended offering such screening for all risk pregnancies. The HERC staff conclusion read:

> Cell free fetal DNA screening for aneuploidies is highly sensitive and specific among high-risk women. It is significantly less sensitive and specific among average risk women, particularly for aneuploidies other than trisomy 21. A recent economic meta-analysis did not find it cost effective as first line screening among average risk women. ACOG recommends some type of aneuploidy screening for average-risk women, but does not specify the recommended testing modality. Private insurer policies vary on coverage of non-invasive prenatal genetic screening.

Several alternative testing modalities are currently available to both high- and average-risk women in the prenatal genetic testing guideline, including blood tests such as the triple or quad screen, and fetal nuchal translucency screening ultrasounds.

Current Prioritized List status:

1) CPT 81420 (Fetal chromosomal aneuploidy (eg, trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21) is on line 1 PREGNANCY
2) CPT 81507 (Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy) is on line 1 PREGNANCY

Excerpt from Diagnostic Guideline D17

DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

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

5. Screening for aneuploidy with any of five screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, and contingency] (CPT 76813, 76814, 81508-81511)
6. Cell free fetal DNA testing (CPT 81420, 81507) for evaluation of aneuploidy in women who have an elevated risk of a fetus with aneuploidy (maternal age >34, family history or elevated risk based on screening).

Evidence

1) **Washington HTA 2019**, evidence review on cell free fetal DNA screening for chromosomal aneuploidies https://www.hca.wa.gov/assets/program/cfdna-final-report-20191213.pdf
    a. 1 RCT (reported in 3 publications), 9 test accuracy studies, and 8 economic studies that met our inclusion criteria. We assessed 2 studies, both economic studies, as having a low risk of bias and all others as moderate or high risk of bias.
    b. The impact of prenatal screening using cfDNA was assessed in 10 studies. We found that cfDNA screening:
        i. Has a lower false-positive (FP) screening rate than conventional first-trimester screening for T21 (FTS) (0% vs. 2.5%; *P* value not reported; low-quality evidence based on 1 RCT)
        ii. Has a test failure rate for the common trisomies T21, T18, and T13 ranging from 0.9% to 8.5% (very-low-quality evidence, based on data from 1 RCT, 8 cohort studies, and 1 case-control study)
        iii. Results in lower rates of invasive testing than conventional screening (low-quality evidence based on 1 RCT and very-low-quality evidence from 2 cohort studies)
    c. No studies compared outcomes or test performance by maternal age.
    d. Based on the 9 studies evaluating test accuracy, we also found that cfDNA screening:
        i. Results in fewer or the same number of missed cases of aneuploidy as conventional screening (moderate-to-very-low quality evidence)
        ii. Results in fewer women undergoing unnecessary invasive testing compared with conventional aneuploidy screening (moderate quality evidence)
        iii. Has a higher positive predictive value (PPV) than conventional aneuploidy screening (moderate-to-very-low quality evidence)
    e. We found limited evidence on the performance of cfDNA screening for common sex chromosome aneuploidies and twin pregnancies, with only 1 study for each.
    f. Universal cfDNA screening was more effective than conventional aneuploidy screening in most of the economic modeling studies we reviewed, but the results varied depending on whether cfDNA represented value for money (low quality evidence). The economic models produced similar results to the test performance studies, with cfDNA screening identifying more cases of aneuploidy and reducing invasive testing.
    g. ***Conclusions:*** Based on the evidence reviewed in this report, universal cfDNA aneuploidy screening appears to be more accurate than conventional screening for the common trisomies (T21, T18, and T13) in general obstetric populations. However, universal cfDNA testing is likely to be more expensive than conventional screening depending on the exact costs of the cfDNA test used, uptake of testing, and any subsequent interventions. Policymakers therefore need to consider the value of expanding cfDNA screening to all pregnant women and whether it is worth the additional associated costs. The economics studies included in this report suggest that universal cfDNA screening can be cost-effective, particularly when the lifetime costs of T21, T18, and T13 and the wider societal costs are included. There is a lack of clinical and cost-effectiveness evidence on the use of cfDNA screening for sex chromosome aneuploidies. Clinical practice guidelines generally recommend that women be informed of the range of tests that are available for prenatal screening, but recommendations regarding the most appropriate test for universal screening in the general obstetric population differ.

Other Medicaid coverage policies
Washington adopted coverage of NIPS for all risk women effective May 15, 2020 based on the WA HTA report.

Surveyed state Medicaid programs are currently mixed on coverage non invasive prenatal genetic, with some only covering for screening high risk women; others are covering for all pregnant women

Other coverage policies:

1) **Aetna 2020**: covers non invasive prenatal genetic screening only for high risk women or women with abnormalities in their initial screening labs or ultrasounds
2) **Premara BCBS 2020**: covers non invasive prenatal genetic screening for all singleton pregnancies
3) **Healthnet 2020**: covers non invasive prenatal genetic screening for only high risk women
4) **Cigna 2019**: covers non invasive prenatal genetic screening for all singleton pregnancies

GAP discussion:
All GAP members were in favor of covering non-invasive prenatal genetic screening to all-risk women. This is in line with ACOG recommendations, and in line with what is occurring in practice in Oregon. Stevens noted that his CCO is finding an equity issue with this testing—it is being ordered and covered by the majority of the patients in the OB-Gyn practice in their network for privately insured patients, but not for OHP patients. NIPS has a lower false positive rate, which lowers the rate of invasive confirmatory testing (amniocentesis and CVS).

There was also discussion that NIPS can be used as a second-tier test, for example, after an abnormal quad screen. In this situation, the higher negative and positive predictive value of the NIPS test is helpful in determining if the first screening test was a false positive and therefore sparing the need for invasive testing like amniocentesis.

Public testimony was heard at GAP unanimously in favor of covering NIPS for low and high-risk women.

HERC staff summary:

Cell-free fetal DNA screening for aneuploidies is highly sensitive and specific among high-risk pregnant women. It is significantly less sensitive and specific among average risk women, particularly for aneuploidies other than trisomy 21. A recent WA HTA report, which the HERC considers a high-quality evidence source, found evidence that NIPS was as accurate as other screening modalities and had a lower invasive follow up testing rate. Based on this report, WA Medicaid adopted NIPS for all pregnancies. Coverage of NIPS is variable among other state Medicaid programs and among private insurers.

NIPS is likely to be more easily accessed for women in rural areas than fetal nuchal lucency screening, but equally accessible to traditional quad screening.

GAP/HERC staff recommendation:

1) Modify DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING as shown below

DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

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

A) Genetic counseling (CPT 96040, HPCPS S0265) for high-risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect.
B) Genetic counseling (CPT 96040, HPCPS S0265) prior to consideration of chorionic villus sampling (CVS), amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening
C) Validated questionnaire to assess genetic risk in all pregnant women
D) Screening high-risk ethnic groups for hemoglobinopathies (CPT 83020, 83021)
E) Screening for aneuploidy with any of ~~five~~ six screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, ~~and~~ contingency, and cell free fetal DNA testing] (CPT 76813, 76814, 81508-81511, 81420, 81507, 81512,82105,82677)
F) ~~Cell free fetal DNA testing (CPT 81420, 81507) for evaluation of aneuploidy in women who have an elevated risk of a fetus with aneuploidy (maternal age >34, family history or elevated risk based on screening).~~
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) 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 those with Ashkenazi Jewish heritage for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255). Ashkenazi Jewish carrier panel testing (CPT 81412) is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing.
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.

Cancer Genetic Testing Guideline
VBBS 2020

HERC staff recommendations:

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

DIAGNOSTIC GUIDELINE D25, HEREDITARY CANCER GENETIC TESTING

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

A) Lynch syndrome (hereditary colorectal, endometrial and other cancers associated with Lynch syndrome) services (CPT 81288, 81292-81300, 81317-81319, 81435, 81436) and familial adenomatous polyposis (FAP) services (CPT 81201-81203) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Colorectal ~~V1.2018 (7/12/18).~~ V1.2020 (7/21/20) www.nccn.org.

B) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81212, 81215-81217) for patients without a personal history of breast, ovarian and other associated cancers should be provided to high-risk patients as defined by the US Preventive Services Task Force or according to the NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic ~~and ovarian~~. ~~V2.2019 (7/30/18).~~ V1.2021 (9/8/20) www.nccn.org.

C) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81212, 81215-81217)) for women with a personal history of breast, ovarian, or other associated cancers and for men with breast or other associated cancers should be provided according to the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic ~~and ovarian~~. ~~V2.2019 (7/30/18).~~ V1.2021 (9/8/20) www.nccn.org.

D) PTEN (Cowden syndrome) services (CPT 81321-81323) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovarian. V2.2019 (7/30/18) or Genetic/Familial High-Risk Assessment: Colorectal ~~V1.2018 (7/12/18).~~ V1.2020 (7/21/20) www.nccn.org.

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

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

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

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

Expanded Carrier Screening
VBBS 2020

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

Question source: Access to Expanded Carrier Screening Coalition

Issue: Coverage of expanded carrier screening was discussed by Genetics Advisory Panel (GAP) at their 2018 meeting. The GAP recommended that it be covered. GAP discussion in 2018: All GAP members felt that this was reasonable to cover. Often cost is the same to test for a single gene as a panel. All pregnant patients should be offered expanded carrier screening per ACOG guidelines. It was noted that carrier panel testing is specifically excluded currently in the prenatal testing guideline

However, subsequent review of this topic by VBBS in November 2018 resulted in VBBS recommending non-coverage. The major concerns of VBBS were

1) Coverage for partners. Partners should only be tested for the few genes that mom tested positive for
2) There was general concern about how to interpret the results. The VBBS members felt that the interpretation would be difficult for most maternity care providers, and that patients should have genetic counseling with this test, which is a limited resource. There was discussion about unintended harm of too much genetic information being given to patients with an unclear idea of how to deal with this information.
3) There was concern over interventions that might be done that might not be needed, or additional testing done that might not be needed. Medicaid is a vulnerable population and needs protections in place.
4) There was also concern about how to control the quality of what genes are in the panel, to ensure that all include genes are recommended by ACOG guidelines.

