Health Evidence Review Commission

(with links to references added)

March 14, 2019

1:30 PM - 4:30 PM

Human Services Building, Rooms 137 A-D 500 Summer Street NE, Salem Oregon [MeetingLocation3]

Section 1.0

Call to Order

AGENDA

HEALTH EVIDENCE REVIEW COMMISSION

Human Services Building, Rooms 137A-D
500 Summer Street
Salem Oregon
March 14, 2019
1:30-4:30 pm
(All agenda items are subject to change and times listed are approximate)

#	Time	Item	Presenter	Action Item
1	1:30 PM	Call to order	Kevin Olson	
2	1:35 PM	Approval of minutes (1/17/19)	Kevin Olson	X
3	1:40 PM	Director's report	Darren Coffman	
4	1:45 PM	Value-based Benefits Subcommittee report • Recommendations approved 1/17/19 • Other recommendations approved 3/14/19 ○ Reprioritization of certain chronic pain conditions	Ariel Smits Cat Livingston	X
5	3:45 PM	Newer Interventions for Osteoarthritis of the Knee • Coverage guidance • Prioritized List changes	Adam Obley Cat Livingston	X
6	4:15 PM	Travel Reimbursement Policy Changes	Jenny Osborne	
7	4:25 PM	Next steps • Schedule next meeting – May 16, 2019 Wilsonville Training Center, Rooms 111-112	Kevin Olson	
8	4:30 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
Wilsonville Holiday Inn, Dogwood Room
25425 SW 95th Ave, Wilsonville, Oregon
January 17, 2019

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, Vice-Chair; Mark Gibson; Leda Garside, RN, MBA (arrived at 1:35 pm); Angela Senders, ND; Gary Allen, DMD (by phone); Devan Kansagara, MD (arrived at 1:45 pm); Lynnea Lindsey, PhD (by phone); Leslie Sutton (arrived at 1:40 pm); Adriane Irwin, PharmD~~,~~; Michael Adler, MD; Kevin Cuccaro, DO.

Members Absent: None

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Jason Gingerich; Daphne Peck.

Also Attending: Renae Wentz, MD, Mark Altenhofen and Wally Shaffer, MD (Oregon Health Authority); Adam Obley, MD and Craig Mosbek (Center for Evidence-based Medicine); Amara M, Carolyn Concia, NP, Windy Sinclair and Sue Griffin (Oregon Pain Action Group); Kristin McGarity; Crispin Davies, MD; Jill Joines, Stacey Bunk, Shannon Russell, Amin Medjamia, Erik Schurlwolf, and Channing Wyles (Abiomed); Cherry Amabisca; Erin Hanussak; Laura Dolph; Jaqueline Conner; Barbara Culpepper; Eric Kirker, MD, Jacob Abraham, MD and Todd Caulfield, MD (Providence); Tim Harless (American Chronic Pain Association).

Call to Order

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

Minutes Approval

MOTION: To approve the minutes of the 11/8/2018 meeting as presented. CARRIES 9-0. *(Absent: Garside, Kansagara, Sutton)*

Director's Report

Scheduling
Coffman asked to change the normal meeting schedule for the January and May VbBS/HERC meetings to be held on the third Thursday and to hold EbGS in the first week of December instead of November. Members voiced approval.

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Policy Change: Public Comments
Coffman informed the Commission about a refinement of the public comment policy, allowing one public comment up to 1,000 words per agenda topic to alleviate any confusion. Further, allowing an additional 1,000 words to address a single topic not appearing on the agenda.

Sutton asked if that was per person or per organization. Coffman said per person would be consistent with what has been allowed with verbal testimony.

Subcommittee Membership
Coffman asked the Commission to consider moving Dr. Adler to the Evidence-based Guidelines Subcommittee (EbGS) as he is an Ob-Gyn and the subcommittee is taking up the topic of Planned Out-of-hospital Birth.

MOTION: To appoint Dr. Mike Adler to EbGS. Carries: 12-0.

Retirement
Coffman reaffirmed him plans to retire in December of 2019.

Topic Nomination Survey
Gingerich announced that the topic nomination survey for coverage guidances is open until January 28, 2019.

Coverage Guidance Topic: Temporary Percutaneous Mechanical Circulatory Support with Impella Devices
Meeting materials, pages 152-247

Temporary mechanical circulatory support (e.g., Impella) is used in patients with cardiogenic shock or who are undergoing elective high-risk coronary interventions.

Obley presented an overview of the evidence. Livingston then presented the remainder of the GRADE Table (page 192) as well as the proposed coverage guidance from EbGS. This included a noncoverage recommendation for the use of an Impella for elective, high-risk PCI in cases of stable angina.

Dr. Crispin Davies was introduced as the appointed ad hoc expert on this topic. He explained that high-risk PCI is confusing because it is not that patients are in danger before the procedure, it is that they will be in danger during the PCI. If the ejection fraction is <30% or you are working on the last remaining artery you will only have 10-20 seconds to complete a procedure without the extra "protection" the Impella device provides.

Davies later explained that Impella only provides support to a single vessel and no oxygenation, so there are definitely situations in which a Ventricular Assist Device (VAD) is the more appropriate intervention because it provides biventricular support and oxygenation. An Impella is a preferred option in other situations because it is less invasive and "offloads" the heart by sucking blood from the central ventricle, whereas a VAD work against the heart without offloading that pressure.

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Sutton wondered if there any benefit in having a guidance like this that doesn't mention Impella 3.5 or 5.0? Is it worth saying 3.5 and up? Obley thought that it would best be left to providers to decide which model is appropriate.

Livingston outlined the two carve-out populations for which coverage is being recommended for Impella in the absence of evidence due to the perceived benefit in life-threatening situations: 1) as a bridge to decision for a LVAD or heart transplant, and 2) to provide support during PCI for NSTEMI patients without cardiogenic shock.

Hodges asked for confirmation that we're just guessing about the benefit in these situations because of the lack of evidence. Davies said we don't know what we don't know.

Olson asked what happens to these patients without Impella today? As a practicing cardiologist, Davies said he would use Impella 3.5 for an elective, high-risk PCI as it's the standard of care. In 2019, if you don't have an Impella you won't be performing a PCI in these situations.

Hodges then asked whether it improve outcomes. Davies said it depends on what you look at. Most elective PCI isn't about death, it's about improving quality of life. There are no ongoing trials, it has an FDA license and it has been accepted as standard of care, so no future trials are likely.

Adler asked what percent of patients would be impacted by this decision? Davies said it would be less than 10% of his practice. It's an incredibly expensive device but the number of people who actually need it is incredibly small.

Kansagara explained that when EbGS discussed this it was really challenging. Part of the reason is this is not dissimilar to things we have made coverage guidance recommendations against. As things stood there was no way in the elective, high-risk PCI group to not be at odds with other things looked at in the past, because there is evidence that it does not work better than the prior standard of care. EbGS came up with the other carve-out populations based on expert opinion in the absence of evidence for these higher risk groups.

Olson explained HERC can accept the coverage guidance as is or make changes, then a separate question will be whether to make any changes to the Prioritized List affecting Medicaid coverage.

Public Testimony

Erin Hanussak testified that she was an Impella heart patient who was invited to come here today and speak by Abiomed. She lives in Roseburg, Oregon. She had a virus attack her heart and an Impella implanted. She was hospitalized for 31 days. The Impella allowed her heart to rest and recover and she did not need a transplant.

Dr. Eric Kirker, cardiac surgeon and Senior Medical Director at Providence Heart Institute of Oregon. He indicates he implants Impella devices and has no financial disclosures otherwise. This is a new and disruptive technology. He discussed the benefits of Impella including relieving cardiac effort (compared to ECMO, particularly in patients with cardiogenic shock and high lactate levels) and reduction in sternotomies (for patients who may need LVAD or transplant). Impella 3.5 and 5.0 have no studies and are completely different that the 2.5 model.

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Erik Schulwolf, an attorney at Foly Hoag LLP who specializes in healthcare reimbursement matters. He is at the meeting representing Abiomed, the manufacturer of the Impella devices. He recommended aligning coverage with other payers, the FDA and clinical society guidelines. He is concerned that the result of this unusually restrictive coverage policy that is currently recommended would leave Medicaid patients in Oregon receiving a level of care inferior to other patients. He recommended changes that were submitted in Abiomed's January 10th comment letter.

Dr. Jacob Abraham, Medical Director of the Center for Advanced Heart Disease at Providence St. Vincent Medical Center. He stated a conflict of interest as being a scientific consultant to Abiomed and he has received travel support to attend research conferences not sponsored by industry. The requirement that two advanced heart-failure and transplant cardiologists have to agree that the Impella should be used as a bridge to transplant or LVAD has some operational challenges since there are only three of them in the entire state right now. Further, he addressed the evidence (or lack of) the use of Impella for cardiogenic shock, as noted by others. Shock is a notoriously difficult state to lend itself to scientific study; shock is a spectrum. Intervention timing is important for outcomes. Lastly, Impella allows for reduction of left ventricular wall stress.

Sutton asked if there are other cardiologists besides the three advanced heart failure and transplant cardiologists in the state who can implant the Impella or would patients need to wait under this policy and possibly have their care stalled?

Dr. Abraham said at his center cardiogenic patients are managed effectively; his concern is patients outside Providence in cardiogenic shock. Being asked to weigh in on whether or not that patient is a candidate for an LVAD or transplant is very challenging. It involves many factors including physiology of their heart, social status, wait time, etc. The default answer would be to go ahead and install an Impella, even as a bridge to decision. There are also other cardiac procedures that you may bridge to, for example in patients with congenital heart defects. His recommendation would be to specify that it doesn't need to be an in-person consultation and he might even go as far as to strike the consultation requirement.

It was clarified that interventional cardiologists around the state have been implanting Impella devices. The Providence center has implanted 234 devices since 2016, about 20% involving Medicaid patients. Implanting for high-risk PCI is a less common indication.

Dr. Todd Caulfield, an interventional cardiologist from Providence and Chief of Medical Staff for Providence-St. Vincent Hospital, disclosed no financial relationship to Abiomed or any other manufacturer. He thanked Dr. Davies for stating that this technology represents the standard of care for elective PCI. Instead of performing a CABG and hoping that the patient survived, they are now able to manage these patients well in the cath lab. He asked that Commission look very closely at the O'Neal paper, particularly at the discussion sections on the intention-to-treat analysis as well as the per-protocol population. This is a small trial that will not tell you about a mortality benefit over the balloon pump. What it is looking to do is bundle adverse outcomes together and see if there is a benefit. There are strong trends there that will play out the longer you follow the patients. There will be less expense due to less repeat procedures. Secondly, he wants to make sure the guideline covers the acute STEMI patient. There isn't time for a consultation on transplant/LVAD candidacy before implanting an Impella in these cases.

Obley clarified that the small studies using Impella 2.5 showed no benefit.

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Gibson asked if there are patient registries that will help us track patient outcomes. Caulfield said Providence was able to look at outcomes across their multi-state system in determining the appropriate utilization. Davies added there is a registry called US Power that the FDA used in 2018 to extend the license to include an even wider population.

Gibson asked for clarification on the statement that there would be fewer CABGs. Caufield said there are some incredibly frail patients who are not great surgical candidates who could handle a percutaneous Impella and see improved quality of life.

Obley noted that 2/3 of patients in PROTECT II were deemed inoperable but there was no subgroup analysis done. There was a subgroup analysis done on STS mortality score, which showed that patients with a high operative risk didn't benefit as much with Impella 2.5, but not at a significant level. Caulfield said an Impella 3.5 or 5.0 would be needed to show benefit for the cardiogenic shock patient. Coffman noted that Impella 5.0 is not within the scope of this coverage guidance.

The Providence team estimated the cardiogenic shock mortality rate for ECMO is about 50% and their mortality rate for all-comers with Impella is 4%.

Kansagara noted the experts are suggesting the elective, high-risk PCI situation is similar to the parachute analogy; we haven't studied the higher volume Impella models but we know they work. The problem is the PROTECT II study was stopped for futility and the positive outcomes were on repeat revascularization in post-hoc analysis. So the only way we can come to a positive recommendation for this population is to say we have no evidence for the newer devices and don't expect to see any. Obley confirmed that the only RCT in this population using Impella 3.5 was very small study involving gravely ill patients.

Olson summarized that we have a technology that has been widely adopted and has studies that were imperfectly designed and didn't show what was anticipated. The technology makes sense from a scientific perspective and in the hands of the providers it seems to make a difference. This group is supposed to be prioritizing based on evidence. The research evidence does not match the real world observation. The nuance of the patient populations and the multiple devices makes it difficult for this group to make an obvious decision. The draft proposal does not seem to capture the nuances heard in public testimony today.

Sutton expressed that there was a lack of clarity about which of the population presented in public testimony would be affected by the draft EbGS coverage recommendations.

Adler suggested the topic be tabled.

Kansagara wondered how to balance evidence-based standards with real-world practice? If Impella 3.5 is a substantially different technology than the 2.5 then perhaps it could be recommended for coverage citing widespread utilization and the likelihood that no new studies are likely.

Livingston reframed the issue by stating that one population involves chronic stable angina the other involves individuals in cardiogenic shock who might die. Those involve very different outcomes and you

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might want to make different coverage decisions based on one potentially being a life-saving intervention and another that might improve quality of life.

There was discussion about which subcommittee should take up the continued work if tabled, but it was ultimately left up to staff to determine.

Motion: To table this topic for further review. CARRIES: 12-0.

Value-based Benefits Subcommittee (VbBS) Report on Prioritized List Changes
Meeting materials, pages 86-150

Ariel Smits reported the VbBS met earlier in the day, 1/17/2019.

Chronic Pain Task Force (CPTF) Report

Olson said that he recognizes that what is coming from the CPTF is complicated and controversial in many ways. The goal is to hear the topic's update today with the idea of hearing a complete report with robust discussion at the March 14, 2019 meeting. Today's public comment will be limited to 5 minutes for the topic.

Smits said the CPTF met in December and came up with a final set of recommendations, after which staff worked with stakeholders to add a few modifications. The revised proposal was not approved by VbBS today. There has been a lot of feedback since this topic was initially brought to VbBS in August: a survey of the CCOs was conducted on their implementation of the back line changes; P&T staff did an evidence review on the pharmacological treatment of fibromyalgia; the Center for Evidence-based Policy updated an evidence review on tapering of chronic opioids; and expert testimony and public testimony, both written and verbal, were received and considered.

The Task Force is proposing is to move 5 diagnoses from the unfunded region to the funded region (approximate line 443) and allow treatments of PT/OT, acupuncture, CBT, non-opioid medications, etc. with a multi-faceted guideline. For conditions other than fibromyalgia, opioids would be allowed following the statewide prescribing guidelines.

Public Testimony

Kristen Garity declared no affiliations and no conflicts. Risk benefit analysis can turn out to be wrong. Tapers should be reversible and there should be an appeals process for patients who try all the alternatives and none of them make a difference. We have to stop making individual decisions based on population level data.

Amara M, volunteers with the Oregon Pain Action Group. As the CPTF and HERC revisits the language of the back and spine guidelines with the taper paragraph she would like to formally request the taper portion of the back and spine lines be re-evaluated.

Larry Gordon, declared no conflicts of interest and shared his experience of being the spouse of a chronic pain patient who was tapered off opioids.

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Next Steps

Smits said that VbBS gave staff direction that they wanted a deeper look at a few pieces of the proposal. Any decision made in March would be effective January 1, 2020. If the decision is delayed, changes made after that date would be effective January 1, 2022.

Coverage Guidance Topic: Newer Interventional Procedures for GERD
Meeting materials, pages 249-318

Gastroesophageal reflux disease (GERD) is a long-lasting and more serious form of gastroesophageal reflux. Common symptoms of GERD include heartburn, bad breath, nausea, pain in the chest or upper part of the abdomen, painful swallowing, and vomiting.

Obley and Shaffer presented an overview of the evidence. Shaffer then read through the remainder of the GRADE Table (page 282) as well as the proposed coverage guidance from HTAS.

Shaffer reviewed the recommendations (page 306) for inclusion on the Prioritized List of Health Services.

There was no discussion.

MOTION: To approve the proposed coverage guidance for Newer Interventional Procedures for GERD as presented. Carries 12-0.

MOTION: To approve the proposed guideline for the Prioritized List as proposed. Carries 12-0.

Approved Coverage Guidance:

HERC Coverage Guidance

Transoral incisionless fundoplication (TIF) is recommended for coverage of GERD treatment only when the following criteria are met *(weak recommendation)*:

- 18 years of age or older
- Confirmed diagnosis of esophageal reflux by endoscopy, ambulatory pH, or barium swallow testing
- History of GERD symptoms for one year, occurring at least two to three times per week in the past month
- History of daily proton pump inhibitor therapy for the most recent six months
- Body mass index (BMI) ≤ 35
- Absence of all of the following conditions
    - Hiatal hernia larger than 2 cm
    - Esophagitis with LA grade of C or D

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- Barrett's esophagus greater than 2 cm
- Achalasia
- Esophageal ulcer
- Esophageal motility disorder
- Altered esophageal anatomy preventing insertion of the device
- Previous failed anti-reflux surgery or procedure

EsophyX® was the only device identified in the evidence reviewed for this coverage guidance. Other transoral fundoplication devices or systems are not recommended for coverage.

For patients who have recurrent symptoms or fail the initial TIF procedure, repeat TIF is not recommended for coverage *(strong recommendation)*.

Magnetic sphincter augmentation for treatment of GERD is not recommended for coverage *(weak recommendation)*.