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

The Access to Expanded Carrier Screening Coalition has requested a re-review of the VBBS/HERC decision from 2018. The major concern of this group is the difficulty in determining a patient's ancestry for ordering specific ethnic-based testing.

Current Prioritized List status:
Line 662/GN173:
CPT **81443** (Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes)

Diagnostic Procedures File:
CPT 81412 is for Ashkenazi Jewish carrier testing panel
CPT 81220 for CF panel testing

Expanded Carrier Screening
VBBS 2020

Evidence reviews

1) **Kraft 2019**, review of expanded carrier screening
    a. There are numerous potential benefits to expanded carrier screening, including maximizing the opportunity for couples to make autonomous reproductive decisions, and efficiency and marginal additional costs of including more conditions if the test is already being offered
    b. Challenges for expanded carrier screening programs include a lack of demand from the public, low prioritization by health systems, the potential for pressure to undergo screening, the possibility of disability-based discrimination, needed adaptations to pre- and post-test counseling, technical limitations, and the evolving technological and socio-political landscape.
    c. 200,000 individuals in the United States, as compared with 4 million annual pregnancies, received expanded carrier screening in 2015.
    d. In one study that took an individual preconception carrier screening approach, 102/131 (76%) women were carriers for at least one condition
    e. In focus groups with US genetics professionals, Cho et al. found major concerns about the limitations of expanded carrier screening, including false positives, ambiguous results, and potential misunderstanding of negative results. Participants in these groups highlighted the need for genetic counseling to overcome the challenges of informed consent and results interpretation.

Expert guidelines

1) **ACOG** 2017 committee opinion **690** (reaffirmed in 2020) **https://www.acog.org/-/media/Committee-Opinions/Committee-on-Genetics/co690.pdf?dmc=1&ts=20181029T1555151910**
    a. Ethnic-specific, panethnic, and expanded carrier screening are acceptable strategies for prepregnancy and prenatal carrier screening.
    b. The disorders selected for inclusion should meet several of the following consensus-determined criteria: have a carrier frequency of 1 in 100 or greater, have well-defined phenotype, have a detrimental effect on quality of life, cause cognitive or physical impairment, require surgical or medical intervention, or have an onset early in life. Additionally, screened conditions should be able to be diagnosed prenatally and may afford opportunities for antenatal intervention to improve outcomes, changes to delivery management to optimize newborn and infant outcomes, and education of the parents about special needs after birth.
    c. Carrier screening panels should not include conditions primarily associated with a disease of adult onset
    d. Carrier screening panels have largely replaced more specific screening because of its efficacy and economy
2) **ACOG 2017 committee opinion 691** **https://www.acog.org/-/media/Committee-Opinions/Committee-on-Genetics/co691.pdf?dmc=1&ts=20170808T1020526802**
    a. The cost of carrier screening for an individual condition may be higher than the cost of testing through commercially available expanded carrier screening panels

GAP discussion:
GAP members were unanimously in favor of adding expanded carrier screening for pre-pregnancy and prenatal genetic screening. GAP members felt unanimously that relying on a patient to define their race or ethnicity was problematic.

There was discussion that the staff proposed requirement for pre-testing genetic counseling was not feasible. However, positive tests would require genetic counseling regarding the results. There was discussion about the fact that several of the labs offering these tests provide free genetic counseling to patients regarding results; however, the quality of this counseling cannot be verified. It was also noted that the labs vary widely in the information they send back to providers and patients; some just send the test result while others send a page or two of interpretive information.

Gap members had concerns about the fact that the commercially available tests vary dramatically in the number and types of genes tested. This larger the number of genes in the panel, the higher the likelihood for finding a positive result. The number of women with positive results could overwhelm the capacity of genetic counselors in the state, although it was noted that virtual visits could help with this. Families could receive information of unknown significance without access to expertise to aid them in interpretation.

There was discussion about adding restrictions on the type of testing offered, such as limiting the included number of genes or only clinically meaningful variants. Other members stated that testing has moved to only include meaningful variants. There was other discussion that the number of genes is a moving target and would not be advisable to add. There was discussion about putting in wording requiring the tests to follow national guidelines like ACOG or ACGME. However, there was concern that if a panel had a gene in addition to the ones in these guidelines, that the entire test might not be covered.
GAP discussed that should be pre-conception expanded carrier screening included in the non-prenatal genetic testing guideline. The restriction proposed by staff to limit to once in a lifetime was felt to be too restrictive, as the tests are constantly changing and in the future, different conditions might be included. The staff proposal to require pre- and post-testing counseling was felt to be useful.

Public testimony was heard, which was unanimously in favor of coverage of expanded carrier screening. It was brought up that screening should be offered pre-conception as well as prenatally. There is an equity issue in that the current coverage is mainly for conditions seen in people of European ancestry, while expanded carrier screening includes tests more likely to be seen in people of other ancestry, such as African. Testifiers felt that there should be pretest education, but not genetic counseling per se.

It was noted that the correct CPT code for expanded carrier screening is CPT 81443.

Expanded Carrier Screening
VBBS 2020

HERC staff summary

Expanded carrier screening is a controversial area of pre-conception and prenatal genetic screening. ECS will identify more at-risk couples; however, the high rate of finding genetic mutations (75% of women) will require pre- and posttest genetic counseling regarding the implications of the results. ACOG recommends ECS as one screening option, and recommends inclusion only of genes with significant childhood disease potential. GAP members and public testimony at the GAP meeting was unanimously in favor of covering expanded carrier screening for both prenatal and pre-conception testing.

GAP/HERC staff recommendations:

1) Add CPT 81443 (Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)) to the Diagnostic Procedures File
2) Remove CPT 81443 from line 662/GN173 as shown below
3) Modify the prenatal genetic testing guideline as shown below
4) Add a clause to DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE section "E"
    i) CPT 81443, expanded carrier screening: This test is only offered for preconception testing. A genetic counseling/geneticist consultation is required prior to ordering test and post-test genetic counseling must be offered. Expanded carrier testing is only covered when the panel would replace and would be similar or lower cost than individual gene testing or targeted panel testing."

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

Line 662

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

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

DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

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

A) Genetic counseling (CPT 96040, HPCPS S0265) for high-risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect.

B) Genetic counseling (CPT 96040, HPCPS S0265) prior to consideration of chorionic villus sampling (CVS), amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening
C) Validated questionnaire to assess genetic risk in all pregnant women
D) Screening high-risk ethnic groups for hemoglobinopathies (CPT 83020, 83021)
E) Screening for aneuploidy with any of five screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, and contingency] (CPT 76813, 76814, 81508, ~~-~~81510,81511,81512,82105,82677,84163)
F) Cell free fetal DNA testing (CPT 81420, 81507) for evaluation of aneuploidy in women who have an elevated risk of a fetus with aneuploidy (maternal age >34, family history or elevated risk based on screening).
G) Ultrasound for structural anomalies between 18 and 20 weeks gestation (CPT 76811, 76812)
H) 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.
I) 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.
J) 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)
K) 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
L) Screening for cystic fibrosis carrier status once in a lifetime (CPT 81220-81224)
M) Screening for fragile X status (CPT 81243, 81244, 81171. 81172) in patients with a personal or family history of
    b. fragile X tremor/ataxia syndrome
    c. premature ovarian failure
    d. unexplained early onset intellectual disability
    e. fragile X intellectual disability
    f. unexplained autism through the pregnant woman's maternal line
N) Screening for spinal muscular atrophy (CPT 81329) once in a lifetime
O) Screening those with Ashkenazi Jewish heritage for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255). Ashkenazi Jewish carrier panel testing (CPT 81412) is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing.
P) Expanded carrier screening only ~~for those genetic conditions identified above~~ with pre- and posttest genetic counseling. Expanded carrier testing is only covered when the panel would replace and would be similar or lower cost than individual gene testing or targeted panel testing.

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.

Neuropsychological Status Exams and Neuropsychological Testing

Questions:

1) Should the guideline regarding neuropsychological status exam and neuropsychological testing procedure codes be modified or deleted?
2) Should such testing be covered after epilepsy surgery?

Question sources: Dr. Sondra Marshall, neuropsychologist in Bend; Dr. Tyler Duffield and Dr. David Spencer, OHSU epilepsy program

Issue: Neuropsychological status exams were moved from line 662/Guideline Note 173 with a new guideline effective January 1, 2020 based on Behavioral Health Advisory Panel (BHAP) recommendations. Similar codes (e.g. CPT 96132-96133 Neuropsychological testing evaluation) were added to this new guideline. These codes are allowed when no other diagnosis explains the symptoms and when the results will affect the treatment plan. There is also a clause to allow this testing prior to epilepsy surgery.

Dr. Marshall is finding that the guideline is creating a lot of work in her clinic with PA's and other paperwork. She requested that BHAP consider modifying or deleting the guideline. From Dr. Marshall: "We process many referrals and the process of requesting authorization for all testing can take a significant amount of time, that takes resources and reduces the ability to provide other important services. "

Drs. Duffield and Spencer requested consideration for such testing after epilepsy surgery, as well as prior. From Dr. Spencer: "Postsurgical neuropsychological testing for many years was routine in all postoperative epilepsy surgery patients to assess for new deficits and for help in managing cognitive concerns. Now we apply it more selectively to assess for postoperative changes in neurocognitive function and develop strategies for cognitive rehabilitation."