Changes for the Prioritized List of Health Services:

1) Remove CPT 43210 (transoral incisionless fundoplication) from line 56 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE
    a. No appropriate GERD type diagnoses on this line
    b. Leave only on line 380 ESOPHAGITIS; GERD

2) Add a new Guideline Note to line 380, as follows:

GUIDELINE NOTE XXX, TRANSORAL INCISIONLESS FUNDOPLICATION FOR TREATMENT OF GERD

Line 380

Transoral incisionless fundoplication (TIF), CPT 43210, utilizing the EsophyX device only, is included on
Line 380 for surgical treatment of GERD only when the patient meets ALL the following criteria:

1) 18 years of age or older; AND
2) Confirmed diagnosis of esophageal reflux by endoscopy, ambulatory pH, or barium swallow testing; AND
3) History of GERD symptoms for one year, occurring at least two to three times per week in the past month; AND
4) History of daily proton pump inhibitor therapy for the most recent six months; AND
5) Body mass index (BMI) ≤ 35, AND
6) Absence of ALL of the following conditions
    a. Hiatal hernia larger than 2 cm
    b. Severe esophagitis, for example LA grade of C or D
    c. Barrett's esophagus greater than 2 cm
    d. Achalasia

e. Esophageal ulcer
f. Esophageal motility disorder
g. Altered esophageal anatomy preventing insertion of the device
h. Previous failed anti-reflux surgery or procedure

Repeat TIF is not included on Line 380~~,~~ for patients who have recurrent symptoms or fail the initial TIF procedure.

3) Add CPT 43284 (magnetic sphincter augmentation) to Line 660, and add an entry to Guideline Note 173 as shown in Appendix A.

Public Comment

There was no additional public comment at this time.

Items for next meeting

- Approve the VbBS report from the 1/17/2019 meeting
- Bring Temporary Percutaneous Mechanical Circulatory Support with Impella Devices coverage guidance topic back to a future meeting

Adjournment

Meeting adjourned at 4:30 pm. Next meeting will be from 1:30-4:30 pm on Thursday, March 14, 2019 at Human Services Building, Room 137A-D, 500 Summer Street NE, Salem, Oregon.

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Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on January 17, 2019

For specific coding recommendations and guideline wording, please see the text of the 1/17/2019 VbBS minutes. Note that due to the length of other items on the 1/17/2019 HERC agenda, only an update on the Chronic Pain Task Force proposal was heard. The remainder of the items will be heard at a future HERC meeting as time allows.

RECOMMENDED CODE MOVEMENT (effective 10/1/2019 unless otherwise noted)

- Add the diagnosis code for failure to thrive in children to a covered line
- Delete the procedure codes for procalcitonin and fecal calprotectin testing from an uncovered line and suggested for addition to the Diagnostic Procedures File
- Make various straightforward coding changes
- Add the Diabetes Prevention Program (DPP) codes to the obesity line

RECOMMENDED GUIDELINE CHANGES (effective 10/1/2019 unless otherwise noted)

- Make various straightforward guideline note changes
- Modify the guideline on human donor breast milk for high risk infants
- Modify the DPP guideline and overweight and obesity guideline to enable coverage of the DPP program for obesity, along with other various straightforward changes

BIENNIAL REVIEW CHANGES (effective 1/1/2020)

- Create a new line above the funding line for hidradenitis suppurativa with a new guideline
- Create a new line above the funding line for minimally invasive surgery for sacroiliac joint dysfunction

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VALUE-BASED BENEFITS SUBCOMMITTEE
Wilsonville Holiday Inn, Dogwood Room
25425 SW 95th Ave, Wilsonville, Oregon
January 17, 2019
8:00 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair; Mark Gibson (at 8:15); Holly Jo Hodges, MD; Gary Allen, DMD (via phone), Adriane Irwin, PharmD (via phone until 10:00, in person beginning at 11:15)

Members Absent: Vern Saboe, DC

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Daphne Peck; Dana Hargunani, MD

Also Attending: Renae Wentz, MD, Mark Altenhofen, Saerom England, and Wally Shaffer, MD (Oregon Health Authority); Adam Obley, MD and Craig Mosbek (OHSU Center for Evidence-based Medicine); Dr. Julie Dhossche and Dr. Tracy Fett (OHSU); Carolyn Concia, NP; Amara M, Windy Sinclair and Sue Griffin, Oregon Pain Action Group; Margaret Olmon and Laura Jeffcoat (Abbvie); Kristin McGarity; Crispin Davies; Jill Joines, Stacey Bunk, Shannon Russell, Amin Medjamia, Erik Schurlwolf, and Channing Wyles (Abiomed); Cherry Amabisca; Erin Hanussak; Jess Flaum (Lund Report); Laura Dolph; Jaqueline Conner; Barbara Culpepper; Todd Caulfield, MD (Providence).

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

  The meeting was called to order by Chair Olson at 8:10 am and roll was called. Minutes from the November 8, 2018 VbBS meeting were reviewed and approved.

  Smits reviewed the HERC change in the VbBS placement recommendation for the new 2019 CPT code for home administration of subcutaneous immunotherapy to line 660, as the MED report supports this change. There was no discussion; this was an informational item only.

- **Topic: Straightforward/Consent Agenda**

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

  Recommended Actions:
  1) Add CPT 44320 (Colostomy or skin level cecostomy) to line 239 CANCER OF OVARY
  2) Add CPT 68110-68130 (Excision of lesion, conjunctiva) to lines 113 CANCER OF EYE AND ORBIT and 310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA
  3) Add CPT 68135 (Destruction of lesion, conjunctiva) to line 310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA
  4) Remove CPT 28111-28114 (Ostectomy, metatarsal head) from line 359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
  5) Modify guideline note 137 as shown in Appendix A

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6) Remove HCPCS G0513 and G0514 (Prolonged preventive service(s)) from all current lines except for Line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

MOTION: To approve the recommendations stated in the consent agenda. CARRIES 4-0. *(Absent: Gibson)*

- **Topic: 2020 Biennial Review: Chronic Pain Taskforce report/reprioritization of certain chronic pain conditions**

Discussion: Hargunani gave an introduction and review of the process to date. Smits presented the December 2018 Chronic Pain Taskforce recommendation with subsequent staff changes.

In the proposed new guideline for the new chronic pain line, there was discussion about the need for training in pain science for providers "managing" or "seeing" patients. Members noted that they agreed with the staff attempt to only require training in pain science for those providers who were managing the chronic pain for the patient, as opposed to specialists who only care for one aspect of the patient such as a cardiologist. HERC staff was requested to identify better wording for this section.

The section of the proposed new guideline for the new line regarding prescribing opioid pain medications generated considerable discussion. The clause that "No concurrent prescribing of benzodiazepines without extenuating circumstances" was felt to be too vague. Most members thought there were no extenuating circumstances. If this phrase is kept in, Hodges requested that what circumstances might be considered should be spelled out. The clause that "Careful reassessment of the evidence of individual benefits and risks should be undertaken for dosages > 50 MED. Dosages >90 MED should be avoided or carefully justified" was felt to be problematic. Hodges wondered if this wording contradicted national and state guidelines. Hargunani replied that this wording actually aligns with state and national guidelines. There was discussion about the requirement to address mental health issues. What if mental health resources are limited and the patient's mental health issues cannot be adequately addressed. Hodges noted that telemedicine and OPAL-A are available as resources to help manage mental health. Irwin requested that a requirement for naloxone co-prescribing be added to this section. Livingston expressed concern that such a change would not be in line with a payer policy; rather, it would be more of a practice guideline. There were questions about what would happen if the prescriber for the opioid did not provide this prescription? It was noted that pharmacists in Oregon can prescribe naloxone if needed. Hodges advocated for adding a clause requiring naloxone as it focuses on patient safety. As one last comment on this section, Olson requested that the patient requirements and the provider requirements be grouped together for clarity.

Next, the group discussed the opioid tapering section of the new guideline. The introductory line was noted to be confusing and not needed. The group suggested deletion. There was then discussion about whether the requirement for tapering patients with fibromyalgia off opioids was intended to apply to prescriptions for fibromyalgia or does it to apply to patients with fibromyalgia who may be getting opioid prescriptions for other indications. The group felt that the intent was it should apply to opioid prescriptions for fibromyalgia. A patient with fibromyalgia with another painful condition such as cancer may receive opioid prescriptions for that other diagnosis.

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There was no discussion regarding line scoring, the additional changes suggested for the back medication or back opioid guideline, the acupuncture guideline or the deletion of the fibromyalgia guideline.

Public Testimony

Amara (advocate, Oregon Pain Action Group) testified that she has chronic back pain due to a back injury. She feels this proposal is cruel and unusual punishment. Policies like these are creating pain refugees. Affects children of whose parents are affected by this proposed policy.

Kristin McGarity: Has interstitial cystitis, a condition that doctors used to think that opioids did not treat. However, high dose opioids is now known to help. Unidirectional tapers do not allow re-evaluation of the risk/benefit analysis. This proposal needs a clear appeal process. Doctors are not perfect. One doctor makes a bad call, and you are tapered for life. The resources reviewed by the Taskforce and VbBS are all from one viewpoint. Chronic pain is more than pain that continues beyond tissue healing. Some things just don't heal. Policy does not account for new evidence, or for new understanding of disease. Stop making individual decisions from population-based data.

Cherry Amabisca: CCOs are right about increased costs in this proposal. Big increase in cost for alternate therapies to reduce a small amount of opioids that are being prescribed for this population. She is concerned about conflict of interest for members of taskforce due to more patients coming into their practice or grants or other funding they might receive. According to Dr. Hedberg, 144 prescription opioids deaths in Oregon (Medicaid plus all other payers). Opioid crisis peaked and is coming down. Why are you punishing patients? Objects to tapering off opioids for back conditions. Her experience is that CCOs are not enforcing opioid tapers for back conditions.

Windy Sinclair: founder of Oregon Pain Action Group. If the intent of the Commission is only adding services, then there is no need for the paragraph on opioid tapering, this is taking away treatment for some patients. Concerned for patients with fibromyalgia. People are getting letters from Medicaid that their doctors are getting instructed to taper them off opioids. Decisions of HERC have unintended consequences—feeds into environment that is shaming chronic pain patients. Absolute need for individualized medical care that allows doctors to give appropriate medical care. Each patient is unique. Don't dictate how doctors practice medicine. Does not agree with statement that opioids are harmful for fibromyalgia. Many fibromyalgia patients are greatly benefiting from opioids. Patients don't take opioids when not effective.

Jacqueline Connor: patient with fibromyalgia and spine conditions. Spent years resisting opioid therapy, not able to work. Starting opioids 15 years ago, which allowed her to work and care for herself. When CDC opioid prescribing guidelines came out, her doctor tapered her dose by 80% in 10 days. Has not been able to work, very limited in functionality since that taper. Blanket statement that opioids don't work are wrong. Interferes with doctors' ability to treat their patients. Oregon law passed in 2006 controlling Sudafed, but meth related deaths are higher than ever---- taking this med away did not help. Chronic shortage in mental health care is another concern.

Carolyn Concia: geriatric NP in private practice. Concerned about patients getting forced tapers off opiates, being forced to say they are drug addicts. Reccommends adding an ethicist on the commission.

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The VbBS decided that staff should work on the sections of the proposal that they had identified as needing further work and bring back suggested changes to the March 2019 VbBS meeting.

Recommended Actions:

1) HERC staff to address the issues raised by VbBS members, along with consideration of public testimony, and bring a revised proposal back to the March 2019 VbBS meeting

- **Topic: 2020 Biennial Review: hidradenitis suppurativa**

Discussion: Smits reviewed the summary document. Dr. Julie Dhossche and Dr. Nicole Fett form OHSU Dermatology provided a presentation about the nature and treatment of hidradenitis suppurativa (HS).

There was discussion about how long adalimumab/Humira therapy would be continued if it was effective. Fett indicated that therapy would be indefinite, similar to other chronic autoimmune diseases. Hodges asked whether HS was autoimmune. Fett responded that it is autoinflammatory, with increase in inflammatory cytokines, rather than autoimmune with a measurable autoantibody.

Hodges wondered if adalimumab therapy would reduce scarring. Fett indicated that the scarring is permanent; adalimumab treats the malodorous discharge, pain, etc.

Hodges asked whether Hurley staging is standard. Fett responded that it is, and it would be reasonable to request Hurley staging from a dermatologist on something like a PA form.

Gibson raised concerns about the risks of Humira. Smits reviewed P&T review of adverse events showing similar rates with Humira vs placebo. Fett also noted that untreated HS increased risk of squamous cell cancer (1-2%).

There was discussion that adalimumab is effective only in a subset of people. The guideline as written was expected to determine which patients benefit. There was also discussion regarding the cost of adalimumab. Dhossche noted that use may reduce cost of ER visits, etc. Wentz also noted that the cost effectiveness of conventional therapy is low and the cost effectiveness of Humira in responding patients is considered reasonable.

Recommended Actions:

1) Create a new line and guideline with line scoring as shown below
2) Leave ICD-10 L73.2 (Hidradenitis suppurativa) on line 512 for cases not meeting the new guideline requirements, and rename this line 512 MILD HIDRADENITIS SUPPURATIVA; DISSECTING CELLULITIS OF THE SCALP

HERC staff proposed line scoring (current scores for line 512 in parentheses)

Category 7 (7)
Impact on Healthy Life Years 3 (2)
Impact on Pain and Suffering 4 (3)
Population effects 0 (0)
Vulnerable populations 0 (0)
Tertiary prevention 2 (1) (decreases risk of scarring down axilla; abscesses)

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Effectiveness 2 (1)
Need for treatment 1 (1)
Net cost 2 (4)
SCORE 360 (120), approximate new line 418 (512)

Line: XXX
Condition: MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA
Treatment: MEDICAL AND SURGICAL THERAPY
ICD-10: L73.2 (Hidradenitis suppurativa)
CPT/HCPCS: those currently appearing on line 512 HIDRADENITIS SUPPURATIVA; DISSECTING CELLULITIS OF THE SCALP

GUIDELINE NOTE YYY, HIDRADENITIS SUPPURATIVA

Line XXX, 512

Hidradenitis suppurativa is included on line XXX only for moderate to severe disease (e.g. Hurley Stage II or Hurley Stage III); otherwise this condition is included on line 512.

Initial treatment with adalimumab is limited to adults whose disease has not responded to at least a 90-day trial of conventional therapy (e.g., oral antibiotics), unless such a trial is not tolerated or contraindicated. Treatment with adalimumab after 12 weeks is only included on line XXX for patients with a clear evidence of response, defined as:

1. a reduction of 25% or more in the total abscess and inflammatory nodule count, AND
2. no increase in abscesses and draining fistulas.

MOTION: To recommend the adoption of the new line, line scoring, and guideline note as presented. CARRIES 4-0. *(Absent: Irwin)*

- **Topic: 2020 Biennial Review: SI joint dysfunction surgical treatment reprioritization**

Discussion: Smits reviewed the summary document, including the Washington HTA report on SI joint fusion.

There was discussion about how nerve dysfunction was an important criteria for coverage of other types of back conditions. Gibson was concerned that coverage of SI joint dysfunction without nerve dysfunction might set a poor precedent. Olson felt that this was not an issue, as there are no nerves exiting in the SI joint area, unlike other anatomic back conditions. Kranenburg noted that requiring neurologic dysfunction would not allow any treatment of the SI joint, as it is does not fall neatly into back pathology.

Hodges requested information on long term outcomes of SI joint fusion. Kranenburg replied that the surgery has been done for about 10 years. Five-year data has been published showing the success of the fusion surgery is durable over time. This makes sense to him, as the fusion does not allow joint movement, and therefore there is no breakdown due to movement like in a knee replacement.

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Hodges wondered what number of people with SI joint dysfunction fail 6 months of conservative therapy. Kranenburg replied that the majority of acute or subacute SI joint injury will improve with conservative care, although there is no published evidence to support this. With chronic SI joint paint (>3 months), about 1 in 5 pts will respond to conservative therapy based on studies with a conservative therapy arm.

The decision was to approve the biennial review changes as recommended.

Recommended Actions:

1) Create a new line for SI joint fusion as shown below
    a. Leave ICD-10 M46.1 (Sacroiliitis, not elsewhere classified) on line 527 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS for mild cases
    b. Leave M46.1 on line 401 CONDITIONS OF THE BACK AND SPINE for medical care
2) Score the new line as shown below
3) Modify guideline note 161 as shown in appendix A

LINE: XXX
CONDITION: SEVERE SACROILIITIS
TREATMENT: SURGICAL THERAPY

ICD-10: ICD-10 M46.1 (Sacroiliitis, not elsewhere classified)

CPT: 27096 (Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed), 27279 (Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device), 98966-98969, 99051, 99060,99070,99078,99201-99215,99281-99285,99304-99337,99340-99404, 99408-99449,99487-99490,99495,99496,99605-99607 (medical office visits, including ER and SNF)

HCPCS: G0260 (Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography), G0396-G0397 (alcohol and substance abuse screening), G0463-G0467,G0469,G0470 (FQHC care), G0490, G0511-G0513 (RFQHC care)

HERC staff proposed line scoring (current scores for line 527 in parentheses)

Category 7 (7)
Impact on Healthy Life Years 4 (4)
Impact on Pain and Suffering 3 (3)
Population effects 0 (0)
Vulnerable populations 0 (0)
Tertiary prevention 0 (0)
Effectiveness 4 (1)
Need for treatment 0.8 (0.8)
Net cost 2 (2)
SCORE 560 (112), approximate new line 418 (527)

MOTION: To recommend the adoption of the new line, line scoring, and guideline note as presented. CARRIES 4-0. *(Absent: Irwin)*

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- **Topic: Human donor breast milk guideline update**

Discussion: Livingston presented the issue summary. There was a concern raised about one of the requirements regarding the ongoing outpatient medical need of human donor breast milk. It was thought that eliminating this requirement may lead to requirements that are too lenient, whereas the current wording would make it impossible for any infants to be eligible for coverage as they would likely be sick enough to require re-hospitalization. It was clarified that OHP does not pay for inpatient use of human donor breast milk and this guideline only applies in the outpatient setting. Members discussed the role of hospitals making decisions about medical necessity for human donor milk and in the end, the group agreed to modify the guideline note to simply require ongoing outpatient medical need for human donor breast milk.

Recommended Actions:

1) Modify GUIDELINE NOTE 183 DONOR BREAST MILK FOR HIGH RISK INFANTS as shown in Appendix A

MOTION: To recommend the guideline note changes, as amended. CARRIES 5-0.

- **Topic: Diabetes Prevention Program (DPP) guideline update**

Discussion: Livingston presented the issue summary. Members clarified the need for using the DPP for patients with obesity but not prediabetes, and that this program would be appropriate given the DPP's ability to result in weight loss. Livingston queried the intent on coverage with programs actively pursuing CDC recognition/certification. There was a concern raised that some programs could pursue certification but fail to achieve it, then OHP dollars could be spent on an ineffective/inappropriate program. Despite this concern, members felt that the likelihood of abuse was small, and that CCOs would let them know if there were to be a problem emerging with DPP programs in the process of certification who do not end up achieving that status. An edit to the proposal was also made for patients who may have a history of type 2 diabetes that has since resolved.

Recommended Actions:

1) Make the following code changes
    a. Add DPP codes to Line 320 OBESITY IN ADULTS AND CHILDREN; OVERWEIGHT STATUS IN ADULTS WITH CARDIOVASCULAR RISK FACTORS
        i. Add G9873-G9885, and G9890-G9891
        ii. Add 0403T and 0488T
    b. Remove Z68.53-Z68.54 from Line 3 for pediatric overweight/obesity (i.e., for 18-19 year olds). Place on Line 320.
    c. Add Z68.25- Z68.29 (overweight BMI codes) to Line 320
        i. Advise HSD to remove from informational file
    d. Remove E66.01 Morbid (severe) obesity due to excess calories from Line 659 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
2) Modify the Diabetes Prevention Program Guideline Note 179 as shown in Appendix A
3) Modify the Obesity and Overweight Guideline Note 5 as shown in Appendix A

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MOTION: To recommend the code and guideline note changes as amended. CARRIES 4-0.
(Abstained: Irwin)

- **Topic: Failure to thrive in children**

Discussion: Smits introduced the summary document. There was minimal discussion.

Recommended Actions:
1) Add ICD10 R62.51 (Failure to thrive (child)) to Line 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES

MOTION: To recommend the code change as presented. CARRIES 5-0.

- **Topic: Procalcitonin**

Discussion: Livingston reviewed the summary document. There was minimal discussion

Recommended Actions:
1) Delete CPT 84145 (Procalcitonin) from Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
2) Remove the entry for CPT 84145 from Guideline Note 173 as shown in Appendix A
3) Recommend HSD add CPT 84145 to the Diagnostic Procedures File

MOTION: To recommend the code and guideline note changes as presented. CARRIES 5-0.

- **Topic: Fecal calprotectin**

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

Recommended Actions:
1) Delete 83993 (fecal calprotectin) from Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
2) Remove the entry for CPT 83993 from Guideline Note 173 as shown in Appendix A
3) Recommend HSD add CPT 83993 to the Diagnostic Procedures File

MOTION: To recommend the code and guideline note changes as presented. CARRIES 5-0.

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- **Topic: Pulmonary rehabilitation**

  Discussion: Smits reviewed the summary document. She noted two errors in the document that need correction. First, HCPCS S9273 was mistakenly noted to be S9237; this was corrected. Line 223 was not included in the list of lines for the new pulmonary rehab guideline and should be added.

  There was discussion about the indications for repeat pulmonary rehabilitation. Hodges noted that the evidence seemed to support it only after lung reduction surgery. Livingston noted that Aetna covered it after lung transplant. Smits noted that the British Thoracic Society recommended it if at least a year had passed since the last pulmonary rehabilitation series. HERC staff was directed to research what the evidence supports for repeat pulmonary rehabilitation and propose alternative wording in the new guideline.

  Hodges advised striking the clause that the required PT/OT done as part of pulmonary rehabilitation be counted towards the 30 visit a year limit. This is not consistent with how cardiac rehabilitation is treated.

  There was discussion about whether 2 sessions a week should be the minimum or the maximum number of visits. There was also discussion about whether 36 total visits should be put in the guideline, to mirror the CMS guidelines. HERC staff will research these issues and propose wording changes to the new guideline.

  Recommended Actions:
  1) HERC staff will research indications for repeat pulmonary rehabilitation and propose alternate wording for this in the proposed new guideline
  2) HERC staff will research overall visit limits for pulmonary rehabilitation
  3) HERC staff will bring this topic back for further discussion at a future VbBS meeting

- **Topic: Coverage Guidance—Newer interventions for GERD**

  Discussion: Obley presented the evidence reviewed by the Health Technology Assessment Subcommittee on two newer procedures for gastroesophageal reflux disease: transoral incisionless fundoplication (TIF) and magnetic sphincter augmentation (MSA). Shaffer presented the HTAS coverage guidance recommendations. Fouad Otaki, MD, OHSU gastroenterologist, who serves as ad hoc expert on this topic, joined the discussion by phone. Otaki noted that an RCT comparing MSA and PPI therapy was just published in print a few days ago. The subcommittee was advised that the study was already included as a result of previous online publication.

  There was minimal discussion of the reviewed evidence, other than noting that the effectiveness of GERD surgical procedures wanes over time, perhaps sooner for TIF than for laparoscopic fundoplication.

  Attention was turned to the staff recommendations for coverage. The TIF procedure is currently in the funded portion of the Prioritized List, but placement on Line 56 (Ulcers, etc.) is not necessary. Continued coverage on Line 380 (Esophagitis, GERD) is recommended, with the addition of guideline

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note criteria based on the coverage guidance recommendations. The MSA procedure is not currently on the List, and addition to Line 660 is recommended.

Gibson expressed concerns regarding the low level of evidence to support TIF coverage, and the limitation of coverage to a specific single device (EsophyX). TIF had previously been added to the List as a straightforward new CPT code, and typically it would require evidence of ineffectiveness to remove TIF from coverage at this point. Obley, Shaffer and Otaki confirmed that TIF evidence included in the CG review was solely based on the EsophyX device, and that a more recently developed system (MUSE) differs significantly in device components and technique, and currently lacks comparative evidence comparable to EsophyX.

Hodges questioned whether gastroenterologists would always include the "LA grade" of esophagitis in requests for TIF authorization, and Otaki confirmed that the LA classification is part of good quality documentation, but it is not always included. Guideline Note criterion 6) b. was amended to "severe esophagitis, for example LA grade of C or D".

Irwin asked about the diagnostic tests included in the guideline note. Otaki stated that all patients considering these surgical interventions would have had previous endoscopic evaluation, but also that ambulatory pH testing could be used for inclusion or exclusion of some patients.

Recommended Actions:

1) Remove CPT 43210 (transoral incisionless fundoplication) from line 56 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE
    a. No appropriate GERD type diagnoses on this line
    b. Leave only on line 380 ESOPHAGITIS; GERD
2) Add a new Guideline Note to line 380, as follows:

GUIDELINE NOTE XXX, TRANSORAL INCISIONLESS FUNDOPLICATION FOR TREATMENT OF GERD

Line 380

Transoral incisionless fundoplication (TIF), CPT 43210, utilizing the EsophyX device only, is included on Line 380 for surgical treatment of GERD only when the patient meets ALL the following criteria:

1) 18 years of age or older; AND
2) Confirmed diagnosis of esophageal reflux by endoscopy, ambulatory pH, or barium swallow testing; AND
3) History of GERD symptoms for one year, occurring at least two to three times per week in the past month; AND
4) History of daily proton pump inhibitor therapy for the most recent six months; AND
5) Body mass index (BMI) ≤ 35, AND
6) Absence of ALL of the following conditions
    a. Hiatal hernia larger than 2 cm
    b. Severe esophagitis, for example LA grade of C or D
    c. Barrett's esophagus greater than 2 cm
    d. Achalasia
    e. Esophageal ulcer
    f. Esophageal motility disorder

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g. Altered esophageal anatomy preventing insertion of the device
h. Previous failed anti-reflux surgery or procedure

Repeat TIF is not included on Line 380 for patients who have recurrent symptoms or fail the initial TIF procedure.

3) Add CPT 43284 (magnetic sphincter augmentation) to Line 660 and add an entry to Guideline Note 173 as shown in Appendix A.

MOTION: To approve the recommended changes to the Prioritized List, as amended, based on the draft coverage guidance Newer Interventions for GERD, scheduled for review by HERC at their January 17, 2019 meeting. CARRIES 5-0.

- **Topic: Coverage Guidance—Temporary percutaneous mechanical circulatory support with Impella devices**

  Discussion: Tabled to the January 17, 2019 HERC meeting

- **Public Comment**

  No additional public comment was received.

- **Issues for next meeting**
  - Reprioritization of certain chronic pain conditions
  - Pulmonary rehabilitation

- **Next meeting:**

  March 14, 2019 at Human Services Building, Rooms 137 A-D, 500 Summer Street NE, Salem, OR.

- **Adjournment:**

  The meeting adjourned at 1:10 PM.

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Appendix A
Revised Guideline Notes

GUIDELINE NOTE 5, OBESITY AND OVERWEIGHT

Line 320

Medical treatment of overweight (with known cardiovascular risk factors) and obesity in adults is limited to intensive counseling on nutrition and physical activity, provided by health care professionals. Intensive counseling is defined as face-to-face contact more than monthly. A multidisciplinary team is preferred, but a single clinician could also deliver intensive counseling in primary care or other settings.

Intensive counseling visits are included on this line for 6 months. Intensive counseling visits may continue for an additional 6 months (up to 12 months) as long as there is evidence of continued weight loss or improvement in cardiovascular risk factors based on the intervention.

Maintenance visits at the conclusion of the intensive treatment are included on this line no more than monthly after this intensive counseling period. The characteristics of effective behavioral interventions include: high intensity programs; multicomponent (including at a minimum diet and exercise), group-based commercial programs; Mediterranean diet; and the following sub-elements -- calorie counting, contact with a dietician, and comparison to peers.

Known cardiovascular risk factors in overweight persons for which this therapy is effective include: hypertension, dyslipidemia, prediabetes, or the metabolic syndrome.

Treatment of prediabetes with the Diabetes Prevention Program (DPP) is addressed on Line 3 in Guideline Note 179. The DPP program can be used as an alternative to the intensive counseling as above, even in the absence of prediabetes as required by Guideline Note 179.

Medical treatment of obesity in children is limited to comprehensive, intensive behavioral interventions. For treatment of children up to 12 years old, interventions may be targeted only to parents, or to both parents and children.

Pharmacological treatments and devices (e.g. gastric balloons, duodenal jejunal bypass liners, and vagus nerve blocking devices) for obesity are not intended to be included as services on this line or any other line on the Prioritized List.

GUIDELINE NOTE 137, BENIGN BONE AND JOINT TUMORS

Lines 400,556

Treatment of benign conditions of joints ~~(ICD-10-CM D18.09 synovial hemangioma, D17.79 lipoma arborescens, D48.1 tenosynovial giant cell tumor, M67.8 synovial chondromatosis and M12.2 villonodular synovitis)~~ are included on Line 400 for those conditions only when there are significant functional problems of the joint due to size, location, or progressiveness of the disease. Treatment of all other benign joint conditions are included on Line 556.

Treatment of benign tumors of bones ~~(ICD-10-CM D16.00-D16.9, K09.0, K09.1, M27.1, M27.40, M27.49, M85.40-M85.69)~~ are included on Line 400 for those neoplasms associated with pathologic fractures, at high risk of fracture, or which cause function problems including impeding joint function due to size, causing nerve compression, have malignant potential or are considered precancerous. Treatment of all other benign bone tumors are included on Line 556.

Appendix A
Revised Guideline Notes

GUIDELINE NOTE 161, SACROILIAC ANESTHETIC INJECTIONS AND SACROILIAC JOINT FUSION

Line XXX,527

Sacroiliac joint (SIJ) injection (CPT 20610 and 27096, and HCPCS G0260) is included on ~~this line~~ these lines for diagnostic sacroiliac injections with anesthetic only, but not for therapeutic injections or corticosteroid injections. Injections are only covered for patients for whom SIJ fusion surgery is being considered.

SIJ fusion (CPT 27279) is included on ~~this~~ line XXX for patients who have all of the following:

A) Baseline score of at least 30% on the Oswestry Disability Index (ODI)
B) Undergone and failed a minimum six months of intensive non-operative treatment that must include non-opioid medication optimization and active therapy. Active therapy is defined as activity modification, chiropractic/osteopathic manipulative therapy, bracing, and/or active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ and hip including a home exercise program. Failure of conservative therapy is defined as less than a 50% improvement on the ODI.
C) Typically unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain.
D) Thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, i.e. at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) in the absence of tenderness of similar severity elsewhere (e.g. greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist.
E) Positive response to at least three of six provocative tests (e.g. thigh thrust test, compression test, Gaenslen's test, distraction test, Patrick's sign, posterior provocation test).
F) Absence of generalized pain behavior (e.g. somatoform disorder) and generalized pain disorders (e.g. fibromyalgia).
G) Diagnostic imaging studies that include ALL of the following:
    1) Imaging (plain radiographs and a CT or MRI) of the SIJ that excludes the presence of destructive lesions (e.g. tumor, infection), fracture, traumatic sacroiliac joint instability, or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion
    2) Imaging of the pelvis (AP plain radiograph) to rule out concomitant hip pathology
    3) Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain
    4) Imaging of the SIJ that indicates evidence of injury and/or degeneration
H) At least 75 percent reduction of pain for the expected duration of two anesthetics (on separate visits each with a different duration of action), and the ability to perform previously painful maneuvers, following an image-guided, contrast-enhanced intra-articular SIJ injection.

Otherwise, SIJ fusion is included on line 527.

Appendix A
Revised Guideline Notes

GUIDELINE NOTE 179 DIABETES PREVENTION PROGRAM

Line 3

Prediabetes (R73.03) and personal history of gestational diabetes (Z86.32) are included on this line only for the Diabetes Prevention Program (DPP). The only programs included are CDC-recognized lifestyle change programs for DPP.

To be eligible for referral to a CDC-recognized lifestyle change program, patients must meet the following requirements:

1) Be at least 18 years old and
2) Be overweight (body mass index ≥25; ≥23 if Asian; BMI percentile ≥85th percentile for 18-19 years old) and
3) Have no ~~previous~~ current diagnosis of type 1 or type 2 diabetes and
4) Not have end-stage renal disease and
5) Have a blood test result in the prediabetes range within the past year:
    a. Hemoglobin A1C: 5.7%–6.4% or
    b. Fasting plasma glucose: 100–125 mg/dL or
    c. Two-hour plasma glucose (after a 75 gm glucose load): 140–199 mg/dL OR
    d. Have a previous diagnosis of gestational diabetes

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

Line 660

The following Interventions are prioritized on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

~~83993~~	~~Calprotectin, fecal~~		
~~84145~~	~~Procalcitonin (PCT)~~	~~Insufficient evidence of effectiveness~~	~~December 2009~~

GUIDELINE NOTE 183 DONOR BREAST MILK FOR HIGH RISK INFANTS

Line 16, 34, 88, 101

Donor breast milk (T2101) is included on these lines for infants up to 6 months of age (adjusted for gestational age) who meet all of the following criteria:

- Low birth weight (<1500g) OR with severe underlying gastrointestinal disease
- Human donor milk was continued through neonatal hospital discharge for a clear medical indication
- Persistent outpatient medical need for human donor breast milk ~~due to ongoing severe concerns with persistent diarrhea or malabsorption with improvement on breast milk compared to formula)~~
-

- When maternal breast milk is not available, appropriate or sufficient to meet the infant's needs, despite lactation support for the mother.

Donor human milk may only be obtained through a milk bank with ~~appropriate quality and infection control standards.~~ accreditation from the Human Milk Banking Association of North America (HMBANA).

MINUTES

Evidence-based Guidelines Subcommittee

Clackamas Community College
Wilsonville Training Center, Rooms 210
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
February 7, 2019
2:00-5:00 pm

Members Present: Devan Kansagara, MD, Chair; Eric Stecker, MD, MPH, Vice-Chair (by phone); Mike Adler, MD; Alison Little, MD, MPH; Lynnea Lindsey, PhD; Angela Senders, ND, MCR (by phone).

Members Absent: Leslie Sutton

Staff Present: Cat Livingston, MD, MPH; Jason Gingerich.

Also Attending: Silke Akerson; Moira Ray, MD, Val King MD, MPH, and Craig Mosbaek (OHSU Center for Evidence-based Policy); Renae Wentz (OHA); Melissa Cheyney, PhD (OSU); Duncan Neilson, MD (Legacy Health Systems).

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1. Call to Order

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

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2. Minutes Review

Minutes from the 11/7/2018 meeting were reviewed and approved 5-0 (Senders not present).

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3. Staff Report

Livingston reported on the VbBS and HERC discussion of the coverage guidance on Temporary Percutaneous Mechanical Circulatory Support with Impella Devices. The Commission did not approve it and specifically requested additional evidence and consideration of alternatives. We will break down the impact of the different recommendations on different types of patients, and a deeper dive into the benefits of high-risk percutaneous coronary interventions, since enabling these procedures to be done safely is part of the rationale for using these devices. She also reported that there has been an FDA alert issued about a harms signal for one of the devices. The discussion will continue at the April EbGS meeting.