When queried, the CCOs reported getting large numbers of requests for this type of testing, most of which did not seem appropriate. The CCOs strongly requested keeping the guideline as it currently stands. Comments from CCO medical directors;

1) we deny about 50% of the time. At one point last year we were getting about 55-60 requests/week
2) [we get requests for] adults with little to no work-up for "memory loss", "early dementia" or post-TBI or post-stroke
3) [we get requests for] adults for evaluation ADHD, "impaired memory" in 30-40 y.o. with no impairment on screening mental status exams, history of head injury years prior, suspicion of autism spectrum disorder (not diagnosed as a kid); in children, "follow up" of concussion in kids with no complaints, school issues in kids with identified diagnoses such as ADHD who are already under treatment, older kids with autism previously diagnosed.
4) We get [requests] for everything and everyone-kids, adults, for suspected autism, developmental delay, school issues, TBI, cognitive decline, concussion reevaluations, seizure disorders

Current Prioritized List status:

CPT	Code Description	Current Line(s)/List
96116	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; first hour	DIAGNOSTIC PROCEDURES
96121	each additional hour	DIAGNOSTIC PROCEDURES
96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour	DIAGNOSTIC PROCEDURES
96133	each additional hour	DIAGNOSTIC PROCEDURES

DIAGNOSTIC GUIDELINE D26, NEUROBEHAVIORAL STATUS EXAMS AND NEUROPSYCHOLOGICAL TESTING

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

A) Symptoms are not explained by an existing diagnosis; AND
B) When the results of such testing will be used to develop a care plan.

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

Utilization:
In the past 12 months, CCOs and FFS data combined showed 63,857 claims (paid and unpaid) for CPT 96116, 96121, 96132 and 96133. These were paired with a wide range of diagnoses.

BHAP input

The panel generally felt that the guideline changes as recommended by staff were reasonable. There was discussion about CPT 96132 and 96133 being "thinking codes" that have a higher RVU that the general testing codes, and therefore they are being used more frequently. The panel unanimously agreed with adding coverage for post epilepsy surgery.

HERC staff recommendation

1) Make the changes shown below to Diagnostic Guideline D26
   a) Add only post-operative epilepsy care. The other portion of the guideline appears to be working

DIAGNOSTIC GUIDELINE D26, NEUROBEHAVIORAL STATUS EXAMS AND NEUROPSYCHOLOGICAL TESTING

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

A) Symptoms are not explained by an existing diagnosis; AND
B) When the results of such testing will be used to develop a care plan.

OR when neuropsychological testing is done as part of the pre-operative evaluation prior to epilepsy surgery or post-operative follow up after epilepsy surgery.

Cognitive Rehabilitation

Question: Should cognitive rehabilitation be removed from several lines on the Prioritized List?

Question source: HERC staff, HSD staff

Issue: Federal mental health parity law effectively does not allow "quantitative treatment limits" for behavioral health and substance abuse diagnoses. HERC and HSD staff have reviewed the Prioritized List guidelines for any such limits that might be in place. Staff have determined that CPT 97129 and 97130 (Therapeutic interventions that focus on cognitive function (eg, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact) and GUIDELINE NOTE 90, COGNITIVE REHABILITATION are on with lines with BH/SUD diagnoses, although the intention has not been to pair cognitive rehabilitation services with these diagnoses.

CPT 97129 and 97130 and GN90 were included on what is now Line 201 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS for pairing with ICD-10 F07.81 (Postconcussional syndrome). However, the actual concussion diagnoses are on line 91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS. ICD-10 F07.81 is in a group of codes for behavioral health and substance abuse which now by mental health parity law can have no "quantitative treatment limits."

CPT 97129 and 97130 and GN90 were also included on what are now Line 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS and Line 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION in 2011. These lines contain ICD10 codes for malignant neoplasm of the brain, which might cause brain injury when removed surgically. These ICD-10 codes also appear on line 294 CANCER OF BRAIN AND NERVOUS SYSTEM. Additionally, lines 345 and 377 contains a range of ICD10 codes related to dementia, intellectual disabilities, autism, and developmental disorders. These codes were not intended to pair with cognitive rehabilitation.

Cognitive rehabilitation had an extensive evidence review done in 2011 that found evidence only on its effectiveness for treatment of traumatic brain injury. Private insurers were also covering it for cerebral vascular insult.

Cognitive Rehabilitation

Current Prioritized List status

CPT Code	Code Description	Current Lines
97129	Therapeutic interventions that focus on cognitive function (eg, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (eg, managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; initial 15 minutes	91 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS 178 NTRACEREBRAL HEMORRHAGE 196 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN 201 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 317 STROKE 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
97130	each additional 15 minutes	91,178,196,201,285,317,345,377

BHAP input:
The panel members unanimously agreed with the staff recommendations.

HERC staff recommendations:

1) Remove CPT 97129 and 97130 from lines 201 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS, 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS, and 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
2) Add CPT 97129 and 97130 to line 294 CANCER OF BRAIN AND NERVOUS SYSTEM
3) Modify GN90 as shown below

GUIDELINE NOTE 90, COGNITIVE REHABILITATION

Lines 91,178,196,~~201,~~285,294,317,~~345,377~~

Once physical stabilization from acute brain injury has occurred, as determined by an attending physician, cognitive rehabilitation (CPT 97129 and 97130) is included on this line for a three month period. This three month period does not have to be initiated immediately following stabilization from the injury. For up to 3 years following the acute event, an additional 6 visits of cognitive rehabilitation are included on this line each time the patient has a major change in status resulting in a significantly improved prognosis. Cognitive rehabilitation is not included on this line for those in a vegetative state or for those who are unable or unwilling to participate in therapy

Repetitive Transcranial Magnetic Stimulation for Treatment Resistant Depression

Question: Should any changes be made to the guideline regarding repetitive transcranial magnetic stimulation?

Question source: Holly Jo Hodges, CCO medical director

Issue: HERC approved the Coverage Guidance: Non-pharmacologic interventions for treatment-resistant depression on August 9, 2012. This coverage guidance was based mainly on an AHRQ review from 2011. The coverage guidance found evidence to support the use of repetitive transcranial magnetic stimulation (rTMS), which until 2012 had not been covered on the Prioritized List. In 2012, the CPT codes for rTMS (CPT 98067-90869) were added to the major depression line, with a new guideline note. The guideline restricted coverage to patients who had failed two antidepressant therapies. This restriction was based on the studies included in the AHRQ report; in all studies in that report, the patients had to have tried and failed to antidepressant medications.

Since the 2011/2012 review, trusted evidence sources have reviewed rTMS, including CADTH, Washington HTA and by NICE. Major private insurers have put in more restrictions on utilization that is currently in GN102.

Repetitive transcranial magnetic stimulation (rTMS) is a neurostimulation technique that uses a magnetic field to induce a strong and focused electrical current that is delivered to specific regions of the brain (e.g., the left pre-frontal cortex, over the left or right dorsolateral prefrontal cortex, or bilaterally over both cortices) with either a hand-held device or a helmet-shaped induction coil. Repetitive transcranial magnetic stimulation (rTMS) delivers the electrical pulse in short bursts at a pre-set interval, with either high-frequency stimulation (5 to 20 Hz) or low-frequency stimulation (1 to 5 Hz). The treatment is delivered in an outpatient setting, without the need for anesthesia. The mechanism by which rTMS may induce its effect in MDD is through inducing action potentials in the targeted brain region. Repeated electrical pulses cause changes in the synaptic connections in the specific target regions and increases or decreases the activity of target brain regions to normalize activity. Different regimens and protocols for rTMS have been studied but typically a therapeutic treatment course requires 20 to 30 sessions (typically five days per week) over a four-week to six-week time period

From Dr. Hodges

While there is a GN note, it is not terribly helpful for determining whom might truly qualify and benefit for this treatment, and for how long??
How do we follow progress??
Can patients actually benefit from more than once daily treatments?? Is there benefit to additional magnet settings, like a different setting for OCD??
Concern is expressed for significant overuse in the amount of treatments per day and the length of treatments.

Repetitive Transcranial Magnetic Stimulation for Treatment Resistant Depression

Current Prioritized List Status

Code	Description	Placement
90867	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management	7 MAJOR DEPRESSION, RECURRENT; MAJOR DEPRESSION, SINGLE EPISODE, SEVERE
90868	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session	7
90869	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management	7 ***note: not currently in GN102***

GUIDELINE NOTE 102, REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION

Line 7

Repetitive transcranial magnetic stimulation (CPT 90867-90868) is covered only after failure of at least two antidepressants.

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 69, ELECTROCONVULSIVE THERAPY (ECT)

Lines 7,22,26

Electroconvulsive therapy (ECT; CPT 90870) is included on these lines for the treatment of major depressive disorder, bipolar disorder, schizophrenic disorder, or schizoaffective disorder when one or more of the following conditions are present:

1) Acute suicidality with high risk of acting out suicidal thoughts
2) Psychotic features
3) Rapidly deteriorating physical status due to complications from the depression, such as poor oral intake
4) Catatonia
5) History of poor response to multiple adequate trails of medications and/or combination treatments, or the patient is unable or unwilling to comply with or tolerate side effects of available medications, or has a co-morbid medical condition that prevents the use of available medications
6) History of good response to ECT during an earlier episode of the illness
7) The patient is pregnant and has severe mania or depression, and the risks of providing no treatment outweigh the risks of providing ECT

The frequency and number of treatments need to be determined by the severity of illness and by the relative benefits and risks of ECT treatment. During the course of ECT, it is important to monitor therapeutic responses and adverse effects of treatment. Continuation treatment of patients who have responded to ECT consists of treatment with antidepressant medications

and/or a tapering schedule of ECT treatments. Continuation treatment reduces the risk of relapse and should be offered to all patients who respond to ECT. Continuation ECT treatments should be tapered and discontinued as the patient's clinical condition allows. Maintenance treatment with ECT is indicated to prevent recurrence of depression in patients whose remission of symptoms cannot be maintained with pharmacologic antidepressant treatment.