Livingston also reported that the Commission decided to open review of the coverage guidance on Planned Out-of-Hospital Birth, despite the EbGS recommendation not to open it. After public testimony,

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including testimony from one of the authors of the Snowden study reviewed at the November EbGS meeting, the Commission requested a search for new evidence and consideration of the policy.

She also reported that Adam Obley of the Center for Evidence-based Policy was unable to attend today. Craig Mosbaek will present the evidence on Community Health Workers for Patients with Chronic Disease. Darren Coffman, HERC director, was also unable to attend.

Gingerich welcomed Adler to the subcommittee. Adler has been on the Health Technology Assessment Subcommittee but will join EbGS for at least the duration of the Planned Out-of-Hospital Birth topic.

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4. Topic Orientation for Planned Out-of-Hospital Birth

Livingston invited experts Melissa Cheyney and Duncan Neilson to introduce themselves.

Dr. Cheyney is a professor of medical anthropology at Oregon State University, with a research focus on the culture and safety of midwifery-led birth. She also served as lead investigator on the Midwifery Association of North America's Statistics Project, which reported outcomes from a large registry of midwife-attended births, with around 270,000 courses of care collected since 2004. She also has a small practice as a licensed midwife at an independent birth center. She declared no other conflicts of interest.

Neilson is Clinical Vice President for Women's Services at Legacy Health and Clinical Vice President for Legacy Medical Group - Surgical Specialties Division. He practiced obstetrics from 1974 to 2006. Both Cheyney and Neilson served as experts on the previous coverage guidance and have been involved in efforts related to improve coordination between health systems and birth attendants who attend out-of-hospital births. He declared no other conflicts of interest related to this topic.

The Commission is also seeking a certified nurse midwife to serve in an expert role, but no one has been appointed yet.

Livingston reviewed the presentation in the meeting materials as well as the recommendations from the 2015 Coverage Guidance.

Kansagara asked how difficult the enrollment and disenrollment process under the Oregon Health Plan (OHP) is for mothers electing out-of-hospital birth. Lindsey said being disenrolled is easy, but being re-enrolled can be complicated, especially when patients begin the process relatively late in pregnancy. Cheyney said she has heard that the process can be difficult, and Wentz agreed. Livingston said that this group does not have power over that; implementation is being addressed elsewhere. There is widespread frustration with many administrative aspects of implementation of these policies and there are efforts to address the frustrations, but that work is not in scope for this report.

There was discussion of the 2018 Public Health report on out-of-hospital births developed from birth certificate data. Livingston explained the findings at a high level but acknowledged that the data is not directly comparable to the prior report due to methodological differencesthough the rate of death is lower in the years since the previous report. The deaths are too rare to calculate a trend, and there are methodological issues which will be discussed extensively at the next meeting.

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Moira Ray provided a brief overview of the evidence based on the meeting materials. She clarified the terms of planned vs unplanned out-of-hospital birth as well as the different types of providers that provide out-of-hospital birth attendance in Oregon.

Adler asked for clarification around the accredited programs for direct-entry midwifery. An accredited training program requires attendance at 55 births, and the apprenticeship program lasts 3 years on average. For some of the 55 births, the midwife must be primary, for others they can assist. Kansagara asked whether direct-entry midwives spend time in hospitals observing complicated births. Cheyney said that is rare. Little asked about didactic training. Cheyney explained that for accredited schools the training is two years. She also explained the examination process, which involves demonstrating skills in front of an approved preceptor. The examination is an alternative to the accredited schools.

Kansagara asked about geographic distribution of out-of-hospital birth. King and Ray said they are more common in Multnomah County as well as in Bend, Ashland and up the I-5 cooridor. Kansagara asked about access in remote areas of Oregon, where there isn't access to a hospital. Cheyney said that some people think that direct-entry midwives can provide a solution to that problem, offering prenatal care and triage to the hospital when needed. There is a national study comparing outcomes in rural versus nonrural areas, but in Oregon midwives are concentrated along the I-5 corridor.

Adler suggested that cesearean rates might be higher in hospitals due to electronic fetal monitoring, which is much more common in hospitals, skewing the data. King said that this is true in the United States but some international studies are done in settings where auscultation is standard of care in hospitals for low-risk women.

In the discussion of systems of care, Adler noted that Washington is identified as a setting with well-integrated care. Ray confirmed that information from Washington will be included. She added, however, that integration is different than cooperation and that many providers on both sides have strong feelings about out-of-hospital birth, which can result in barriers to transfer of care. Out-of-hospital attendants may delay transfers of care if they feel that the hospital-based provider might be resistant to accepting a transfer.

Adler asked about the ability to transfer from birthing centers to hospitals. Freestanding birthing centers are often located near hospitals, facilitating transport. Akerson said that the majority of transfers are not emergent and don't involve ambulance services. If there is an emergency, they call 911. Cheyney said that some hospitals have better coordination for transfer of care than others.

Kansagara said that we aren't meant to go into the implementation realm. He asked whether we will be attempting to prove noninferiority. The Oregon data doesn't show a statistically significant rate of neonatal death. We need to think carefully about how to describe that finding. A lot of this will come down to implementation, so it seems strange not to address implementation at all. Livingston said we can discuss some elements as it relates to coverage. There are necessary criteria for coverage. Cheyney said that any agreements between hospitals and out-of-hospital providers would be informal. Adler suggested a formal agreement might make it much easier to transfer care. The last thing a midwife wants is to face hostility during a transfer. Cheyney cited a study which found that 12 percent of the difference in mortality was directly tied to lack of professional collaboration. It was the second most important factor after race. Kansagara suggested this sort of analysis may be useful.

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Adler said that with a state licensing board for midwives and collaboration agreements with hospitals, whether care could be covered under a coordinated care organization (CCO). Wentz said many CCOs can't credential licensed direct-entry midwifes. Livingston said malpractice insurance may be a barrier. Neilson said that Dana Hargunani is developing an effort to get a statewide program going, similar to the program in Washington to attempt to make progress on this. He suggested the evidence review this group is doing could be a parallel process. Many of the same people are involved.

Kansagara noted that the United States Preventive Services Task Force included language about systems of care in its recommendation on depression screening, so it might be appropriate for EbGS to do the same. He also suggested staff consult with someone involved in the Washington program. Neilson said he could provide contact information for the person involved with Washington. Cheyney added that the Oregon Board of Direct Entry Midwifery has been revising its licensing rules. This rule speaks to similar issues around safety. She said midwives find it confusing that coverage criteria and the licensing board have different safety standards.

Adler asked whether there could be members from the Board at these meetings. Gingerich said that for many provider specialties, there are services that can be offered in the scope of a provider's practice that aren't covered under the Oregon Health Plan. They are in some sense different processes; coverage is a financial matter, and there are different stakeholders on the Direct Entry Midwifery Board. Adler said that because this effort is about safety, it may be appropriate to coordinate. Livingston said that there is a lot of familiarity with what the midwifery board is doing. There already is some interplay but perhaps staff could request an update on the board's rules process and include it for the next meeting. Livingston said she did present the 2015 coverage guidance to the midwifery board.

King said the majority of out-of-hospital births occur in homes, but that there are around 15 freestanding birthing centers in Oregon. Some have a national accreditation and others do not. Those with accreditation comport with guidelines about the patient, the facility and the provider. The non-accredited centers do not necessarily use the same standards.

Kansagara asked about situations where the need for consult or transfer arises during the course of care. Livingston explained that the intent is for the care to be covered until the woman "risks out" and is appropriately transferred. For example, if a woman is low risk up to and through birth and has a postpartum hemorrhage and is transferred, the services of the out-of-hospital attendant would be covered to the point at which the risk factor develops. If the patient is appropriately transferred, then coverage would continue through the transfer. This level of coverage decision requires retrospective review. Wentz said that the payment is difficult because the disenrollment causes churn, which has a lot of side effects. CCOs provide physical health, oral health and behavioral health care. When a woman disenrolls from a CCO, she loses the physical health care provided by that CCO. She is supposed to keep behavioral health and dental care, but sometimes that doesn't happen due to confusion. Theorectically a woman should return to the CCO when a contraindication occurs, then if the risk is resolved she should return to fee-for-service. This could happen multiple times. She said there are efforts to make it so that the woman can stay in the CCO, but fee-for-service would reimburse the out-of-hospital birth cost.

Kansagara invited public comment. Silke Akerson offered testimony. She is a certified professional midwife (CPM) and licensed direct-entry midwife (LDM) in Portland and Executive Director for the Oregon Midwifey Council, which represents all the midwife types who provide out-of-hospital birth:

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licensed direct-entry midwives, certified nurse midwives and naturopathic doctors who provide midwifery services.

She offered comments on the Oregon birth certificate data. She said that from the quality improvement efforts and case reviews that they did, the quality and safety issues reflected in the 2012-2013 data were not present in later years. She would like to ask that those periods be compared separately. We have a really clear reason to believe that the quality assurance issues from 2012-2013 were addressed. There has been a pretty comprehensive quality improvement program since that time. In 2012-2013 there was a perinatal mortality rate of 3.9 per ten thousand, while for 2015-2017 the rate was just over 1 per ten thousand. She acknowledged that the difference is not statistically significant. She also said even though Oregon has more accurate reporting than some states regarding planned place of birth, the numbers reported in the report by the Oregon Health Authority and the Snowden study included unattended births along with births attended by midwives. There are about 50 planned unattended home births per year, and in the six years of data we have, there are 5 deaths from that category. Currently all of those deaths are attributed to the planned out-of-hospital birth, whereas the real question for this report is about planned *attended* out-of-hospital birth. She said with such a rare event, five deaths are a significant number to have attributed to the out-of-hospital birth category.

She appreciated the discussion of written agreements. The vast majority of hospitals will not consent to a written agreement with out-of-hospital birth providers. The only instances we know of in Oregon of written agreements with hospitals and out-of-hospital birth attendants are when the providers in the birth center are also providers (certified nurse midwives) in the hospital.

Even where there are excellent transfer relationships, they are informal agreements because of legal liability issues, despite Oregon statute saying that receiving providers can't be liable for care that occurred prior to the transfer.

She added that implementation issues are relevant to HERC decision-making. It may not change what you do, but some of the guideline note is easy to implement and some parts are difficult to implement; those implementation challenges can cause health complications. She will think of some examples for future discussions. Adler asked whether the certified professional midwives (CPMs) have formal relations with the CCOs? Akerson said no, most of the contracts CCOs have for out-of-hospital birth are with certified nurse midwives operating in a birthing center. Liability issues often complicate efforts for CCOs to credential CPMs.

Akerson said that even though the systems issues are really important, trying to tie the HERC guidance to systems issues would be a real mistake as it would create even more burdens on the out-of-hospital birth attendants. Many of these issues are outside providers' control; they can only be addressed by health plans and the Oregon Health Authority. A midwife can't comply with something that doesn't exist in a system.

The initial review of the evidence is planned for the April 4 meeting of the EbGS.

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5. Community Health Workers for Patients with Chronic Disease

Livingston introduced the topic of multisector interventions. These reports look at what kinds of interventions outside the clinical setting might improve health outcomes. These reports apply similar evidence standards and look at things which might occur at a community level, a clinic level or at a population level that might make a difference in health outcomes. These don't have recommendations per say, as multisector interventions are not technically covered services, but plans might use other funds to implement programs to improve the health of members and communities.

Mosbaek and Livingston reviewed the content in the meeting materials. In response to a question, Mosbaek clarified that community health workers and doulas are subsets of traditional health workers.

Kansagara asked how people with preventable emergency room or hospital utilization might be identified. He could see the potential for people to use community health workers for every hospitalized person if these populations aren't defined. King said these studies are generally defined with reference to a defined population, like children with asthma exacerbations or people with hypertensive crises. Kansagara noted that congestive heart failure was listed as not having evidence, though it would lead to preventable hospitalization.

Livingston said defining patients at risk for preventable hospitalization would be up to the plans and providers, who would have flexibility. He asked for clarification about the impact of the box language for this report. Livingston clarified that this report is not a recommendation for coverage but that it would be appended to the end of the Prioritized List and could be used by CCOs as they wished as they considered spending dollars on health-related services. Health-related services are not benefits but can be used at CCO discretion to improve population health. Gingerich added that CCOs are required to meet certain criteria to use dollars for health-related services, and that having a basis in evidence or guidelines is one of those criteria; a statement from this subcommittee could help them check that box or help them make decisions about developing programs in a way more likely to be effective.

After discussion, the subcommittee discussed striking the bullet about populations with prior preventable emergency and inpatient hospital utilization, since it could be due to any number of conditions. Kansagara said that there are groups marketing lists of preventable conditions based on faulty data with lists that don't make clinical sense. A group could recommend community health workers for patients with any of the conditions on that list and you could get less benefit from community health workers. Little asked staff to describe the population representing the studies related to that bullet point. Staff found that the Jack systematic review had 14 studies of asthma, 6 studies of diabetes, 1 study of hypertension and 1 study of stroke. After more discussion, the subcommittee struck the bullet. Kansagara said that there are other programs targeted more broadly at "high utilizers" and they include broader interventions, so it's best not to confuse community health workers alone with these broader programs.

Adler asked about doulas, and evidence they reduce cesarean section rates. Livingston said she has looked and there is some evidence, but that is out of scope for this discussion, as doulas are a different kind of traditional health worker. Little asked whether substance use disorder is included; it was stated that it was excluded in the scope statement. Livingston said definitions of community health workers differ widely from place to place. Oregon has its own definition defined by the legislature, and staff has sought to include evidence that would represent the kind of services community health workers in Oregon might do.

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Lindsey asked that the document be clarified to indicate these workers work as part of teams; they should not be reimbursed individually on a fee-for-service basis. Payment might be included in value-based payments or payments for team-based care; it's not a matter of just opening codes as it would be for clinical services. After discussion, the subcommittee asked to add language around integrated care teams to make it part of the definition since most of the research showing effectiveness was about these types of settings.

The subcommittee voted 5-0 (Stecker absent) to post the draft report for public comment. Review will continue at the April 4, 2019 meeting.

DRAFT MULTISECTOR INTERVENTIONS

To improve beneficial outcomes in patients with chronic conditions, the preponderance of evidence supports that community health workers (CHWs) serving as a part of an integrated care team appear to improve outcomes in:

- Children with asthma with preventable emergency department visits
- Adults with uncontrolled diabetes or uncontrolled hypertension

This evidence includes an emphasis on minority and low-income populations.

Characteristics of effective interventions include:

- Higher intensity interventions including longer duration
- Targeting populations with more severe chronic disease at baseline

Limited or insufficient evidence is available on the use of CHWs to improve outcomes for the following:

- HIV
- Serious mental illness
- Congestive heart failure

6. Adjournment

The meeting was adjourned at 5:00 pm. The next meeting is scheduled for April 4, 2019 from 2:00-5:00 pm at Clackamas Community College, Wilsonville Training Center, Room 210, 29353 SW Town Center Loop E, Wilsonville, Oregon 97070.

MINUTES

Health Technology Assessment Subcommittee

Clackamas Community College
Wilsonville Training Center, Rooms 111-112
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
February 21, 2019
1:00-4:00pm

Members Present: Vinay Prasad, MD, MPH (Chair); Kathryn Schabel, MD; Brian Duty, MD (absent 2:00-3:00 pm); Kevin Cuccaro, DO.

Members Absent: Leda Garside, RN, MBA; Mary Beth Engrav, MD; Mike Adler, MD.

Staff Present: Darren Coffman; Wally Shaffer, MD; Jason Gingerich.

Also Attending: Adam Obley, MD & Craig Mosbaek (OHSU Center for Evidence-based Policy); Joyce Caramella, RN (CareOregon); Mark Norling, MD (Oregon Anesthesiology Group), by phone; Valerie Halpin, MD (Legacy Health), by phone; Johnathan Sherman, MD (KeiperSpine), by phone.

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1. Call to Order

Vinay Prasad called the meeting of the Health Technology Assessment Subcommittee (HTAS) to order at 1:07 pm.

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2. Minutes Review

Minutes from the November, 2018 meeting were reviewed and approved 4-0.

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3. Staff Report

Coffman reported that the Commission's report to the legislature is now planned for June, not April as previously announced. This will allow the legislature to receive the completed report if approved by HERC in May, rather than a report that is still in draft form and open for public comment. Coffman also noted that Mike Adler will be moving to the EbGS subcommittee, at least for the planned out-of-hospital birth coverage guidance. Coffman also announced that Wally Shaffer will end his work with HTAS by June 30 and thanked him for his service to the Commisison. Coffman also said that he will be retiring December 1. Staff has begun searching for Shaffer's replacement.

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4. Extended Stay Centers: Patient characteristics and appropriate procedures

Shaffer introduced the ad hoc experts. Joyce Caramella is a registered nurse with expertise in quality and safety, currently working for HealthInsight. Jonathan Sherman is an orthopedic surgeon who

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practices in ASCs as well as hospitals. Mark Norling is an anesthesiologist who practices primarily in ASCs. Valerie Halpin is a bariatric surgeon who practices primarily in a hospital setting.

Gingerich also introduced Mellony Bernal, a policy analyst with the Oregon Health Authority's Health Care Regulation and Quality Improvement section, with expertise on the licensing of ASCs and ESCs in Oregon.

Shaffer reviewed the meeting materials and goal of the meeting, to put a version of the report out for public comment for review in April. Obley reviewed the evidence section and horizon scan.

Schabel asked about the sponsors of the bill authorizing licensing of ESCs. Shaffer said it came from the Oregon Ambulatory Surgery Center Association, which has been working on it for several years. The Oregon Association of Hospitals and Health Systems supported the bill, and it passed in 2018.

Schabel asked about whether the comparative studies summarized in the draft report were using matched cohorts. Obley said it depends on the individual study but in general they tended not to have rigorous cohort methodology. Schabel said that in that case it's a bad thing if the outcomes are similar, since ASC patients tend to be healthier. The paucity of data makes this subcommittee's charge extremely challenging.

Shaffer asked Dr. Norling to offer his comments. He said that techniques have changed a lot during his career. They now use opioid sparing techniques and rapidly advancing local anesthesia techniques. They have done over 150 total joint replacements (knees, hips and shoulders) and each patient gets regional blocks and a light general anesthesia. They also use nerve block catheters, though joint replacements can be done without catheters. This allows them to do the operations safely and get the patients home. His experience is mostly orthopedic, but he doesn't do spine surgeries. A few years ago it involved a multiday hospital stay; in his center today there is a four-hour recovery period after the surgery and patients go home comfortable. They initially set up their center to allow a 23-hour stay but they never have had a patient stay that long. Patients are followed up on on a daily basis. They've never had complications.

Sherman asked whether there are specific anesthesia exclusion criteria, such as body mass index or sleep apnea. All patients fill out an anesthesia questionnaire. Sleep apnea and BMI are two of the main criteria. Initially they limited procedures to patients with BMI under 30, but have since allowed BMI up to 35. They will, depending on the patient, go up to 40. For sleep apnea, they do score the patients, but they can still be seen in the ASC if they are using a CPAP at night. Inorder for surgery to occur in the ASC, they need to be using their CPAP. The other major criteria is that chronic medical diseases are controlled and that they don't have a current infection.

Schabel asked about the criteria that resulted in zero complications and what are the methods for tracking. Norling said they follow patients daily for the first three days, and patients have the joint coordinator's cell phone number. They also track infections (but have not had any). The nurse asks about pain levels and opiate use and makes sure the patient is up and moving. They also track deep vein thrombosis. Prasad asked how long patients are tracked. Norling said that surgeons need to fill out a form reporting any complications that each patient has. This is done for all surgeries.

Prasad asked whether even with perfect care there would be some DVTs or other complications? Norling acknowledged that there are DVTs and corrected his previous statement about no

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complications. The patients have all done well and gone home and have not been transferred to the hospital from the surgery center. DVTs happen 4-5 times a year out of the entire population.

Schabel asked about abandoning spinal anesthetics. Norling said for hip and knee they get a regional block including a continuous catheter as well as low dose spinal anesthesia.

Prasad said that it would appear ESCs would not be needed for the patients Norling is describing. Shaffer said that in the literature, the average length of stay was very low.

Sherman offered his comments. He and his partner have a spine surgery center, which also does peripheral nerve and spinal injections. Their center has not kept people for 24 hours. Most people are kept 1-2 hours after the surgery. The vast majority of cases are lumbar discectomies or laminectomies, with some one-level lumbar fusions and one- to three-level anterior cervical discectomy and fusions (ACDFs) or posterior cervical decompressions or discectomies. They perform around 300 cases a year and once a year someone needs to be admitted to the hospital. Usually it's due to a bronchiospasm, shortness of breath or low blood pressure. He doesn't ever recall it being something neurologically related. They have a BMI cutoff of 40, and anesthesiologists use screening criteria for sleep apnea. They have what they believe is a low complication rate, even comparing like cases. They have had one infection in eight years. When comparing to routine lumbar decompressions and some other surgeries performed at the hospital the number is significantly higher. At the same time many of the people being operated on in the hospital are at higher risk because of age or obesity.

He said that ACDFs often makes providers nervous in an outpatient setting. There have been at least 8 papers on the safety of that procedure in the outpatient setting. One study is corrected for selection bias and found fewer complications in an outpatient setting than in an inpatient setting. He said that you might be able to do more two-level fusions in his ASC. With those surgeries if you started getting into trouble from a pain standpoint, you might have to admit them to the hospital. An ESC might enable them to do more cases in an ASC.

Obley said that we were focused on studies of ASCs specifically; there is a body of literature affirming the safety of these procedures in an outpatient setting, but it is mostly an outpatient hospital setting. Sherman said that two of the studies were done in ASCs but the others would have been in outpatient hospitals.

Shaffer said Medicare is reviewing safety of cervical spine procedures due to safety concerns. Sherman said that ACDF is still an inpatient only code in Medicare.

Caramella expressed concern about the lack of evidence. She said in her experience anyone that she has transferred into the hospital has had something serious that a day in the ESC isn't going to take care of. The data from the ASC safety measures from 2016 shows four facilities that are outliers in Oregon and have pretty high transfer rates. It would be interesting to see what procedures those folks had and why they were admitted. That's an interesting outlier.

Schabel said she is confused about why the people were asking to license these types of facilities. The need for transfer for uncommon complications is always going to happen, it's not saying anything bad about ASCs if the rate is reasonable. The ESC would not be a solution for those situations. Sherman said their nursing director does follow-up at 90 days to check on outcomes and can check those records.

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Duty said a TURP, a valve surgery or hysterectomy might benefit from an ESC as they have an extended course after the initial surgery where the patient would be monitored. Shaffer said it could allow more complex procedures that might need a longer stay such as a two-level lumbar fusion and you don't want to take chance that they would have to be transferred to the hospital. Sherman said when he does these in the hospital, 30% are discharged in two days. But without an ESC, over half these patients would have to be transferred to the hospital, which wouldn't be right. Shaffer said that the concern is that older patients with more comorbid conditions might be operated on in an ASC because of the ESC.

Schabel and Prasad echoed these concerns; these sicker patients may need care that can't be provided in an ESC. Schabel proposed that the discharge criteria for an ASC not change because of the ESC being present. She is concerned that there is no real reporting in place for ASCs, though there is for inpatient and outpatient hospital settings. She said surgeons may not be able to see all complications for their patients; if the surgeon doesn't have privileges in the hospital they are admitted to or if it's in another community.

Obley suggested that there are complications that will always necessitate transfer. However, extended need for pain control or waiting for bowel and bladder control might be appropriate uses of an ESC. In addition, there are social factors such as living far away from the ASC or lack of a caregiver at home that might lead to a benefit from an ESC.

Prasad suggested requiring data collection and analysis to determine if an ESC has a high rate of 30-day re-admission. Gingerich said that the Commission's mandate is an evidence-based guideline. The bill that authorized this work does require data reporting, but it would be discharge data and not include information if a patient was admitted to a hospital where the surgeon did not have privileges.

The subcommittee approved the following language:

> Although such research is unlikely to be funded, the Oregon Health Authority plans to collect discharge data for ASCs and ESCs in the future, and analysis of these data, linked to all-payer claims data to capture all outcomes related to patients seen in ESCs, could inform decisions about the need for more research on the impact of these facilities.

Prasad there is no evidence to guide who and who should not go to these settings. In the absence of such question, we can suggest that the data be collected.

Schabel suggested that criteria for surgery in an ASC should not change. Duty said that even though the Medicare discharge criteria still apply to ASCs, you might see physicians more likely to take on more complex cases where patients might need to get closer to that 24-hour period and require monitoring or recovery after that. The safety criteria should remain the same. This would allow surgeries requiring an extended monitoring period without adding risk of serious complications.

Schabel and Caramella said the ESC should be for patient comfort, not the need for medical care.

Halpin came on the call. Prasad asked for her comments. The most common bariatric procedure commonly done in an ASC is sleeve gastrectomy. Nausea can be problematic following bariatric surgery. There are plenty of patients who won't be ready to go home the morning after a procedure but will be ready to go sometime in the next 24 hours. They wouldn't need treatment other than antiemetic fluids

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and pain medicine. However, there may not be more people who can be operated on in the ASC simply because of the cardiopulmonary risk associated with the patient population.

Discussion turned to the executive summary. The subcommittee added language recommending more research and data collection involving an all-payer claims database to capture readmission not captured in ASC/ESC discharge data. Sherman said that this makes sense. We don't want someone getting into an emergent situation in an ASC. You can't avoid it completely, but we want to minimize that risk, so expanding the criteria beyond current standards would create risk.

The subcommittee discussed the risk calculator data and approved the corrections to Attachment B shown in the handout. Subcommittee members and experts testified to the limited value of risk calculator data. There are risks providers can detect clinically that would not be factored into a risk calculator. They also discussed the available quality data and accreditation standards.

After discussion, the subcommittee added the guideline statement below, partially based on current Medicare rules:

> Thus we conclude, in the presence of an ESC, the surgical services provided in an ASC should be for patients not requiring hospitalization and for whom the expected duration of services in the ASC would not exceed 24 hours after an admission to the ASC. The presence of an ESC should not expand the surgical risk profile or the procedures permissible in an ASC. ESCs should be utilized for patients who need extra time for managing pain or bodily functions, who do not have a caregiver at home, or who may require extended travel time to return home after a surgical procedure.

A motion was made to refer the draft report to be posted for public comment with the additional language discussed. **Motion approved 4-0.**

5. Adjournment

The meeting was adjourned at 3:20 pm. The next coverage guidance topic will be spinal cord stimulators, and there may be scope statements for new topics to be reviewed later this year including vertebroplasty, kyphoplasty and sacroplasty as well as indications for total knee arthroplasty. The next meeting is scheduled for April 18, 2019 from 1:00-4:00 pm at Clackamas Community College, Wilsonville Training Center, Rooms 111-112, 29353 SW Town Center Loop E, Wilsonville, Oregon 97070.

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Section 2.0

VbBS Report

Home Administration of Subcutaneous Immunotherapy

Issue: At the November 8, 2018 VBBS meeting, the VBBS voted to recommend that 2019 HCPCS code G0069 (Professional services for the administration of subcutaneous immunotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes) be placed on all the lines with immunotherapy (lines 9,124,223,313,531,550,559, 566). At the subsequent HERC meeting on November 8th, the HERC changed this placement to line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS. The HERC heard testimony from Val King, MD MPH that the Center for Evidence Based Policy had recently done a MED review on home immunotherapy and found that subcutaneous immunotherapy was not recommended for home administration due to concerns for anaphylaxis. HERC staff was directed to obtain the MED report and bring to the January meeting to ensure that this was indeed the correct placement of this code.

MED 2018 Allergy Immunotherapy for Rhinoconjunctivitis: Recommendations, Coding, and Billing Practices

1) Key findings:
    a. Subcutaneous immunotherapy (SCIT) should occur in a medically supervised setting, not in the home
    b. Sublingual immunotherapy (SLIT) can be used in the home if there were no adverse events after first administration under the medical supervision of a provider capable of managing anaphylaxis.
2) These findings were based on expert guidelines

HERC staff recommendation:

1) This is an informational item only. Staff concurs with the HERC placement of HCPCS G0069 (Professional services for the administration of subcutaneous immunotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes) on line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS with the following entry to GN173

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

Line 660

The following Interventions are prioritized on Line 660 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
G0069	Subcutaneous immunotherapy in the home	Insufficient evidence of effectiveness; evidence of harm	November, 2018

VBBS Issue Summaries 1/17/2019

Consent Agenda Issues—January 2019

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
44320	Colostomy or skin level cecostomy	239 CANCER OF OVARY	Colostomy is found on several pelvic malignancy lines and may be required based on the type of resection surgery done.	Add 44320 to line 239
68110 68115 68130 68135	Excision of lesion, conjunctiva; up to 1 cm Over 1 cm Excision of lesion, conjunctiva; with adjacent sclera Destruction of lesion, conjunctiva	113 CANCER OF EYE AND ORBIT 310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	A CCO requested review of conjunctiva procedures. There are conjunctival lesion diagnoses on both lines 113 and 310. 68110, 68115 and 68130 are only on uncovered lines, and 68135 is missing from one line.	Add 68110-68130 to lines 113 and 310 Add 68135 to line 310
28111-28114	Ostectomy, metatarsal head	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS 540 DEFORMITIES OF FOOT	These CPT codes were part of a hearings case. They are used for bunion surgery. This placement has not been reviewed in 10+ years. The appropriate placement is line 540, on which they also appear. Bunion diagnosis codes appear only on line 540.	Remove 28111-28114 from line 359

VbBS Issue Summaries 1/17/2019

Straightforward Correction of Benign Bone and Joint Tumor Guideline

Question: Should the benign bone and joint tumor guideline be updated to reflect correct CPT coding?

Question source: Holly Jo Hodges, CCO medical director; HERC staff

Issue: Several of the CPT codes in GN137 BENIGN BONE TUMORS are incorrect and do not reflect the entirety of the conditions appearing on this line. Additionally, the guideline title does not reflect the inclusion of benign joint tumors.

HERC staff recommendations:

1) Rename GN137 to reflect inclusion of benign joint tumors
2) Remove specific CPT codes in the guideline as shown below and simply have the guideline refer to all diagnoses on this line

GUIDELINE NOTE 137, BENIGN BONE AND JOINT TUMORS

Lines 400,556

Treatment of benign conditions of joints ~~(ICD-10-CM D18.09 synovial hemangioma, D17.79 lipoma arborescens, D48.1 tenosynovial giant cell tumor, M67.8 synovial chondromatosis and M12.2 villonodular synovitis)~~ are included on Line 400 for those conditions only when there are significant functional problems of the joint due to size, location, or progressiveness of the disease. Treatment of all other benign joint conditions are included on Line 556.

Treatment of benign tumors of bones ~~(ICD-10-CM D16.00-D16.9, K09.0, K09.1, M27.1, M27.40, M27.49, M85.40-M85.69)~~ are included on Line 400 for those neoplasms associated with pathologic fractures, at high risk of fracture, or which cause function problems including impeding joint function due to size, causing nerve compression, have malignant potential or are considered precancerous. Treatment of all other benign bone tumors are included on Line 556

VbBS Issue Summaries 1/17/2019

Prolonged Preventive Services Codes

Question: Should the placement of the Prolonged Preventive Services Codes be modified?

Question source: Alison Little, PacificSource CCO

Issue:
There seem to be increases in use of prolonged preventive services codes by non-PCP providers (e.g. physical therapists and speech therapists), for unclear reasons. These 2 codes, G0513 and G0514, are currently on more than 600 lines on the Prioritized List. These codes were new in 2018 and were added to the same lines as other preventive codes. Preventive services codes in general are widely distributed across the list, and these new codes mirrored that wide distribution. However, they are somewhat vague and there is a concern that they are not being used appropriately with regard to evidence-based preventive services. If prolonged preventive services were being done, then submission of a preventive ICD-10 code would be appropriate, and the services rendered should be on Line 3.

Codes in Question
G0513

Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes (list separately in addition to code for preventive service)

G0514

Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (list separately in addition to code G0513 for additional 30 minutes of preventive service)

HERC Staff Recommendations:

1) Remove G0513 and G0514 from all lines except for Line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

VbBS Issue Summaries 1/17/2019

Chronic Pain Task Force
Proposal for Review by VbBS
January 2019

Since the August VbBS meeting, the Chronic Pain Taskforce met twice. At its December meeting, it completed a revised proposal to create a new line for a limited number of chronic pain conditions (see September CPTF Minutes, December CPTF Minutes). This revised proposal takes into several sources of new information, evidence and perspectives:

- extensive public testimony
- conversations with the pharmacy directors on what types of medication controls are implementable
- discussions with partners in public health and experts in Oregon on best practices for opioid prescribing
- a Pharmacy and Therapeutics Committee report on effective pharmacologic treatments for fibromyalgia
- feedback from CCOs on possible coverage changes
- the new CEBP MED report on opioid tapering

The key issues and discussion items are summarized below, followed by a description of other changes introduced by staff since the December CPTF meeting.

CCO survey take home points

1) For the back line changes:
    a. Most CCOs answering the survey are implementing all or most of the back line guideline and providing new back/neck pain services
    b. Most CCOs noted increased costs with the addition of these services
    c. Almost universally, the CCOs do not want the current back guideline or back opioid guideline merged into a broader chronic pain guideline
2) For the proposed new coverage of chronic pain conditions:
    a. Most CCOs are concerned about the increased cost of the nonpharmacological services for these conditions as well as significant concerns about the cost of Lyrica and other medications that would be covered if these conditions become funded
    b. Most CCOs do not want non-opioid medications addressed in any chronic pain guideline
    c. The CCOs were mixed on whether they thought coverage for fibromyalgia and chronic pain would improve the health of their patients or simplify administration
    d. Nearly all responding CCOs were interested in incorporating Oregon opioid prescribing guidelines (acute and chronic)

CEBP MED report on opioid tapering take home points:

1) Overall quality of the evidence is very low
2) Overall, no change in conclusions since previous review
    a. Findings suggested that pain, function, and quality of life might improve during and after opioid discontinuation or dose reduction
    b. Scant evidence on harms associated with tapering strategies
3) Adverse events—mortality, suicide or overdose
    a. 5 studies in the Frank review included adverse events
        i. 1 opioid-related overdose death in a patient in a buprenorphine treatment program (after discontinuation of buprenorphine) out of a total of 5 studies (no N given)

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   b. A retrospective cohort study conducted in a VA population whose opioid therapy was discontinued by their clinician (primarily for aberrant behaviors) reported that 12% of the cohort had documented suicidal ideation and nonfatal suicidal self-directed violence (SSV) in the 12 months after opioid discontinuation
      i. This study identified Hispanic ethnicity (adjusted odds ratio [OR] 7.25 (95% CI 1.96–27.18), PTSD diagnosis: 2.56 (1.23–5.32), and psychotic-spectrum disorder diagnoses (OR 3.19; 95% CI 1.14 to 8.89) were correlated with suicidal ideation and SSV in the 12 months following clinician-initiated opioid discontinuation.
   c. Other new studies did not report information on serious adverse events such as mortality, suicide, or overdose events.