Repetitive Transcranial Magnetic Stimulation for Treatment Resistant Depression

Evidence

1) **CADTH 2019**, Repetitive Transcranial Magnetic Stimulation for Patients with Depression: A Review of Clinical Effectiveness, Cost- Effectiveness and Guidelines – An Update https://www.cadth.ca/sites/default/files/rr/2019/RC1142%20rTMS%20Final.pdf
    a. N=3 systematic reviews and 5 RCTs
    b. The definition of treatment resistant major depression (TRMD) differed in the systematic reviews, with one of the three reviews requiring patients to have failed to respond to two pharmacotherapy regimens of adequate dose and duration. The other two reviews did not specify a particular number of prior treatments required.
    c. All studies excluded patients with bipolar disorder and some forms of depression (e.g., depression with psychotic features).
    d. In two studies patients received 20 treatments over four weeks, in one study patients received 30 treatments over six weeks, in one study patients received 20 to 30 treatments in five session blocks, and in one study patients received 10 treatments over two weeks.
    e. The rates of response to treatment and remission of symptoms were significantly greater with repetitive transcranial magnetic stimulation than sham treatment in all three systematic reviews
    f. The clinical relevance of the magnitude of the change in depressive symptoms in all studies was unclear
    g. an analysis from the perspective of the Ontario healthcare system suggested repetitive transcranial magnetic stimulation was cost-effective relative to pharmacotherapy if the willingness to pay was greater than C$98,242 per quality adjusted life year
2) **NICE 2015**, repetitive transcranial magnetic stimulation for depression guidance
    a. The evidence on repetitive transcranial magnetic stimulation for depression shows no major safety concerns. The evidence on its efficacy in the short-term is adequate, although the clinical response is variable. During the consent process, clinicians should, in particular, inform patients about the other treatment options available, and make sure that patients understand the possibility the procedure may not give them benefit. NICE encourages publication of further evidence on patient selection, details of the precise type and regime of stimulation used, the use of maintenance treatment and long-term outcomes
    b. Systematic review of 40 RCTs (1592 patients) of rTMS vs sham
        i. meta-analysis of mean changes in unspecified depression rating scales showed a significant effect in favor of rTMS (Hedges' g value of 0.55, $p<0.001$).
    c. Systematic review of 63 studies (3236 patients) of rTMS vs sham
        i. For patients with any type of depression, the mean percentage reduction in HDRS scores was 37% (CGI-I equivalent 2.8) in the rTMS group and 22% (CGI-I equivalent 3.4) in the sham stimulation group ($p<0.05$). For patients with treatment-resistant depression, the mean percentage reduction in HDRS scores was 48% (CGI-I equivalent 2.4) in the rTMS group and 23% (CGI-I equivalent 3.4) in the sham stimulation group ($p<0.05$).

   d. Systematic review of 10 RCTs (634 patients) with treatment resistant depression treatment with rTMS or sham
      i. Meta-analysis of clinical response rates in patients treated by bilateral rTMS or sham stimulation revealed a risk ratio of 3.29 in favor of bilateral rTMS (95% confidence interval [CI] 1.69 to 6.38, p=0.0004). In the same study, meta-analysis of remission data (classified according to predefined criteria in each included study) revealed no significant difference between patients treated by bilateral rTMS or sham stimulation (risk ratio 0.5; 95% CI 0.19 to 1.31, p=0.16).
   e. Safety
      i. 1 reported partial seizure, 1 hypomanic episode, headache reported in 10% of rTMS patients (vs 3% of sham patients); scalp discomfort reported in 9% of rTMS patients (vs 2% of sham patients); facial twitching reported by 2% of rTMS patients (0% sham), drowsiness in 3%of rTMS patients (0% sham)

3) **Washington HTA 2014**, Nonpharmacologic Treatments for Treatment-Resistant Depression https://www.hca.wa.gov/assets/program/TRD_final_report_022114[1].pdf
   a. There is no established definition for TRD
   b. 1 meta-analysis of 24 sham-controlled RCTs (AHRQ 2011 review) plus 3 additional RCTs
   c. Moderate quality evidence of efficacy
   d. A small quantity of data suggested that the durability of effect, i.e., the continued advantage of active rTMS over sham rTMS, may not last beyond 2 or 3 weeks after the end of treatment; rTMS may serve primarily to accelerate recovery (**low**-quality evidence).
   e. Five RCTs suggested that if rTMS has any effect on QOL or function, it is very small (**low**-quality evidence).
   f. No studies evaluated the use of rTMS as maintenance therapy after acute response (**insufficient** evidence).

Expert guidelines

1) **McClintock 2018**, consensus recommendations for the clinical application of rTMS for the treatment of depression https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5846193/pdf/nihms946565.pdf
   a. FDA approval for rTMS is limited to adults
   b. Treatment sessions using the parameters found in the large-scale clinical trials typically last approximately 30–40 minutes. Treatments are typically 5 times a week…a standard acute course of 20 to 30 treatment sessions over 6 weeks will very likely be needed to achieve results consistent with published regulatory trials.
   c. Several prospectively designed extension trials indicate that patients who show no response to a standard acute course of 20–30 treatment sessions may respond if their course is continued with ongoing daily (5/wk) sessions
   d. At this time, there is no 1 recommended maintenance antidepressant strategy for patients after a beneficial rTMS acute course. Rather, it is recommended that available evidence-based antidepressant strategies be used after successful acute rTMS treatment. Such strategies include repeat rTMS,111–113

pharmacotherapy,114 manualized psychotherapy,115,116 exercise,117 and combination of those treatments.114 Further research is needed to systematically develop evidenced-based antidepressant maintenance strategies following acute clinical benefits with rTMS.

e. There is insufficient evidence to support routine clinical rTMS use in patients with bipolar disorder, panic disorder, obsessive-compulsive disorder, depersonalization disorder, posttraumatic stress disorder, and schizophrenia.

Other payer policies

1) Aetna 2020

a. Aetna considers transcranial magnetic stimulation (TMS) in a healthcare provider's office medically necessary when the following criteria are met:
   i. Administered by an FDA cleared device and utilized in accordance with the Food and Drug Administration (FDA) labeled indications; *and*
   ii. The member is age 18 years or older; *and*
   iii. The member has a confirmed diagnosis by a psychiatrist of severe major depressive disorder (single or recurrent episode), documented by standardized rating scales that reliably measure depressive symptoms (eg, Beck Depression Scale [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], etc.); *and*
   iv. There is documentation via legible medical records of failure of a trial of a psychotherapy known to be effective in the treatment of major depressive disorder of an adequate frequency and duration, without significant improvement in depressive symptoms, as documented by standardized rating scales that reliably measure depressive symptoms (e.g., Beck Depression Scale [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], etc.); *and*
   v. The member is currently receiving or is a candidate for electroconvulsive therapy (ECT) and TMS is considered a less invasive equally effective treatment option (e.g., in cases with psychosis, acute suicidal risk, catatonia or life-threatening inanition TMS should not be utilized); *and*
   vi. The member has no contraindications to TMS (refer to contraindications below); *and*
   vii. The member has experienced inadequate response during the current depressive episode with:
      1. Two antidepressants from at least 2 different classes having different mechanisms of action (see Appendix) at the maximally tolerated labeled dose, each used for at least 8 weeks; *and*
      2. Augmentation therapy (see Appendix); *and*
   viii. Treatment consists of a maximum of 30 sessions (5 days a week for 6 weeks) plus 6 tapering sessions. **Notes**: Treatments beyond 36 sessions (e.g., 30 treatment sessions followed by 6 tapering sessions) may be reviewed for medical necessity. There is a lack of evidence that persons who fail to respond or become refractory to one brand of

repetitive transcranial magnetic stimulation (rTMS) device will respond to another brand of rTMS or deep TMS (dTMS) device.

ix. Aetna considers TMS contraindicated and experimental and investigational in persons with any of the following contraindications to TMS because the safety and effectiveness in person with these contraindications has not been established:
    1. Persons with high alcohol or illicit drug consumption; *or*
    2. The member is suicidal; *or*
    3. The member has a metal implant in or around the head (eg, aneurysm coil or clip, metal plate, ocular implant, stent); *or*
    4. The member has neurological conditions (eg, cerebrovascular disease, dementia, history of repetitive or severe head trauma, increased intracranial pressure or primary or secondary tumors in the central nervous system); *or*
    5. There is presence of implanted devices, (eg, cardiac pacemaker or defibrillator, cochlear implant, deep brain stimulator, implantable infusion pump, spinal cord stimulator, vagus nerve stimulator, etc.); *or*
    6. If the member has severe cardiovascular disease, he has been evaluated and cleared for TMS treatment by a cardiologist.

x. Aetna considers TMS re-treatment medically necessary for persons with depression relapse who meet initiation criteria above and who have previously had at least a 50 percent reduction in depressive symptoms with TMS, as documented by standardized rating scales that reliably measure depressive symptoms (e.g., Beck Depression Scale [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], etc.).

xi. Aetna considers one TMS re-mapping during a course of TMS for depression medically necessary **Note**: Remapping does not increase the medically necessary number of TMS sessions, as treatment is provided during remapping.

xii. Aetna considers TMS maintenance therapy for depression to be experimental and investigational because the effectiveness and safety of TMS maintenance therapy has not been established.