4) Adverse events—opioid withdrawal symptoms
   a. In the systematic review by Frank et al., 18 studies (3 fair and 15 poor methodological quality) reported opioid withdrawal symptoms. Rates of withdrawal symptoms ranged widely across the studies (0% to 100%).
   b. The new studies we identified for this update did not provide information on withdrawal symptoms experienced by patients receiving the interventions.
5) Taper length
   a. Not able to draw any conclusions regarding rapid versus slow tapering.
6) Patient-initiated vs nonpatient-initiated tapering
   a. Very little information found on this issue. In almost all of the studies included in the previous MED report and in this update, patients had some autonomy in the decision to taper their opioids.
   b. VA database study found that the reason for discontinuation (patient-initiated vs. clinician-initiated) was not correlated with pain score trajectory.
   c. Demidenko et al. studied clinical-initiated discontinuation of opioids
      i. Approximately 75% of the clinician-discontinued patient group had opioids stopped because of aberrant behaviors such as abnormal urine drug test results, opioid diversion, and drug misuse.
      ii. Of the total sample of 509 patients, 59 had suicidal ideation or SSV documented in their charts; 47 had suicidal ideation alone, and 12 had SSV. Half of these patients attempted suicide with overdoses of prescription medications, primarily benzodiazepine drugs. Fifteen of the 59 patients had previous suicidal ideation or SSV events before discontinuation of opioid therapy.
   a. 1 new study was identified that compared mandatory opioid dose reduction in a health system in Washington to usual care

The researchers found no indication that patients in the intervention clinics had clinically meaningful differences in pain intensity, interference with activities and enjoyment of life, or depressive symptoms compared with control group patients.

<u>Additional important information/resources</u>

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

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C. Oregon Opioid Prescribing Guidelines for Dentists
https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/taskforce/oregon-opioid-prescribing-guidelines-dentists.pdf
D. Institute for Chronic Pain, description of centralized pain syndromes
http://www.instituteforchronicpain.org/understanding-chronic-pain/what-is-chronic-pain/neuromatrix-of-pain

Fibromyalgia guideline issue

HERC staff have noted that action needs to be taken on current Prioritized List fibromyalgia guideline. This guideline was developed based on evidence reviews conducted in 2008 and 2013, as well as expert input. The guideline largely mirrors the current CPTF proposal, with an additional sentence: "Use of opioids should be avoided due to evidence of harm in this condition." This sentence was added to the guideline based on expert input which indicated that opioids for fibromyalgia actually exacerbated the condition and therefore were a source of harm. Subsequently, Cochrane has conducted a systematic review of oxycodone for fibromyalgia published in 2016 which showed no evidence of benefit. Kim Jones, PhD has previously testified to the CPTF regarding the possible benefits of tramadol, a type of opioid, for treatment of fibromyalgia. The OHA Pharmacy and Therapeutics Committee recently completed a review of tramadol for fibromyalgia and found no evidence of benefit for this medication.

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Staff-introduced changes

Since the Chronic Pain Task Force (CPTF) completed their proposal in December, HERC staff has considered late public testimony, revisited state and national guidelines, and held extensive internal discussions. Based on these considerations, HERC staff has several proposed changes to the CPTF proposal to bring forward for VBBS consideration.

These changes include

1) Remove the suggestion to HERC to conduct a multi-sector intervention review for Tai Chi for chronic pain conditions. Such a review would require a large amount of staff resources. Encouragement for coverage for Tai Chi could be addressed by simply adding it to the list of services that should be covered "if available." HERC staff received confirmation from OHA that this section of services should have "no wrong door," meaning that they can be paid for with medical services funds or health related services funds by the CCOs.
2) There were concerns about using the term "compendia" for non-opioid medications raised by CCOs. In further discussions with P&T, HERC staff and P&T staff concluded that the entire statement "The medication is FDA approved or supported by compendia for treatment of chronic, non-neuropathic pain" should be removed. This statement does not add much to the guideline effect, as CCO contracts already contain similar wording; however, the clause is a source of confusion.
3) The PEG assessment scale was added to the list of examples for validated instruments for evaluation of the effectiveness of opioids. This change is based on the statement from the CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016: "Experts agreed that clinicians may use validated instruments such as the three-item "Pain average, interference with Enjoyment of life, and interference with General activity" (PEG) Assessment Scale to track patient outcomes."
4) Removal of "centralized pain syndrome" from the new line guideline. This is not a formal diagnosis and does not have accepted diagnostic criteria. Use of this term is confusing to patients and providers and could be a source of variation in how the guideline is implemented by various CCOs. Staff feels that a patient with centralized pain syndrome would likely not receive functional benefit from opioids, and in that case would fail to meet the opioid prescribing criteria in the guideline. Therefore, further calling out of this diagnosis is not required to follow the CPTF intent.
5) Wording was added to the proposed new guideline to allow some discretion in provider management of patients on concurrent benzodiazepines and opioids.
6) Wording was changed in the proposed new guideline section regarding the need to taper patients on opioids over 90 MED, due to a desire to allow some provider discretion in patient management. The new proposed wording is based on the Oregon Opioid Prescribing Guidelines.
7) Wording was added to the opioid section of the new guideline and to the opioid for back conditions guideline clarifying that a taper can be slowed or paused if the prescribing provider feels that the clinical situation justifies such action.
8) Addition of wording requiring behavioral health evaluation and management during opioid tapers in both the new guideline and the back conditions opioid guideline. This change is in

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response to public testimony expressing concerns for mental health issues, including suicidality, that might be brought out by the opioid taper process if the patient requires such tapering.

Additional requests from stakeholders include:

1) Information on the number of patients who would be affected by the proposed changes to the Prioritized List. Staff is working on obtaining these numbers and will present them in the formal Powerpoint presentation at the meeting.
2) A summary of evidence reviewed for opioids in the treatment of fibromyalgia. The Pharmacy and Therapeutics Committee staff have prepared a formal evidence review on this topic which is included in the packet. Expert input brought additional literature to P&T staff attention and is included in this review if it met inclusion criteria.
3) OHA create a plan to monitor outcomes of the changes to coverage based on the CPTF changes. HERC staff will work with OHA staff to create an evaluation plan.
4) Clarification for the rationale for why non-opioid medications need evidence of a 15% improvement in function but opioids medications need a 30% improvement.
    a. Coverage guidance criteria for the HERC generally uses a 15% improvement in function as a cut off for clinically significant change
    b. The CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016 used the following: "Clinically meaningful improvement has been defined as a 30% improvement in scores for both pain and function."
    c. A higher threshold is appropriate in a case like this due to the known harms associated with opioid therapy in order to ensure benefits outweigh harms at a similar level compared to treatments without significant harms.

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Chronic Pain Taskforce Revised Proposal for HERC consideration with additional staff suggestions:

1) Create a new line for five chronic pain conditions and fibromyalgia for the 2020 Biennial Review as shown below
2) Adopt a new guideline for treatments included on this line as shown below
3) Score this new line as shown below
    a. Proposed ranking would put this line in the funded region, around line 443 (near the funding line, which is currently below line 469).
4) Modify line 528 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME AND RELATED CONDITIONS as shown below
    a. Remove all diagnoses other than chronic fatigue syndrome and modify line title
5) Modify GUIDELINE NOTE 56, NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE as shown below
    a. Matches changes in the new chronic pain conditions guideline
    b. Removes obsolete table
6) Modify GUIDELINE NOTE 60, OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE as shown below
    a. Modifies the paragraph on tapering for chronic opioid use to match wording in new chronic pain conditions guideline
    b. Removes flares of chronic pain as an indication for opioids
7) Modify GUIDELINE NOTE 92, ACUPUNCTURE as shown below
    a. Adds the new chronic pain line to the guideline
    b. **consider wording limiting all acupuncture to 30 visits a year to mirror PT guideline**
8) Delete GUIDELINE NOTE 135, FIBROMYALGIA
    a. Components are all incorporated into the new guideline

Note: HERC staff suggested changes to the Chronic Pain Taskforce's recommendations are shown in purple.

LINE: XXX
CONDITION: FIBROMYALGIA, CHRONIC PAIN SYNDROME, AND RELATED CONDITIONS
TREATMENT: LIMITED PHYSICAL MODALITIES, COGNITIVE BEHAVIORAL THERAPY, MEDICAL THERAPY

ICD-10: G89.21 (Chronic pain due to trauma), G89.28 (Other chronic postprocedural pain), G89.29 (Other chronic pain), G89.4 (Chronic pain syndrome), M79.7 (fibromyalgia)

CPT: 90785, 90832-90840, 90853 (psychotherapy—for CBT and ACT), 96150-96155 (Health and behavior assessment and intervention), 97110-97124, 97140-97168, 97530, 97535 (PT/OT), 97810-97814 (acupuncture), 98966-98969, 99051, 99060,99070,99078,99201-99215,99281-99285,99304-99337,99340-99404,99408-99449,99487-99490,99495,99496,99605-99607 (medical office visits, including ER and SNF)

HCPCS: G0157-G0160 (PT/OT assistant), G0396-G0397 (alcohol and substance abuse screening), G0463-G0467,G0469,G0470 (FQHC care), G0490, G0511-G0513 (RFQHC care), G0514 (prolonged office visit)

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GUIDELINE NOTE XXX TREATMENT OF FIBROMYALGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS

Lines XXX

Chronic pain syndrome (ICD-10 G89.4), chronic pain due to trauma (ICD-10 G89.21), other chronic postprocedural pain (ICD-10 G89.28), other chronic pain (ICD-10 G89.29), and fibromyalgia (ICD-10 M79.7) are included on line XXX when symptoms have been present for at least 3 months.

The following treatments are included on line XXX:

- Office evaluation, consultation and education.
    - Pain education, if done, should include but not be limited to sleep, nutrition, stress reduction/mood, exercise, and knowledge of pain as a biopsychosocial phenomenon. All providers ~~seeing~~ managing chronic pain patients should be trained in pain science (e.g., a contemporary understanding of the central and peripheral nervous system in chronic pain), motivational interviewing, culturally sensitive care, and trauma informed care. Care should be multidisciplinary and focus on active therapies.
- Cognitive behavioral therapy (CBT). The necessity for CBT should be re-evaluated every 90 days and coverage will only be continued if there is documented evidence of decreasing depression or anxiety symptomatology, improved ability to work/function, increased self-efficacy, or other clinically significant, objective improvement.
- The following therapies, when available, may be provided: adaptive and restorative yoga, Tai Chi, mindfulness training, massage, supervised exercise therapy (land based and aquatic), intensive interdisciplinary rehabilitation. HCPCS S9451 is only included on Line XXX for the provision of yoga or supervised exercise therapy.
- A total of 30 visits per year of any combination of the following therapies when available and medically appropriate. These therapies are only included on these lines if provided by a provider licensed to provide the therapy and when there is documentation of measurable clinically significant progress toward the therapy plan of care goals and objectives using evidence-based objective tools. Once the pre-determined goals of care have been achieved, an additional two visits may be authorized for maintenance therapy to maintain these improvements. These 30 visits count toward the visit totals in GUIDELINE NOTE 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE if the patient has comorbid back or spine conditions.
    1) Rehabilitative therapy (physical and/or occupational therapy), if provided according to Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES. Rehabilitation services provided under this guideline also count towards visit totals in Guideline Note 6. CPT 97124 is included in this category.
    2) Acupuncture

Non-opioid medications are only included on line XXX if all of the following apply:

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~~1) The medication is FDA approved or supported by compendia for treatment of chronic, non-neuropathic pain.~~
2) The patient is also being treated with active therapy (e.g., physical therapy, CBT) or is continuing maintenance of self-management strategies learned from such therapy.
3) The benefit of non-opioid medication is re-evaluated at least every 90 days and medications are only continued if there is documented evidence of initial improvement of function of at least fifteen percent as compared to baseline based on a validated tool (e.g., Pain average, interference with Enjoyment of life, and interference with General activity" (PEG) Assessment Scale, Oswestry, SF-MPQ, MSPQ), and function is maintained thereafter. Less frequent monitoring may be appropriate for certain medications after safety and efficacy are established.

Opioids for chronic pain syndrome ~~(when not representing centralized pain syndrome)~~, chronic pain due to trauma, other chronic postprocedural pain, and other chronic pain
Chronic opioids (>90 days) are only covered for chronic pain syndrome (ICD-10 G89.4~~; when not representing centralized pain syndrome~~), chronic pain due to trauma (ICD-10 G89.21), other chronic postprocedural pain (ICD-10 G89.28), and other chronic pain (ICD-10 G89.29) when all of the following are met:

- In alignment with the Oregon Opioid Prescribing Guideline (2017-2018 version) https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/taskforce/oregon-opioid-prescribing-guidelines.pdf
- Appropriate risk assessment has been performed (e.g., Opioid Risk Assessment Tool)
- PDMP checked at least annually and shows no aberrant behavior
- No concurrent prescribing of benzodiazepines without extenuating circumstances
- Urine drug testing is performed at least once per year and is appropriate
- No illicit drug use or active substance use disorder (excluding tobacco)
- ~~MED < 50, or between 50 and 90 with extenuating circumstances [MED=morphine equivalent daily dose]. For patients at or above 50 MED, every attempt should be made to taper according to the taper guidelines (ideally to MED <50)~~ Careful reassessment of the evidence of individual benefits and risks should be undertaken for dosages > 50 MED. Dosages >90 MED should be avoided or carefully justified.
- Initial functional improvement has been documented of at least 30%, and function is maintained throughout the prescribing period
- Comorbid mental health disorders are appropriately addressed
- No additional opioids are prescribed for flares of the chronic pain condition, although opioids may be prescribed separately for other acute injuries or surgeries as clinically appropriate
- Prescriber has updated opioid prescribing CME and ideally has completed the Oregon Pain Management Commission (OPMC) ~~OPMC~~ pain module
- Patient and provider have assessed the relative risks and benefits of therapy and agree benefits outweigh risks, and have completed a material risk notice https://www.oregon.gov/omb/OMBForms1/material-risk-notice.pdf
- The patient be prescribed the patient pain education module through OPMC when it becomes available
- When prescribed with nonpharmacologic treatment options for managing pain

Opioid tapering for fibromyalgia and ~~other chronic pain conditions on this line~~ patients failing to meet the opioid prescribing criteria above:

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Opioids are not intended for inclusion on this line for the following conditions/situations due to the evidence for harm:

- fibromyalgia
- ~~centralized pain syndrome (sometimes coded as chronic pain syndrome, ICD-10 G89.4)~~
- patients who fail to meet the guideline requirements regarding opioids above who have chronic pain syndrome ~~(when not representing centralized pain syndrome)~~, chronic pain due to trauma, other chronic postprocedural pain, and other chronic pain conditions included on this line

If a patient is already receiving chronic opioid therapy for these conditions/situations, then tapering is indicated. Opioid tapering should be done on an individualized basis which includes a taper goal of zero. Tapering should be unidirectional with a shared goal set by the patient and provider, generally with a 5-10% decrease monthly, and can be paused or slowed if the prescriber believes this is medically appropriate 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 opioid use disorder, treatment is included on Line 4 SUBSTANCE USE DISORDER**.**

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Line Scoring

Line 401 CONDITIONS OF THE BACK AND SPINE (current scoring shown)
Category: 7
HL: 4
Suffering: 3
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 2
Effectiveness: 3
Need for service: 0.8
Net cost: 2
Score: 432
Current line placement: 401

Line XXX FIBROMYALGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS
Category: 7
HL: 4
Suffering: 3
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 2
Effectiveness: 2
Need for service: 0.8
Net cost: 2
Score: 288
Approximate line placement: 443

Line 528 CHRONIC FATIGUE SYNDROME (current scoring of line FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS shown)
Category: 7
HL: 4
Suffering: 3
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 0
Effectiveness: 1
Need for service: 0.8
Net cost: 2
Score: 112
Current line placement: 528

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Line: 528

Condition: ~~FIBROMYALGIA,~~ CHRONIC FATIGUE SYNDROME~~, AND RELATED DISORDERS~~ (See Guideline Notes 64,65~~,135~~)

Treatment: MEDICAL THERAPY

ICD-10: ~~G89.21,G89.28-G89.29,G89.4,M79.7,~~R53.82

CPT: 90785,90832-90840,90846-90853,93792,93793,98966-98969,99051,99060,99070,99078, 99201-99215,99281-99285,99341-99378,99381-99404,99408-99449,99487-99490,99495-99498,99605-99607

HCPCS: G0248-G0250,G0396,G0397,G0463-G0467,G0490,G0511,G0513,G0514

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GUIDELINE NOTE 56, NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE

Lines 361,401

Patients seeking care for back pain should be assessed for potentially serious conditions ("red flag" symptoms requiring immediate diagnostic testing), as defined in Diagnostic Guideline D4. Patients lacking red flag symptoms should be assessed using a validated assessment tool (e.g. STarT Back Assessment Tool) in order to determine their risk level for poor functional prognosis based on psychosocial indicators.
For patients who are determined to be low risk on the assessment tool, the following services are included on these lines:

- Office evaluation and education,
- Up to four total visits, consisting of the following treatments: OMT/CMT, acupuncture, and PT/OT. Massage, if available, may be provided as part of these four total visits.
- First line medications: NSAIDs, acetaminophen, and/or muscle relaxers. Opioids may be considered as a second line treatment, subject to the limitations on coverage of opioids in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE. ~~See evidence table.~~

For patients who are determined to be medium- or high risk on the validated assessment tool, as well as patients undergoing opioid tapers as in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE, the following treatments are included on these lines:

- Office evaluation, consultation and education
- Cognitive behavioral therapy (CBT). The necessity for CBT should be re-evaluated every 90 days and coverage will only be continued if there is documented evidence of decreasing depression or anxiety symptomatology, improved ability to work/function, increased self-efficacy, or other clinically significant, objective improvement.
- Prescription and over-the-counter medications; opioid medications subject to the limitations on coverage of opioids in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE. ~~See evidence table.~~
- The following evidence-based therapies, when available, may be provided: yoga, massage, supervised exercise therapy, intensive interdisciplinary rehabilitation. HCPCS S9451 is only included on Line 401 for the provision of yoga or supervised exercise therapy.
- A total of 30 visits per year of any combination of the following evidence-based therapies when available and medically appropriate. These therapies are only included on these lines if provided by a provider licensed to provide the therapy and when there is documentation of measurable clinically significant progress toward the therapy plan of care goals and objectives using evidence based objective tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ). These 30 visits count toward the visit totals in GUIDELINE NOTE XXX TREATMENT OF FIBROMYALGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS if the patient has one or more of these comorbid chronic pain conditions.
    3) Rehabilitative therapy (physical and/or occupational therapy), if provided according to Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES. Rehabilitation services provided under this guideline also count towards visit totals in Guideline Note 6. CPT 97124 is included in this category.
    4) Chiropractic or osteopathic manipulation
    5) Acupuncture

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Mechanical traction (CPT 97012) is not included on these lines, due to evidence of lack of effectiveness for treatment of back and neck conditions.