xiii. Aetna considers transcranial magnetic stimulation experimental and investigational for the following indications because its value and effectiveness has not been established (long list of other indications)

2) Regence BCBS 2020

a. Transcranial magnetic stimulation (TMS) of the brain may be considered **medically necessary** as a treatment of *major depressive disorder* when all of the following criteria are met (A. – C.):
    i. Confirmed diagnosis of severe major depressive disorder (single or recurrent) when both of the following criteria are met (1. –2.):
        1. Diagnosis is confirmed by standardized rating scales (see Policy Guidelines) that reliably measure depressive symptoms; and
        2. Documentation is submitted of both the rating scale that was used and the score.
    ii. One of the following conditions is present:

1. Symptoms are ongoing despite treatment with at least 3 psychopharmacologic regimens, and each has been ineffective, not tolerated (as evidenced by distinct side effects), or is contraindicated (see Policy Guidelines); or
2. History of response to TMS in a previous depressive episode (at least 3 months since the prior episode); or
3. Both of the following criteria are met (a. – b.):
    a. Patient is a candidate for electroconvulsive therapy (ECT); and
    b. The patient does not have psychosis, acute suicidal risk, catatonia, significantly impaired essential function, or other condition for which ECT would be clinically superior to TMS.

iii. Failure of a trial of a psychotherapy (see Policy Guidelines) known to be effective in the treatment of major depressive disorder, when both of the following criteria are met (1. – 2.):
    1. Documentation is submitted showing that psychotherapy was conducted for a minimum duration of 6 weeks at least 1 time per week; and
    2. No significant improvement in depressive symptoms has occurred, as documented by standardized rating scales (see Policy Guidelines) that reliably measure depressive symptoms.

b. Transcranial magnetic stimulation (TMS) of the brain is considered **not medically necessary** as a treatment for major depressive disorder when Criterion I. above is not met.

c. Transcranial magnetic stimulation (TMS) of the brain is considered **investigational** as a treatment for all other indications

<u>Behavioral Health Advisory Panel (BHAP) input</u>

BHAP members were concerned about the use of rTMS in children and adolescents and requested that HERC staff research the evidence and FDA regulations around rTMS use in children. HERC staff have determined that the FDA approval of rTMS is limited to adults and private insurers require patients to be 18 year of age or older. Studies reviewed found only adult patients included.

There was some discussion about the use of rTMS for indications other than depression, particularly OCD. HERC staff reviewed the literature included in this review and found that experts do not feel that there is sufficient evidence to support the use of rTMS for any indication other than major depression.

There was also discussion about an upper limit of sessions. BHAP members were concerned about possible adverse effects of multiple sessions. Dr. Bischof noted that CareOregon reviews cases after approximately 30 sessions to determine if a change in therapy is indicated.

Repetitive Transcranial Magnetic Stimulation for Treatment Resistant Depression

HERC staff summary

Trusted evidence-based sources (CADTH, WA HTA, NICE) have all found that evidence supports the use of rTMS for treatment of depression. The definition of "treatment resistant depression" varies across studies, and the number and frequency of rTMS sessions also varies across studies. It appears from expert guidelines that rTMS should be administered five times a week for 6 weeks for initial treatment. Maintenance treatment is a more controversial area. Major insurers cover rTMS, with much more extensive guidelines that the current Prioritized List guideline.

HERC staff recommendation:

1) Modify GN 102 as shown below

GUIDELINE NOTE 102, REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION

Line 7

Repetitive transcranial magnetic stimulation (CPT 90867-90869 ~~90868~~) is ~~covered~~ included on this line only ~~after failure of at least two antidepressants.~~ when ALL of the following criteria are met

1) The patient has a confirmed diagnosis of severe major depressive disorder based on standardized rating scales, AND
2) The patient has treatment resistant depression as evidenced by BOTH of the following
    a. ongoing symptoms despite treatment with at least 2 psychopharmacologic regimens each used for 8 weeks unless not tolerated or contraindicated, AND
    b. failure of a trial of psychotherapy conducted for a minimum duration of 6 weeks at least 1 time a week with no improvement in depressive symptoms as documented by standardized rating scales; AND
3) The patient does not have psychosis, acute suicidal risk, catatonia, significantly impaired essential function, or other condition for which electroconvulsive therapy (ECT) would be clinically superior to TMS; AND
4) The patient has no contraindications to rTMS such as implanted devices in or around the head, increased risk of seizure, etc.; AND
5) The therapy is administered by an FDA approved device in accordance to labeled indications; AND
6) The patient is 18 years of age or older.

Repetitive transcranial magnetic stimulation is covered for a maximum of 30 sessions (up to 5 times a week for 6 weeks) for initial treatment. Repeat treatment may be covered if the patient responded to the initial treatment (defined as at least of 50 percent reduction in depression score on standardized rating scale) and at least 3 months have elapsed since the initial treatment.

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.

Code	Code description	Placement Recommendation
30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)	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
32408	Core needle biopsy, lung or mediastinum, percutaneous, including imaging guidance, when performed	DIAGNOSTIC PROCEDURES
33741	Transcatheter atrial septostomy (TAS) for congenital cardiac anomalies to create effective atrial flow, including all imaging guidance by the proceduralist, when performed, any method (eg, Rashkind, Sang-Park, balloon, cutting balloon, blade)	Any line which currently has 92992-92998
33745	Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, including all imaging guidance by the proceduralist, when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (eg, atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); initial intracardiac shunt	All congential heart disease lines
33746	Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, including all imaging guidance by the proceduralist, when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (eg, atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); each additional intracardiac shunt location (List separately in addition to code for primary procedure)	All congential heart disease lines
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only	69 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION

Code	Code description	Placement Recommendation
33997	Removal of percutaneous right heart ventricular assist device, venous cannula, at separate and distinct session from insertion	69 CUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION 81 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS 97 HEART FAILURE 264 CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE
55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
57465	Computer-aided mapping of cervix uteri during colposcopy, including optical dynamic spectral imaging and algorithmic quantification of the acetowhitening effect (List separately in addition to code for primary procedure)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral	654 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral	654 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
71271	Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
76145	Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report	EXCLUDED ***new recommendation***
80143	Acetaminophen	DIAGNOSTIC PROCEDURES
80151	Amiodarone	DIAGNOSTIC PROCEDURES
80161	Carbamazepine; -10,11-epoxide	DIAGNOSTIC PROCEDURES
80167	Felbamate	DIAGNOSTIC PROCEDURES
80179	Salicylate	DIAGNOSTIC PROCEDURES
80181	Flecainide	DIAGNOSTIC PROCEDURES
80189	Itraconazole	DIAGNOSTIC PROCEDURES
80193	Leflunomide	DIAGNOSTIC PROCEDURES
80204	Methotrexate	DIAGNOSTIC PROCEDURES
80210	Rufinamide	DIAGNOSTIC PROCEDURES

Code	Code description	Placement Recommendation
81168	CCND1/IGH (t(11;14)) (eg, mantle cell lymphoma) translocation analysis, major breakpoint, qualitative and quantitative, if performed	DIAGNOSTIC PROCEDURES
81191	NTRK1 (neurotrophic receptor tyrosine kinase 1) (eg, solid tumors) translocation analysis	DIAGNOSTIC PROCEDURES
81192	NTRK2 (neurotrophic receptor tyrosine kinase 2) (eg, solid tumors) translocation analysis	DIAGNOSTIC PROCEDURES
81193	NTRK3 (neurotrophic receptor tyrosine kinase 3) (eg, solid tumors) translocation analysis	DIAGNOSTIC PROCEDURES
81194	NTRK (neurotrophic-tropomyosin receptor tyrosine kinase 1, 2, and 3) (eg, solid tumors) translocation analysis	DIAGNOSTIC PROCEDURES
81278	IGH@/BCL2 (t(14;18)) (eg, follicular lymphoma) translocation analysis, major breakpoint region (MBR) and minor cluster region (mcr) breakpoints, qualitative or quantitative	DIAGNOSTIC PROCEDURES
81279	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) targeted sequence analysis (eg, exons 12 and 13)	DIAGNOSTIC PROCEDURES
81338	MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; common variants (eg, W515A, W515K, W515L, W515R)	DIAGNOSTIC PROCEDURES
81339	MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; sequence analysis, exon 10	DIAGNOSTIC PROCEDURES
81347	SF3B1 (splicing factor [3b] subunit B1) (eg, myelodysplastic syndrome/acute myeloid leukemia) gene analysis, common variants (eg, A672T, E622D, L833F, R625C, R625L)	DIAGNOSTIC PROCEDURES
81348	SRSF2 (serine and arginine-rich splicing factor 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, P95H, P95L)	DIAGNOSTIC PROCEDURES
81351	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; full gene sequence	DIAGNOSTIC PROCEDURES ***new recommendation***
81352	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; targeted sequence analysis (eg, 4 oncology)	DIAGNOSTIC PROCEDURES ***new recommendation***