The development of this guideline note was informed by HERC coverage guidances on Low Back Pain Non-Pharmacologic, Non-Invasive Intervention, Low Back Pain, Pharmacological and Herbal Therapies. See http://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx.

[delete the table below]

~~**Evidence Table of Effective Treatments for the Management of Low Back Pain**~~

Intervention Category*	Intervention	Acute < 4 Weeks	Subacute & Chronic > 4 Weeks
Self-care	Advice to remain active	●	●
	Books, handout	●	●
	Application of superficial heat	●	
Nonpharmacologic therapy	Spinal manipulation	●	●
	Exercise therapy		●
	Massage		●
	Acupuncture		●
	Yoga		●
	Cognitive-behavioral therapy		●
	Progressive relaxation		●
Pharmacologic therapy (Carefully consider risks/harms)	Acetaminophen	●	●
	NSAIDs	●(▲)	●(▲)
	Skeletal muscle relaxants	●	
	Antidepressants (TCA)		●
	*Benzodiazepines***	●(▲)	●(▲)
	*Tramadol, opioids***	●(▲)	●(▲)
Interdisciplinary therapy	Intensive interdisciplinary rehabilitation		●

- Interventions supported by grade B evidence (at least fair-quality evidence of moderate benefit, or small benefit but no significant harms, costs, or burdens). No intervention was supported by grade "A" evidence (good-quality evidence of substantial benefit).

▲ *Carries greater risk of harms than other agents in table.*

NSAIDs = nonsteroidal anti-inflammatory drugs; TCA = tricyclic antidepressants.

*These are general categories only. Individual care plans need to be developed on a case by case basis. For more detailed information please see: http://www.annals.org/content/147/7/478.full.pdf

**Associated with significant risks related to potential for abuse, addiction and tolerance. This evidence evaluates effectiveness of these agents with relatively short term use studies. Chronic use of these agents may result in significant harms.

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

Lines 346,361,401,527

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. Pain average, interference with Enjoyment of life, and interference with General activity" (PEG) Assessment Scale, Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
   b) When prescribed in conjunction with therapies such as spinal manipulation, physical therapy, yoga, or acupuncture.
   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) Chronic opioid treatment (>90 days) after the initial injury~~/flare/~~surgery is not included on these lines except for the taper process described below.

Transitional coverage for patients on long-term opioid therapy ~~as of July 1, 2016~~:
For patients ~~on covered chronic~~ receiving long-term opioid therapy (>90 days) for conditions of the back and spine ~~as of July 1, 2016, opioid medication is included on these lines only from July 1, 2016 to December 31, 2016. During the period from January 1, 2017 to December 31, 2017~~, continued coverage of opioid medications requires an individual treatment plan which includes a taper plan ~~developed by January 1, 2017 which includes a taper with an end to opioid therapy no later than January 1, 2018~~. Opioid tapering should be done on an individualized basis and include a taper goal to zero. Tapering should be unidirectional with a shared goal set by the patient and provider, generally with a 5-10% decrease monthly and can be paused or slowed if the prescriber believes this is medically appropriate based on the patient's overall status. Taper plans ~~must~~ should include nonpharmacological treatment strategies for managing the patient's pain ~~based on Guideline Note 56 NON-INTERVENTIONAL~~

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~~TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE~~. 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 ~~dependence and/or addiction related to their opioids~~ opioid use disorder, treatment is ~~available~~ included on Line 4 SUBSTANCE USE DISORDER**.**

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,5,202,361,401,409,461,538

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

Line 1 PREGNANCY

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

Hyperemesis gravidarum

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

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

Breech presentation

ICD-10-CM: O32.1

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

Back and pelvic pain of pregnancy

ICD-10-CM: O99.89

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

Line 5 TOBACCO DEPENDENCE

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

Line 202 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS

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

Line 361 SCOLIOSIS

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

Line 401 CONDITIONS OF THE BACK AND SPINE

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

Line 409 MIGRAINE HEADACHES

Acupuncture pairs on Line 409 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), for up to 12 sessions per year.

Line XXX FIBROMYAGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS

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Acupuncture is included on this line with visit limitations as in Guideline Note XXX TREATMENT OF FIBROMYAGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS

Line 461 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 461 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions per year.

*Line 538 TENSION HEADACHES

Acupuncture is included on Line 538 for treatment of tension headaches (ICD-10-CM G44.2), for up to 12 sessions per year.

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

*Below the current funding line

~~**GUIDELINE NOTE 135, FIBROMYALGIA**~~

~~*Line 528*~~

~~Fibromyalgia (ICD-10-CM M79.7) treatment should consist of a multi-modal approach, which should include two of more of the following:~~

~~A) medications other than opioids~~
~~B) exercise advice/programs~~
~~C) cognitive behavioral therapy.~~

~~Care should be provided in the primary care setting. Referrals to specialists are generally not required. Use of opioids should be avoided due to evidence of harm in this condition~~

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Hidradenitis Suppurativa

Question: Should hidradenitis suppurativa be moved to a higher priority line on the Prioritized List?

Question source: John Young, MD and LaDessa Christensen NP-C, Silver Falls Dermatology; Jill Moore, MD, Phoebe Rich Dermatology; Julie Dhossche, MD and Tracy Funk, MD, OHSU Dermatology

Issue: Hidradenitis suppurativa (HS) (ICD-10 L73.2) is currently on line 512 HIDRADENITIS SUPPURATIVA; DISSECTING CELLULITIS OF THE SCALP. Multiple dermatology providers are requesting that it be considered for a covered line on the List based on the development of newer, more effective treatments for this condition, specifically adalimumab (Humira). Adalimumab was approved for treatment of hidradenitis suppurativa by the FDA in 2015. It was not considered in the most recent review of this condition, the 2012 ICD-10 Dermatology review. During the 2012 review, no effective treatments were found for HS, and therefore the condition was placed on a low priority line. Adalimumab is an antibody that inhibits tumor necrosis factor (TNF). It is given by subcutaneous injection. Other biologic medications such as infliximab and etanercept are being used to treat HS, although neither has FDA approval for treating HS. HS is considered a similar condition to acne conglobata, which was moved to a covered line with the 2012 ICD-10 Dermatology review.

Background:
Hidradenitis suppurativa (HS) is a chronic inflammatory skin condition characterized by recurrent painful boils in flexural sites, such as the axillae and groin, that affects about 1% of the population, with onset in early adulthood. The exact cause is unclear but believed to involve a combination of genetic and environmental factors. Diagnosis is based on the symptoms. There is no known cure. Warm baths may be tried in those with mild disease. Cutting open the lesions to allow them to drain does not result in significant benefit. While antibiotics are commonly used, evidence for their use is poor. Immunosuppressive medication may also be tried. In those with more severe disease laser therapy or surgery to remove the affected skin may be carried out.

Hurley's staging system:

Stage	Characteristics
I	Solitary or multiple isolated abscess formation without scarring or sinus tracts (A few minor sites with rare inflammation; may be mistaken for acne.)
II	Recurrent abscesses, single or multiple widely separated lesions, with sinus tract formation. (Frequent inflammation restrict movement and may require minor surgery such as incision and drainage.)
III	Diffuse or broad involvement across a regional area with multiple interconnected sinus tracts and abscesses (Inflammation of sites to the size of golf balls, or sometimes baseballs; scarring develops, including subcutaneous tracts of infection. Patients at this stage may be unable to function.)

Sartorius staging system

- Anatomic regions involved (axilla, groin gluteal, or other region or inframammary region left or right)
- Number and types of lesions involved (abscesses, nodules, fistulas [actually sinuses], scars, points for lesions of all regions involved)
- The distance between lesions, in particular the longest distance between two relevant lesions (i.e., nodules and fistulas in each region or size if only one lesion present)

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- The presence of normal skin in between lesions (i.e., are all lesions clearly separated by normal skin?)

Points are accumulated in each of the above categories and added to give both a regional and total score. In addition, the authors recommend adding a visual analog scale for pain or using the dermatology life quality index (DLQI, or the Skindex) when assessing HS.

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Previous review:

From the ICD-10 Dermatology review:

1) HYDRADENITIS SUPPURATIVA; DISSECTING CELLULITIS OF THE SCALP

Both of these conditions are very resistant to treatment. The severity may be reduced with oral isotretinoin, antibiotics, dapsone, and injected or systemic steroids.

Category 7.
Impact on Healthy Life Years 2
Impact on Pain and Suffering 3
Population effects 0
Vulnerable populations 0
Tertiary prevention 1 (decreases risk of scarring down axilla; abscesses; but surgery end stage decision, cure, but 50% graft entire axilla and get disease around graft)
Effectiveness 1
Need for treatment 1
Net cost 4
SCORE 120, PUTS ON LINE 550

From Dr. Young:

Patients afflicted with this disease have purulent filled nodules abscesses with sinus tracts. It typically affects the groin, armpits, and under the breasts. It causes difficulty with walking, using the restroom, personal intimacy, and self-image/depression. This has caused many people to seek disability benefits (due to limiting ability to be employed and work) and has possibly contributed to narcotic use for pain control in some cases.

Until recently, all we had to offer were treatments that made minimal impact on patients. However, there is a new FDA approved biologic treatment which is making a significant impact on people's lives. We live in a very hopeful time where we can have treatments like this which make such a remarkable difference in people's lives. No doubt that this will allow us to have fewer people on disability benefits.

I humbly request that you consider covering this new treatment for HS in moderate to severe cases by covering it with an "above the line" designation.

From Ms. Christensen,

I am writing to request your consideration of hidradenitis supprativa as a covered diagnosis for patients enrolled in your insurance plans.

This request is medically necessary for the following reasons:

- It is a painful condition
- It increases the risk of infection
- It causes emotional and physical distress

It will assist the individual to achieve or maintain maximum functional capacity in performing daily activities. Many of my patients who have this diagnosis have to take days off of work and make multiple trips to the emergency department due to pain and to have incision and drainage procedures. This increases the risk of infection and are expensive healthcare visits which could be properly managed at a medical clinic. Pain medications are becoming the standard treatment used to manage this condition due to the lack of coverage and additional treatment options that are not currently covered.

Please take into count the financial toll this condition can have on our communities and on the individuals suffering with this condition as you consider this diagnosis for coverage on your insurance plans.

From Dr. Moore:

I am writing to advocate for inclusion of Hidradenitis Suppurativa (ICD10 L73.2) as an above-the-line diagnosis for Oregon Medicaid patients. I am regretfully unable to attend the meeting, but I submit this message in the hopes it will be shared with the committee and considered in the discussion.

Hidradenitis Suppurativa is a chronic inflammatory disease that primarily affects the skin of intertriginous areas such as the axillae, inframammary skin, groin folds, inner thighs, and buttocks. It begins with small pustules and inflammatory nodules that may lead to sterile (non-infectious) abscesses in deeper portions of the skin. These abscesses are usually painful, and require treatment by a physician with drainage or injection of anti-inflammatory medication. When they occur on the buttocks or in groin fold areas, it makes sitting for long periods of time very painful for the patient. As this process recurs over time, these repeated nodules and abscesses can lead to formation of sinus tracts that chronically drain pus and malodorous fluid. Scars eventually form in the diseased areas, creating disfiguration of the skin and as painful or restricted movement of the limbs. In severe and long-standing disease, there is increased risk for skin cancer in the affected areas. Patients with this disease live with chronic malodorous discharge from their skin that is beyond their control, as well as painful recurring nodules in sensitive areas; this leads to social isolation, difficulty in pursuing romantic relationships, higher rates of depression, and overall poor quality of life. When their disease flares, they have loss of wages due to need for visits to their physician's office or an urgent care / emergency setting. These patients have a high level of need for medical care, which if uncovered or below-the-line, creates a significant economic burden to them. This condition is also often under-recognized or mis-diagnosed as recurrent infections, which may lead to inappropriate treatment. There is often a delay of several years before an accurate diagnosis is made.

Treatment of this condition involves incision and drainage of painful nodules, topical and oral antibiotics (tetracycline, a combination of clindamycin and rifampicin) or immunomodulating agents (acitretin, isotretinoin, dapsone, and cyclosporine). In severe disease with sinus tracts and scarring, surgery is often necessary, though the disease can recur at the sites of surgery. Early recognition and treatment of the disease may help to prevent further flares and

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slow or stall progression of the disease to more severe and costly states. Furthermore, accurate diagnosis and treatment by a specialist may improve patient's quality of life and reduce their medical economic burden.

If Hidradenitis Suppurativa is listed as an above-the-line condition, I expect patients with Oregon Medicaid will get diagnosed earlier, as they will be referred to the appropriate specialist in a more timely fashion. This will also facilitate more appropriate treatment, less costly visits to an emergent care facility, and improved quality of life for these patients. Hopefully earlier intervention will help to slow down or stall progression of the disease, and limit the need for costly hospitalizations and surgeries. I believe this will lead to less cost to the system overall.

From Dr. Dhossche:

HS is a chronic, debilitating disease, and those affected experience worsening quality of life measures the worse the disease. For mild to moderate disease, topical clindamycin and oral antibiotics have been shown to be helpful in small studies. Intralesional steroids have been shown to be helpful at least in the short term with individual flaring lesions. For moderate to severe disease, surgery has traditionally been pursued, but biologics offer a new avenue of treatment, with adalimumab being the most studied and having moderate quality evidence behind its use. Infliximab has in smaller studies been shown to improve quality of life.

Given the evidence presented regarding the personal and societal impact of hidradenitis suppurativa, as well as the range of treatments available, I am advocating for the coverage of hidradenitis suppurativa by Oregon Health Plan. Our patients with this disease suffer greatly. Please do the right thing for them.

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Evidence

1) **OHA P&T 2018, review of adalimumab for HS**
    a. Evidence for adalimumab in HS comes from two phase 3 trials and a systematic review from the Cochrane Collaboration. A technology appraisal of adalimumab in HS was also completed by the National Institute for Health and Care Excellence (NICE).
        i. Two phase 3 trials (PIONEER 1 and PIONEER 2): Both trials were manufacturer-funded and the manufacturer participated in data collection, data analysis, data interpretation, and manuscript writing, review, and approval. Additionally, all of the authors disclosed potential conflicts of interest including conflicts specific to the manufacturer (such as employment, consulting fees, grant support, honoraria, etc.).
        ii. Patients enrolled in both PIONEER 1 (n=307) and PIONEER 2 (n=326) had moderate to severe HS. Both trials ran for 36 weeks
    b. Effectiveness
        i. There is low quality evidence from 2 randomized controlled trials (RCTs) that adalimumab 40 mg weekly improves the proportion of patients achieving a Hidradenitis Suppurativa Clinical Response (HiSCR), defined as at least a 50% reduction in total abscess and inflammatory nodule count from baseline with no increase in the abscess or draining-fistula count, compared to placebo at 12 weeks (41.8% vs. 26.0%, respectively, number needed to treat [NNT] 7; and 58.9% vs. 27.6%, NNT 4).
        ii. There is insufficient evidence from 2 conflicting RCTs that adalimumab 40 mg weekly increases the proportion of patients with a 0-2 total abscess and inflammatory-nodule count at week 12 for patients with Hurley stage 2 disease at baseline compared to placebo (28.9% vs. 28.6%, respectively, p=0.96; and 51.8% vs. 32.2%, respectively, p=0.01, NNT 6).
        iii. There is insufficient evidence from 2 conflicting RCTs that adalimumab 40 mg weekly increases the proportion of patients with at least 30% reduction and at least 1 unit reduction in pain score from baseline compared to placebo at week 12 (27.9% vs. 24.8%, respectively, p=0.63; and 45.7% vs. 20.7%, respectively, p<0.001, NNT 4). Clinical significance of a 30% reduction is unclear and it has been suggested that a 50% reduction in baseline pain is considered clinically meaningful.
        iv. There is insufficient evidence from 2 conflicting RCTs that adalimumab 40 mg weekly improves the mean change in modified Sartorius score compared to placebo from baseline to week 12 (-24.4 points vs. -15.7 points, respectively, p=0.12; and -28.9 points vs. -9.5 points, respectively, p<0.001).
        v. There is moderate quality evidence that adalimumab 40 mg weekly improves the Dermatology Life Quality Index (DLQI) score compared to placebo in moderate to severe HS at week 12 and week 16. Evidence from 2 RCTs found decreases of 5.4 points and 5.1 points with adalimumab compared with decreases of 2.9 points and 2.3 points with placebo at 12 weeks. The differences between placebo and adalimumab group changes do not meet the suggested minimum clinically significant difference of 4-5 points. Additionally, another RCT assessed in the Cochrane review found a benefit with adalimumab compared to placebo at 16 weeks in DLQI score (mean difference 4 points; 95% confidence interval [CI], 6.5 to 1.5 points lower).