Code	Code description	Placement Recommendation
81353	TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; known familial variant	DIAGNOSTIC PROCEDURES ***new recommendation***
81357	U2AF1 (U2 small nuclear RNA auxiliary factor 1) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, S34F, S34Y, Q157R, Q157P)	DIAGNOSTIC PROCEDURES
81360	ZRSR2 (zinc finger CCCH-type, RNA binding motif and serine/arginine-rich 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variant(s) (eg, E65fs, E122fs, R448fs)	DIAGNOSTIC PROCEDURES
81419	Epilepsy genomic sequence analysis panel, must include analyses for ALDH7A1, CACNA1A, CDKL5, CHD2, GABRG2, GRIN2A, KCNQ2, MECP2, PCDH19, POLG, PRRT2, SCN1A, SCN1B, SCN2A, SCN8A, SLC2A1, SLC9A6, STXBP1, SYNGAP1, TCF4, TPP1, TSC1, TSC2, and ZEB2	30 EPILEPSY AND FEBRILE CONVULSIONS ***new recommendation***
81513	Infectious disease, bacterial vaginosis, quantitative real-time amplification of RNA markers for Atopobium vaginae, Gardnerella vaginalis, and Lactobacillus species, utilizing vaginal-fluid specimens, algorithm reported as a positive or negative result for bacterial vaginosis	DIAGNOSTIC PROCEDURES
81514	Infectious disease, bacterial vaginosis and vaginitis, quantitative real-time amplification of DNA markers for Gardnerella vaginalis, Atopobium vaginae, Megasphaera type 1, Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), and Lactobacillus species (L. crispatus and L. jensenii), utilizing vaginal-fluid specimens, algorithm reported as a positive or negative for high likelihood of bacterial vaginosis, includes separate detection of Trichomonas vaginalis and/or Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata, Candida krusei, when reported	DIAGNOSTIC PROCEDURES

Code	Code description	Placement Recommendation
81529	Oncology (cutaneous melanoma), mRNA, gene expression profiling by real-time RT-PCR of 31 genes (28 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk, including likelihood of sentinel lymph node metastasis	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81546	Oncology (thyroid), mRNA, gene expression analysis of 10,196 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81554	Pulmonary disease (idiopathic pulmonary fibrosis [IPF]), mRNA, gene expression analysis of 190 genes, utilizing transbronchial biopsies, diagnostic algorithm reported as categorical result (eg, positive or negative for high probability of usual interstitial pneumonia [UIP])	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
82077	Alcohol (ethanol); any specimen except urine and breath, immunoassay (eg, IA, EIA, ELISA, RIA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)	DIAGNOSTIC PROCEDURES
82681	Estradiol; free, direct measurement (eg, equilibrium dialysis)	DIAGNOSTIC PROCEDURES
86408	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); screen	EXCLUDED
86409	Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); titer	EXCLUDED
90377	Rabies immune globulin, heat- and solvent/detergent-treated (RIg-HT S/D), human, for intramuscular and/or subcutaneous use	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
92229	Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
92517	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report; cervical (cVEMP)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

Code	Code description	Placement Recommendation
92518	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report; ocular (oVEMP)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
92519	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report; cervical (cVEMP) and ocular (oVEMP)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
92650	Auditory evoked potentials; screening of auditory potential with broadband stimuli, automated analysis	DIAGNOSTIC PROCEDURES
92651	Auditory evoked potentials; for hearing status determination, broadband stimuli, with interpretation and report	DIAGNOSTIC PROCEDURES
92652	Auditory evoked potentials; for threshold estimation at multiple frequencies, with interpretation and report	DIAGNOSTIC PROCEDURES
92653	Auditory evoked potentials; neurodiagnostic, with interpretation and report	DIAGNOSTIC PROCEDURES
93241	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation	DIAGNOSTIC PROCEDURES
93242	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)	DIAGNOSTIC PROCEDURES
93243	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report	DIAGNOSTIC PROCEDURES
93244	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation	DIAGNOSTIC PROCEDURES
93245	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation	DIAGNOSTIC PROCEDURES

Code	Code description	Placement Recommendation
93246	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)	DIAGNOSTIC PROCEDURES
93247	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report	DIAGNOSTIC PROCEDURES
93248	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation	DIAGNOSTIC PROCEDURES
94619	Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry; without electrocardiographic recording(s)	DIAGNOSTIC PROCEDURES
99417	Prolonged office or other outpatient evaluation and management service(s) beyond the minimum required time of the primary procedure which has been selected using total time, requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service, each 15 minutes of total time (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management services)	All lines with E&M codes
99439	Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)	All lines with E&M codes

Medical Physics Dose Evaluation
VBBS November 2020

1) **76145** Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report
    a. Listed as a "practice expense" only code in the AMA guidelines. Practice expense–only codes require the presence of a qualified health care provider on premises to bill
    b. At the October, 2020 VBBS meeting, the discussion was that this code would be used for evaluation of an employee whose radiation safety badge had a reading higher than an allowed value. This exposure would need further evaluation, both of the employee for health issues and of the workplace for radiation exposure sources.
    c. Inquiries to specialists indicate that this is not a code that would be used for radiation therapy or for diagnostic radiation services
    d. After the October VBBS meeting, HERC staff reached out to various radiation safety officers at OHA and OHSU. None had any input on how this code would be utilized. Staff have determined that if this code is to be use for workplace evaluation, then it should be covered under employee health or workman's compensation, not the employee's personal health plan.
    e. This code appears to be an administrative code, which are generally non-covered. The recommendation is for placement on the Excluded File, with other administrative codes. If utility is found for this in the future, then HSD has more flexibility in moving this code to another covered file such as Diagnostic Procedures File or the Ancillary File.
    f. <u>HERC staff recommendation</u>:
        i. Advise HSD to place CPT **76145** on the EXCLUDED FILE

Question: 2021 HCPCS Code Review

Question source: Staff

Issue: HCPCS codes for 2021 have not been released, and will be provided as a handout if they become available in time for the meeting.

Home Intraocular Pressure Monitoring

Question: should home intraocular pressure monitoring be added to the glaucoma line?

Question source: Holly Jo Hodges, CCO medical director

Issue: the FDA has approved several devices in the past couple of years which patients can use at home to monitor their intraocular pressure (IOP). Intraocular pressure is elevated in glaucoma, and appropriate management of IOP is crucial for avoiding the negative outcomes of glaucoma such as blindness. Traditionally, IOP is measured by various devices in the ophthalmologist office and then glaucoma medications are adjusted if indicated. The new devices are designed for home use by the patient. The manufacturers claim that home monitoring provides a more accurate picture of IOP and thus more accurate medication changes or decision to undergo glaucoma surgery.

Home IOP measurements can be done periodically by the patient or caregiver using a device such as the ICare home tonometry unit. There are also the Triggerfish Contact Lens Sensor, which continuously monitors IOP for 72 hours.

There are currently no HCPCS codes for the home IOP measurement devices. The manufacturer recommends the use of the home physiologic monitoring CPT codes (e.g. 99453) for use by the ophthalmologist who reviews the home IOP measurements.

Current Prioritized List status
Line 139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE
CPT 99453 [Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment] is on 30+ lines (not including line 139)

Evidence

1) **Meier-Gibbons 2018**, review of home IOP measurements
    a. Continuous IOP measuring devices (intra-ocular or extra-ocular) have been under investigation and development for years; however, at present, no accurate and cost-effective measuring device has reached the market.
    b. Self-tonometry or home-tonometry devices are promising, but some practical aspects of the methodology remain in need of improvement, especially whenever compared with the effectiveness of Goldmann Applanation Tonometer (GAT) measurements
    c. We do not have adequate evidence that the progression of glaucoma can be slowed down by obtaining additional IOP measurements.
    d. At present, there is no recommendable method which measures actual IOP and for which reproducibility and comparability to Goldman IOP has been proven. Further studies related to the capabilities and effectiveness of these devices and the introduction of new devices are necessary and desirable.
2) **Go 2019**, use of home tonometry in pediatric glaucoma
    a. N=19 patients
    b. Home tonometry prompted 94 documented medication changes and validated 1 surgical decision among 14 patients.

   c. Conclusions: Home rebound tonometry … [allowed] clinicians to promptly and appropriately respond to these events. Home tonometry- augmented GDD management in childhood glaucoma may improve the care of these challenging patients.
3) **Takagi 2017**, comparison of ICare home with Goldmann Applanation Tonometer
   a. N=128 patients
   b. The mean IOP was 12.2±2.8mmHg (range, 7 to 20mmHg) via GAT,12.8±3.7mmHg (range, 6 to 24mmHg) with HOMEp and 13.1±3.8mmHg (range, 6 to 25mmHg) by Icare HOME specialist measurement [Icare HOME performed by the ophthalmologist (HOMEo)]. The mean difference between HOMEp and HOMEo was 0.21mmHg (P=0.068; paired t test). The mean difference between the HOMEp and GAT measurements was 0.70mmHg (P<0.001; paired t test), and between the HOMEo and GAT measurements it was 1.00mmHg (P<0.001; paired t test). The IOP difference between the HOMEp and GAT measurements was >3mmHg in 9.4% of cases (12/128), and >5mm Hg in 2.3% of cases (3/128).
   c. Conclusions: The Icare HOME tonometer is feasible for use in selfmonitoring of IOP. Icare HOME tonometry measurements tend to overestimate IOP relative to GAT measurements.

<u>HERC staff summary</u>

Home intraocular pressure monitoring may be useful for management of glaucoma, but is still in the investigational phase.

<u>HERC staff recommendation</u>

1) Do not add CPT 99453 [Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment] to Line 139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE

Developmental Motor Delay and Therapy Update

Question: Should coverage of physical and occupational therapy for developmental delays in children be modified?

Question source: Schools and CCOs; Resa Bradeen, MD, CMO Metropolitan Pediatrics

Issue: In 2018 HERC reviewed several codes relating to developmental delay which were only on the Diagnostic Workup File and placed some of them on the dysfunction lines to allow pairing with therapies. The issue had originally come to HERC from a concern from the schools that therapies for children were not being adequately covered via OHP for developmental delays.

There are concurrent concerns by CCOs that there is a lot of therapy utilization in children, some of which they are concerned is not resulting in clinically significant improvements.

When codes are on the diagnostic workup file, they cannot be used to pair with physical therapy, occupational therapy, or speech therapy. There would need to be a diagnosis on a funded line in order for them to pair.

The following code would commonly be used for physical developmental delay, but is only on the Diagnostic File:

R62.50	Unspecified lack of expected normal physiological development in childhood	DIAGNOSTIC WORKUP FILE (DWF)

R62.0 and F88 were previously added to 3 dysfunction lines to allow pairing with physical therapy, occupational therapy, and speech therapy.

R62.0	Delayed milestone in childhood	292,345,377
F88	Other disorders of psychological development	292,345,377

R62.5 is fairly nonspecific but are codes that would be commonly used for delays in children in which a diagnosis may still be emerging. According to Dr. Bradeen, clinically, R62.5 is a preferred code in children over R62.0 who are no longer undergoing routine milestone assessments (e.g. 0-5 years).

Current Prioritized List Status:

Code	Code Description	Prioritized List Line Placement
F70-79	Intellectual disabilities *(code first any associated physical or developmental disorders)*	Dysfunction lines (all except mild) 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
F80	Specific developmental disorders of speech and language	345
F81	Specific developmental disorders of scholastic skills	Undefined conditions
F82	Specific developmental disorder of motor function • Clumsy child syndrome • Developmental coordination disorder • Developmental dyspraxia *Excludes:* • *Abnormalities of gait and mobility (R26)* • *Lack of coordination (R27)* • *Lack of coordination secondary to intellectual disabilities (F70-79)*	661 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
F84	Pervasive developmental disorders	Dysfunction and autism lines (variable)
F88	Other disorders of psychological development Applicable To	292,345,377

Code	Code Description	Prioritized List Line Placement
	• Developmental agnosia • Global developmental delay • Other specified neurodevelopmental disorder Approximate Synonyms • Borderline cognitive developmental delay • Cognitive development, borderline • Cognitive developmental delay • Developmental delay, cognitive • Developmental delay, global • Developmental disorder, mixed • Developmental disorder, specific • Developmental neurologic disorder • Global developmental delay • Mixed developmental disorder • Neurodevelopmental disorder • Neurodevelopmental disorder, other specified • Sensory integration disorder • Specific developmental disorder	
R26.0	Abnormalities of gait and mobility *Excludes* • *Ataxia* • *Hereditary ataxia* • *Locomotor (syphilitic) ataxia* • *Immobility syndrome (paraplegic)*	DIAGNOSTIC WORKUP FILE (DWF)
R26.1	Paralytic gait	DIAGNOSTIC WORKUP FILE (DWF)
R26.2	Difficulty in walking, not elsewhere classified	DIAGNOSTIC WORKUP FILE (DWF)
R26.81	Unsteadiness on feet	DIAGNOSTIC WORKUP FILE (DWF)
R26.89	Other abnormalities of gait and mobility	DIAGNOSTIC WORKUP FILE (DWF)
R26.9	Unspecified abnormalities of gait and mobility	DIAGNOSTIC WORKUP FILE (DWF)

Code	Code Description	Prioritized List Line Placement
R27.0	Ataxia, unspecified	DIAGNOSTIC WORKUP FILE (DWF)
R27.8	Other lack of coordination	DIAGNOSTIC WORKUP FILE (DWF)
R27.9	Unspecified lack of coordination	DIAGNOSTIC WORKUP FILE (DWF)
R62.0	Delayed milestone in childhood Applicable To • Delayed attainment of expected physiological developmental stage • Late talker • Late walker Approximate Synonyms • Delayed milestone • Delayed milestones • Delayed speech milestone • Not yet speaking	292,345,377
R62.50	Unspecified lack of expected normal physiological development in childhood	DIAGNOSTIC WORKUP FILE (DWF)
R62.59	Other lack of expected normal physiological development in childhood • Constitutional delay of growth and puberty • Constitutional delayed growth and puberty	DIAGNOSTIC WORKUP FILE (DWF)
M62.3	Immobility syndrome (paraplegic)	71,292,345,377

Coding specification
ICD-10-CM R62.0 is included on Lines 292, 345 and 377 for children 8 and under. ICD-10-CM F88 is included on these lines for developmental delay. When it is used to indicate sensory integration disorder or sensory processing disorder, it is included on Line 661.

Evidence summary

Hughes, 2016

- Systematic review and meta-analysis of motor interventions for preterm infants
- 42 publications, including 36 trials (25 RCTs and 11 nonrandomized studies) with a total of 3484 infants
- A meta-analysis found positive effects found at 3 months (mean 1.37; confidence interval 0.48–2.27), 6 months (0.34; 0.11–0.57), 12 months (0.73; 0.20–1.26), and 24 months (0.28; 0.07–0.49).
- At 3 months, there was a large and significant effect size for motor-specific interventions (2.00; 0.28–3.72) but not generic interventions (0.33; –0.03 to –0.69).
- Limitations: Studies were not excluded on the basis of quality; therefore, heterogeneity was significant
- Author conclusions: A positive intervention effect on motor skills appears to be present up to 24 months' corrected age. There is some evidence at 3 months that interventions with specific motor components are most effective.

Valentín-Gudiol, 2017 *https://www.ncbi.nlm.nih.gov/pubmed/28755534*

- Cochrane systematic review of treadmill interventions in children under six years of age at risk of neuromotor delay.
- 7 studies in 175 children (children with Down syndrome, cerebral palsy, developmental delay or at moderate risk for neuromotor delay); 5 studies included in the meta-analysis
- The effects of treadmill intervention on independent walking onset compared to no treadmill intervention was population dependent
    - No overall effect (mean difference (MD) -2.08, 95% confidence intervals (CI) -5.38 to 1.22, 2 studies, 58 children; moderate-quality evidence)
    - 30 children with Down syndrome benefited from treadmill training (MD -4.00, 95% CI -6.96 to -1.04), but 28 children at moderate risk of developmental delay did not (MD -0.60, 95% CI -2.34 to 1.14).
    - Treadmill intervention did not improve overall gross motor function (MD 0.88, 95% CI -4.54 to 6.30, 2 studies, 36 children; moderate-quality evidence) or gross motor skills related to standing (MD 5.41, 95% CI -1.64 to 12.43, 2 studies, 32 children; low-quality evidence), and had a negligible improvement in gross motor skills related to walking (MD 4.51, 95% CI 0.29 to 8.73, 2 studies, 32 children; low-quality evidence).
    - Overall, treadmill intervention showed a very small increase in walking speed compared to no treadmill intervention (MD 0.23, 95% CI 0.08 to 0.37, 2 studies, 32 children; high-quality evidence). Treadmill intervention increased walking speed in 20 ambulatory children with developmental delay (MD 0.25, 95% CI 0.08 to 0.42), but not in 12 children with cerebral palsy (MD 0.18, 95% CI -0.09 to 0.45).

- AUTHORS' CONCLUSIONS: The current findings indicate that treadmill intervention may accelerate the development of independent walking in children with Down syndrome and may accelerate motor skill attainment in children with cerebral palsy and general developmental delay. Future research should first confirm these findings with larger and better designed studies, especially for infants with cerebral palsy and developmental delay. Once efficacy is established, research should examine the optimal dosage of treadmill intervention in these populations.

Lucas, 2016 https://www.ncbi.nlm.nih.gov/pubmed/27899082

- Systematic review and meta-analysis of interventions to improve gross motor performance in children with developmental disabilities
- RCTs children 3 to ≤18 years with (i) Developmental Coordination Disorder (DCD) or Cerebral Palsy (CP) (Gross Motor Function Classification System Level 1) or Developmental Delay or Minimal Acquired Brain Injury or Prematurity (<30 weeks gestational age) or Fetal Alcohol Spectrum Disorders
- Only two of 9 trials showed an effect for treatment. Using the least conservative trial outcomes a large beneficial effect of intervention was shown (SMD:-0.8; 95% CI:-1.1 to −0.5) with "very low quality" GRADE ratings. Using the most conservative trial outcomes there is no treatment effect (SMD:-0.1; 95% CI:-0.3 to 0.2) with "low quality" GRADE ratings. Study limitations included the small number and poor quality of the available trials.
- Author conclusion: Although we found that some interventions with a task-orientated framework can improve gross motor outcomes in children with DCD or CP, these findings are limited by the very low quality of the available evidence. High quality intervention trials are urgently needed.

Novak, 2019
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6850210/pdf/AOT-66-258.pdf

- Systematic review of pediatric occupational therapy for children with disabilities
- 129 articles met inclusion (n = 75 (58%) SRs; n = 54 (42%)) RCTs, measuring the effectiveness of 52 interventions, across 22 diagnoses, enabling analysis of 135 intervention indications.
- 30% of the indications were graded 'do it' (Green Go): Behavioural Interventions; Bimanual; Coaching; Cognitive Cog-Fun & CAPS; CO-OP; CIMT; CIMT plus Bimanual; Context-Focused; Ditto; Early Intervention (ABA, Developmental Care); Family Centred Care; Feeding interventions; Goal Directed Training; Handwriting Task-Specific Practice; Home Programs; Joint Attention; Mental Health Interventions; occupational therapy after toxin; Kinesiotape; Pain Management; Parent Education; PECS; Positioning; Pressure Care; Social Skills Training; Treadmill Training and Weight Loss 'Mighty Moves'.

- 56% were 'probably do it' (Yellow Measure); 10% (n = 14/135) 'probably don't do it' (Yellow Measure); and
- 4% were 'don't do it' (Red Stop).
    - Neurodevelopmental therapy in cerebral palsy
    - Handwriting sensory approach in developmental coordination disorder
    - Sensory integration in autism spectrum disorder
    - Weighted blankets in autism spectrum disorder
- Authors Conclusion: Evidence supports 40 intervention indications, with the greatest number at the activities-level of the International Classification of Function. Yellow light interventions should be accompanied by a sensitive outcome measure to monitor progress and red light interventions could be discontinued because effective alternatives existed.

<u>Recommendations from others</u>

American Academy of Pediatrics, 2019

- Clinical guidance for prescribing physical therapy, occupational therapy, and speech therapy for children with disabilities

Summary
A commonly used, appropriate code (R62.50) for indicating developmental delay is currently on the Diagnostic File and does not allow pairing with physical, occupational, and speech therapies. There may be cases in children (less than 8) in which there is not another more specific diagnosis.

Additionally, CCOs and HSD have given feedback to HERC staff that coding specifications are more difficult to administer than guidelines. HERC staff are trying to convert coding specifications to guidelines where feasible and when they arise in the course of reviewing topics.

HERC Staff Recommendations:

1) Add R62.50 *Unspecified lack of expected normal physiological development in childhood* to the 3 dysfunction lines to enable pairing with physical, occupational, and speech therapy.
   - 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
   - 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS
   - 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
2) Delete the coding specification from lines 292, 345 and 377
   - ~~ICD-10-CM R62.0 is included on Lines 292, 345 and 377 for children 8 and under. ICD-10-CM F88 is included on these lines for developmental delay. When it is used to indicate sensory integration disorder or sensory processing disorder, it is included on Line 661.~~
3) Adopt a new guideline for lines 292, 345 and 377 as shown below

GUIDELINE NOTE XXX DEVELOPMENTAL DELAY CODING
Lines 292,345,377,661
ICD-10-CM R62.0 and R62.50 are included on these lines for children 5 and under used to identify dysfunction substantially below chronological age, when significantly and persistently interfering with activities of daily living appropriate for chronological age, and there is an opportunity for skill learning. ICD-10-CM F88 is included on these lines for developmental delay. When it is used to indicate sensory integration disorder or sensory processing disorder, it is included on Line 661.

OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE
VBBS November 2020

Question: Should the guideline regarding opioid therapy for conditions of the back and spine be modified to more closely align with statewide opioid prescribing guidelines?

Question source: HERC

Issue: At the August, 2020 meetings, VBBS and HERC reviewed the guideline regarding opioids for back and spine conditions. A large volume of written and verbal public testimony was considered. There was discussion at the August HERC meeting about possible misinterpretation of the taper language in Guideline Note 60. This the current language was causing harm, then the group felt that it should be modified. There was discussion about having the guideline mirror the statewide opioid prescribing and tapering guidelines, in order to provide consistency across the state. HERC decided to send the guideline back to VBBS to rework the taper language. Staff was directed to work with Oregon Health Authority (OHA) leadership to determine how best to align GN60 with the statewide opioid prescribing and tapering guidelines.

Oregon Acute Opioid Prescribing Guidelines:
https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/Acute-Prescribing-Guidelines.pdf

Oregon Chronic Opioid Prescribing Guidelines:
https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/Chronic-Opioid-Prescribing-Guidelines.pdf

Oregon Opioid Tapering Guidelines:
https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/le2589.pdf

GUIDELINE NOTE 60, OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE

Lines 346,361,402,529

Opioid medications are only included on these lines under the following criteria:

For acute injury, acute flare of chronic pain, or after surgery:

1) During the first 6 weeks opioid treatment is included on these lines ONLY:
   a) When each prescription is limited to 7 days of treatment, AND
   b) For short acting opioids only, AND
   c) When one or more alternative first line pharmacologic therapies such as NSAIDs, acetaminophen, and muscle relaxers have been tried and found not effective or are contraindicated, AND
   d) When prescribed with a plan to keep active (home or prescribed exercise regime) and with consideration of additional therapies such as spinal manipulation, physical therapy, yoga, or acupuncture, AND
   e) There is documented verification that the patient is not high risk for opioid misuse or abuse.
2) Treatment with opioids after 6 weeks, up to 90 days after the initial injury/flare/surgery is included on these lines ONLY:

a) With documented evidence of improvement of function of at least thirty percent as compared to baseline based on a validated tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
b) When prescribed with a plan to keep active (home or prescribed exercise regime) and additional therapies such as spinal manipulation, physical therapy, yoga, or acupuncture, when available.
c) With verification that the patient is not high risk for opioid misuse or abuse. Such verification may involve
    i) Documented verification from the state's prescription monitoring program database that the controlled substance history is consistent with the prescribing record
    ii) Use of a validated screening instrument to verify the absence of a current substance use disorder (excluding nicotine) or a history of prior opioid misuse or abuse
    iii) Administration of a baseline urine drug test to verify the absence of illicit drugs and non-prescribed opioids.
d) Each prescription must be limited to 7 days of treatment and for short acting opioids only

3) Long-term opioid treatment (>90 days) after the initial injury/flare/surgery is not included on these lines except for the taper process described below.

<u>Transitional coverage for patients on long-term opioid therapy:</u>

For patients receiving long-term opioid therapy (>90 days) for conditions of the back and spine, continued coverage of opioid medications requires an individual treatment plan which includes a taper plan when clinically indicated. Opioid tapering should be done on an individualized basis with a shared goal set by the patient and provider based on the patient's overall status. Taper plans should include nonpharmacological treatment strategies for managing the patient's pain. During the taper, behavioral health conditions need to be regularly assessed and appropriately managed. In some situations (e.g., in the setting of active substance use disorder, history of opioid overdose, aberrant behavior), more rapid tapering or transition to medication assisted treatment may be appropriate and should be directed by the prescribing provider. If a patient has developed an opioid use disorder, treatment is included on Line 4 SUBSTANCE USE DISORDER.

HERC staff recommendation

1) Modify GN60 as shown below

GUIDELINE NOTE 60, OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE

Lines 346,361,402,529

Opioid medications are only included on these lines under the following criteria. Time periods described below are relative to the patient's initial injury or condition for which opioids were originally prescribed, regardless of whether the individual or any plan paid for the medication. Providers are encouraged to consider the recommendations of the Oregon Opioid Prescribing Guidelines Task Force when prescribing opioid medications: Oregon Acute Opioid Prescribing Guideline (October 2018) and the Oregon Chronic Opioid Prescribing Guidelines (2017-2018).

~~For acute injury, acute flare of chronic pain, or after surgery:~~

For acute conditions and flares

During the first 6 weeks after an acute injury, acute flare of chronic pain, or surgery opioid treatment is included on these lines ONLY:

1) When each prescription is limited to 7 days of treatment, AND
2) For short acting opioids only, AND
3) When one or more alternative first line pharmacologic therapies such as NSAIDs, acetaminophen, and muscle relaxers have been tried and found not effective or are contraindicated, AND
4) When prescribed with a plan to keep active (home or prescribed exercise regime) and with consideration of additional therapies such as spinal manipulation, physical therapy, yoga, or acupuncture, AND
5) There is documented ~~verification that~~ evaluation of the patient's risk factors ~~is not high risk~~ for opioid misuse or abuse (e.g. history of opioid misuse, verification of prescription history in the PDMP, etc.).

During subacute period

Treatment with opioids after 6 weeks of continuous therapy and up to 90 days after the initial injury/flare/surgery is included on these lines ONLY:

1) With documented evidence of improvement of function of at least thirty percent as compared to baseline based on a validated tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
2) When prescribed with a plan to keep active (home or prescribed exercise regime) and with consideration of additional therapies such as spinal manipulation, physical therapy, yoga, or acupuncture, AND
3) With verification that the patient is not high risk for opioid misuse or abuse. Such verification may involve
   a) Documented verification from the state's prescription monitoring program database that the controlled substance history is consistent with the prescribing record
   b) Use of a validated screening instrument to verify the absence of a current substance use disorder (excluding nicotine) or a history of prior opioid misuse or abuse
   c) Administration of a baseline urine drug test to verify the absence of illicit drugs and non-prescribed opioids.
4) Each prescription must be limited to 7 days of treatment and for short-acting opioids only

Long-term opioid therapy

Long-term opioid treatment (>90 days) after the initial injury/flare/surgery is ~~not~~ included on these lines ~~except for the taper process~~ as described below.

~~Transitional coverage for patients on long-term opioid therapy:~~

For patients receiving long-term opioid therapy (>90 days) for conditions of the back and spine, continued coverage of opioid medications requires a comprehensive individual treatment plan for chronic pain, taking into account the biological, behavioral, psychological and social factors which may influence each individual's experience of chronic pain as well as any current and past treatments. Treatment plans must be prescribed with a plan to keep active (home or prescribed exercise regime) and must include additional therapies such as spinal manipulation, physical therapy, yoga or acupuncture if available in a patient's community and reasonably accessible to the patient. The treatment plan should conform with the Oregon Chronic Opioid Prescribing Guidelines (2017-2018). A taper plan may be included if clinically appropriate.

Opioid tapers

Opioid taper plans are not required in order for continued inclusion of long-term opioid therapy on these lines. Providers initiating taper plans are encouraged to follow Oregon Opioid Tapering Guidelines (January 2020). ~~For patients receiving long-term opioid therapy (>90 days) for conditions of the back and spine, continued coverage of opioid medications requires an individual treatment plan which includes a taper plan when clinically indicated. Opioid tapering should be done on an individualized basis with a shared goal set by the patient and provider based on the patient's overall status.~~ Taper plans should include nonpharmacological treatment strategies for managing the patient's pain. During the taper, behavioral health conditions need to be regularly assessed and appropriately managed.

~~In some situations (e.g., in the setting of active substance use disorder, history of opioid overdose, aberrant behavior), more rapid tapering or transition to medication assisted treatment may be appropriate and should be directed by the prescribing provider. If a patient has developed an opioid use disorder, treatment is included on Line 4 SUBSTANCE USE DISORDER.~~