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vi. There is insufficient evidence to determine the effect of adalimumab on the need for surgery from clinical trials. However, NICE guidance based on post-hoc analyses of draining fistulas and non-draining fistulas concludes there is a decreased need for some types of surgical procedures (likely minor surgeries such as narrow margin excisions and incision and drainage procedures). No definite conclusions could be made on the effect of adalimumab on surgical-inpatient admissions. The post hoc analysis assessed by NICE found that a greater proportion of patients treated with adalimumab as compared to placebo had improvement in draining fistulas (33% vs. 19%; p<0.001; NNT 8) and non-draining fistulas (15% vs. 9%; p=0.017; NNT 17).

c. Adverse events
   i. There is low quality evidence that adalimumab 40 mg weekly and placebo have similar risks of serious adverse events [SAEs] (1.3%-1.8% vs. 1.3%-3.7%, respectively; RCT = 2), infections (24.8%-25.2% vs. 28.3%-32.5%, respectively; RCT = 2), and serious infections (0.6-0.7% vs. 0-1.2%, respectively; RCT = 2) through 12 weeks.
   ii. There is low quality of evidence from patients who remained continuously on the respective treatment that adalimumab-treated patients have a similar risk of SAE at 12-36 weeks of therapy compared to placebo (2.1-3.9% vs. 4.6%, respectively; RCT=2 for adalimumab and 1 for placebo). Similarly, there is low quality of evidence in the same time frame that adalimumab- and placebo-treated patients have similar risk for serious infections (0-2.0% vs. 1.3%; RCT=2 for adalimumab and 1 for placebo). This evidence is limited by a high rate of overall attrition (41.3% and 52.8% for the two RCTs).
   iii. There is insufficient evidence to determine the long-term safety of adalimumab for HS beyond 36 weeks. However, the safety profile of adalimumab dosed every other week for other conditions has been well characterized since the drug's initial U.S. approval in 2002. Like other immunosuppressants, adalimumab has FDA boxed warnings for serious infections and malignancies.

d. Possible PA criteria for adalimumab if HS is moved to a funded line:
   i. Require trial and failure, intolerance, or contraindication to conventional therapy (such as oral antibiotics) and
   ii. Require evidence of response (a reduction of 25% or more in the total abscess and inflammatory nodule count and no increase in abscesses and draining fistulas) for renewal of authorization.

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Cost:
Adalimumab wholesale acquisition cost: $8,882/month at the weekly dosing recommended for use for HS ($106,584 annual cost). It is unclear how long an optimal course of therapy is for HS.

Current utilization:
Despite being a below the line condition, HS had a significant number of paid claims for 2016.

-1324 individuals with claims for dates of service in CY2016, FFS and CCO. 6974 paid clean claims had this diagnosis (not necessarily as primary).

-Claims were for a variety of services, including office visits, ER visits, drainage of abscesses, excision of skin lesions, and skin grafts

-total paid was approximately $1.2 million for this diagnosis in 2016

Other coverage for adalimumab for HS:

1) **NICE 2016** https://www.nice.org.uk/guidance/ta392/resources/adalimumab-for-treating-moderate-to-severe-hidradenitis-suppurativa-pdf-82602906813637
    a. Adalimumab is recommended, within its marketing authorisation, as an option for treating active moderate to severe hidradenitis suppurativa in adults whose disease has not responded to conventional systemic therapy. The drug is recommended only if the company provides it at the price agreed in the patient access scheme.
    b. Assess the response to adalimumab after 12 weeks of treatment, and only continue if there is clear evidence of response, defined as:
        1. a reduction of 25% or more in the total abscess and inflammatory nodule count and
        2. no increase in abscesses and draining fistulas.
2) **Aetna 2017** policy on adalimumab (Humira): Hidradenitis suppurativa - Treatment of moderate to severe hidradenitis suppurativa (Hurley Stage II or Hurley Stage III) (see appendix) in persons who have had an inadequate response to at least a 90 day treatment of oral antibiotics for treatment of hidradenitis suppurativa, unless contraindicated

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Hidradenitis Suppurativa

HERC staff summary:
Hidradenitis suppurativa (HS), in its severe forms, is a serious, disabling disease. Previously there were no treatments that were considered reasonably effective for HS; however, since the last review of HS, adalimumab received FDA approval for treating HS. There is moderate quality evidence (based on two manufacturer sponsored and influenced studies with a total N=632) that adalimumab improves the proportion of patients achieving at least 50% reduction in total abscess and inflammatory nodule count and improves the Dermatology Quality of Life Index (CQLI), although the increase in DQLI was below the level felt to be clinically meaningful. There is insufficient evidence to determine if adalimumab decreases pain or reduces need for surgery or surgical hospitalization.

OHP is already paying for a considerable volume of care for patients with HS, but this would be expected to increase if HS was moved above the funding line unless office treatment could significantly reduce the rate of ER visits, surgical procedures or other complications. An estimated 1500 OHP patients have HS based on claims data.

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HERC staff recommendation:
Consider re-prioritization of hidradenitis suppurativa based on the development of newer, more effective therapies

If re-prioritization is desired, HERC staff have identified two possible options:

1) **Option 1**: create an entirely new line as shown below, with the new guideline and scoring as shown below
    a. Leave ICD-10 L73.2 (Hidradenitis suppurativa) on line 512 for cases not meeting the new guideline requirements, and rename this line 512 MILD HIDRADENITIS SUPPURATIVA; DISSECTING CELLULITIS OF THE SCALP

Line XXX MODERATE TO SEVERE HYDRADENITIS SUPPURATIVA
Treatment: MEDICAL AND SURGICAL THERAPY
ICD-10 codes: L73.2 (Hidradenitis suppurativa)
CPT/HCPCS codes: those currently appearing on line 512 HIDRADENITIS SUPPURATIVA; DISSECTING CELLULITIS OF THE SCALP

GUIDELINE NOTE XXX HIDRADENITIS SUPPURATIVA
Line XXX, 512
Hidradenitis suppurativa is included on line XXX only for moderate to severe disease (e.g. Hurley Stage II or Hurley Stage III); otherwise this condition is included on line 512.

Initial treatment with adalimumab is limited to adults whose disease has not responded to at least a 90-day trial of conventional therapy (e.g., oral antibiotics), unless such a trial is not tolerated or contraindicated. Treatment with adalimumab after 12 weeks is only included on line XXX for patients with a clear evidence of response, defined as:

1. a reduction of 25% or more in the total abscess and inflammatory nodule count, AND
2. no increase in abscesses and draining fistulas.

HERC staff proposed line scoring (current scores for line 512 in parentheses)

Category 7 (7)
Impact on Healthy Life Years 3 (2)
Impact on Pain and Suffering 4 (3)
Population effects 0 (0)
Vulnerable populations 0 (0)
Tertiary prevention 2 (1) (decreases risk of scarring down axilla; abscesses)
Effectiveness 2 (1)
Need for treatment 1 (1)
Net cost 2 (4)
SCORE 360 (120), approximate LINE 418 (512)

Current funding line is 469

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2) **Option 2**: add hidradenitis suppurativa to the new severe acne line created for the 2020 Biennial Review Prioritized List
    a. Rename this line to reflect the additional diagnoses, add ICD-10 and CPT codes as noted below
    b. Leave ICD-10 L73.2 (Hidradenitis suppurativa) on line 512 for cases not meeting the new guideline requirements, and rename this line 512 MILD HIDRADENITIS SUPPURATIVA; DISSECTING CELLULITIS OF THE SCALP
    c. Include the new guideline note for hidradenitis suppurativa as in option 1
    d. The severe cystic acne line previously was scored to approximately line 451

Line XXX SEVERE CYSTIC ACNE; MODERATE TO SEVERE HYDRADENITIS SUPPURATIVA
Treatment: MEDICAL AND SURGICAL TREATMENT
    a. ICD-10 codes: L70 (acne), L73.2 (Hidradenitis suppurativa)
    b. CPT/HCPCS codes: all included currently on line 373 ACNE CONGLOBATA (SEVERE CYSTIC ACNE); those currently appearing on line 512 HIDRADENITIS SUPPURATIVA; DISSECTING CELLULITIS OF THE SCALP [this would include a series of CPT codes for "Excision of skin and subcutaneous tissue for hidradenitis"

GUIDELINE NOTE XXX HYDRADENITIS SUPPURATIVA
Line [severe cystic acne line], 512
Hidradenitis suppurativa is included on line [severe acne line] only for moderate to severe disease (e.g. Hurley Stage II or Hurley Stage III); otherwise this condition is included on line 512.

Initial treatment with adalimumab is limited to adults whose disease has not responded to at least a 90 day trial of conventional therapy (e.g. oral antibiotics), unless such a trial is not tolerated or contraindicated. Treatment with adalimumab after 12 weeks is only included on line XXX for patients with a clear evidence of response, defined as:
    1. a reduction of 25% or more in the total abscess and inflammatory nodule count, AND
    2. no increase in abscesses and draining fistulas.

From August, 2018:
Line scoring
Current scoring in parentheses for lines 373 ACNE CONGLOBATA (SEVERE CYSTIC ACNE)/530 ROSACEA; ACNE
    Category 7 (7,7)
    Impact on Healthy Life Years 1 (2,1)
    Impact on Pain and Suffering 3 (3,2)
    Population effects 0 (0)
    Vulnerable populations 0 (0)
    Tertiary prevention 0 (2,0)
    Effectiveness 4 (4,4)
    Need for treatment 0.8 (1,0.5)
    Net cost 3 (3,3)
SCORE 256, PUTS ON LINE 451

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Sacroiliac Joint Dysfunction Prioritization

Question: Should SI joint dysfunction paired with surgical fusion be moved to a higher priority line?

Question source: Andy Kranenburg, MD orthopedic surgeon from Medford; SI-Bone, manufacturer of SI fusion device

Issue: SI joint fusion is a surgical treatment used to address pain that originates from the joint between bones in the spine and hip (sacrum and ilium). The clinical presentation of SI joint pain varies from patient to patient, but buttock pain extending into the posterolateral thigh is the most common pattern. SI joint pain is thought to be the primary source of pain for approximately 10% to 30% of cases of mechanical low back pain. However, estimating an accurate prevalence of SI joint pain is challenging because no universally accepted gold standard for diagnosis exists. The current reference standard for diagnosis is relief of pain after anesthetic SI joint injection. Although diagnosis can be challenging, the impact of SI joint pain on quality of life is significant.

Andy Kranenburg, MD from Medford, testified at the August and October 2018 VBBS meetings regarding the treatment of sacroiliac joint pain and dysfunction. Currently, there is a guideline on the Prioritized List regarding when treatment is appropriate, but the diagnosis is on an uncovered line. He requested reconsideration of the prioritization of sacroiliac joint dysfunction to a line above the funding level.

At the October, 2018 VBBS meeting, Dr. Kranenburg gave a presentation outlining his proposed scoring for SI joint dysfunction. Kranenburg argued that SI joint dysfunction is inappropriately classified as a back condition when it should be categorized as a hip or pelvic condition. The guideline restricting coverage of surgery for back conditions to those with abnormal neurological findings is not appropriate for SI joint conditions. His suggested scoring is shown later in this document.

The discussion amongst VbBS members centered on the need to re-look at the published RCTs to look at the reported effectiveness. It was later identified that the Washington Health Technology Assessment group was doing an evidence review on SI joint fusion and further discussion of this topic was tabled until that review was available.

There has been concern among VBBS members that SI joint fusion had higher levels of adverse events than reported in the literature reviewed to date.

Current Prioritized List status:
ICD-10 M46.1 (Sacroiliitis, not elsewhere classified) and CPT 27279 (Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device) are currently on line 527 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS along with a guideline regarding when fusion should be covered. Sacroiliitis is also on line 401 CONDITIONS OF THE BACK AND SPINE for non-surgical treatments.

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Evidence

Washington HTA 2018, Sacroiliac join fusion https://www.hca.wa.gov/assets/program/si-fusion-final-rpt-20181130.pdf

1) N=43 studies
    a. 8 were controlled studies (2 RCTs and 6 CCSs), 32 were uncontrolled studies, and 3 were cost studies
    b. All studies included in the VBBS/HERC 2016 review were included in the HTA report except:
        i. Duhan: article was submitted by the manufacturer
        ii. **Schoell, 2016** [submitted by Vern Saboe]
            1. Retrospective database study of the nationwide Humana database, specifically looking at harms of SI joint fusion
            2. N = 469 within the Humana insurance database who received minimally invasive SI fusion between 2007 and 2014.
            3. Overall complication rate of 13.2% (n=62) was seen at 90 days postoperatively and 16.4% (n=77) at 6 months.
2) Pain, disability, and quality of life
    a. Two RCTs and 1 CCS compared minimally invasive SI joint fusion surgery using the iFuse Implant System with conservative management and observed larger improvements in a visual analog scale for pain (between-group differences at 6 months based on the RCTs: -40.5 mm [95% CI, -30.9 to -50.1], -38.1 mm [95% CI not reported; P < 0.0001] and at 6 months to 3.5 years based on the CCS: -6 cm [95% CI, not reported; P < 0.001]). These studies also observed larger improvements in physical function measured using the Oswestry Disability Index (ODI) (between-group differences at 6 months based on the RCTs: -25.4 points [95% CI, -18.3 to -32.5] and -19.8 points [95% CI, not reported, P < 0.0001] and at 6 months to 3.5 years: -24 points [95% CI, not reported; P < 0.001]) based on the CCS). We graded these outcomes as moderate quality from the RCTs and very low quality from the CCS.
        i. Note: the minimal clinically important difference in the visual analog scale for pain is reported to be 20-40 mm (varies by study and condition)
        ii. Note: minimally clinically important difference (MCID) in the ODI generally found to be 12-15 points. FDA standard for good to excellent surgical outcomes is a change in 15 points on the ODI
    b. One CCS compared open fusion to no surgery at 11 to 32 years and observed no difference in pain, physical function, or quality of life; we graded these outcomes as very low quality.
    c. Three CCSs compared minimally invasive fusion with iFuse to open fusion. We graded all outcomes for this comparison as very low quality. One CCS reported larger improvements in pain measured with a visual analog scale (between-group difference over 2 years: -3 cm [95% CI, -2.1 to -4.0]; the other 2 studies did not report pain outcomes but found mixed findings for physical function measured by the ODI. All 3 studies observed significantly shorter hospital length of stay among iFuse recipients compared to open fusion; the range of difference was 1.3 to 3.8 days. All 3 studies reported a similar incidence of adverse events between groups but reported mixed findings for the incidence of revision surgery. One of the 3 studies reported significantly fewer revisions among participants that received iFuse (absolute risk difference [ARD] -

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51.3% [95% CI, -60.1% to -42.4%]); the other 2 studies reported infrequent revisions in both the iFuse and the open fusion groups.

   d. One CCS compared minimally invasive fusion with iFuse to minimally invasive fusion with screw fixation; significantly fewer revisions were required among participants who received iFuse (ARD -57.5% [95% CI, -74.8% to -40.2%]). We graded this outcome as very low quality.

3) Opioid use
   a. At 6 months, no change found in percent of opioid use with surgery based on 1 RCT (N=148). Low quality of evidence.
   b. At 6 months to 3.5 years, significant difference ($P < 0.001$) between groups in oral morphine equivalents used at the time of last follow-up: iFuse (3.1 mg/day), SI denervation (32.2 mg/day), conservative management (38.5 mg/day). Based on 1 CCS (N = 137), very low quality of evidence
4) Cost effectiveness
   a. One cost-effectiveness study reported a cost per additional quality-adjusted life year gained of $13,313; we graded this outcome as very low quality.
5) Safety
   a. Thirty-two uncontrolled studies reported safety outcomes for a variety of open and minimally invasive fusion procedures. We evaluated many as having a high risk of bias; further outcome definition and ascertainment methods varied widely. One study, which used an insurance claims database to identify 469 minimally invasive fusion procedures between 2007 and 2014 reported a 90-day incidence of complications of 13.2%. Another study, which used a post market surveillance database of 11,388 iFuse procedures, reported an incidence of revision surgery of 2.8% over the years 2009 to 2014.
6) **Conclusions:** Among patients meeting diagnostic criteria for SI joint pain or dysfunction and who have not responded adequately to conservative care, minimally invasive SI joint fusion surgery with the iFuse Implant System is more effective than conservative management for reducing pain and improving function, and is likely cost-effective. Minimally invasive SI joint fusion surgery with iFuse is also more effective than open fusion for reducing pain and is associated with a shorter hospital length of stay. Serious adverse events from surgery with iFuse are infrequently reported in controlled studies but may be higher in usual practice based on evidence from uncontrolled studies. The incidence of revision surgery is likely no higher than 3.4% at 2 years. Limited evidence is available that compares open fusion to minimally invasive fusion or that evaluates procedures other than iFuse.

<u>Letter from Dr. Saboe:</u>

There have been three new studies since we last visited this issue, two of which were again funded by the device manufacturer and a third independent. There has also been a review of evidence by our HERC counterparts in Washington State and recommendations that are favorable toward the procedure however, I remain skeptical.

I respectfully suggest that at the very least chiropractic and/or osteopathic manipulative therapy must be added to the list of non-operative treatments listed in our proposed, guideline/medical policy. Those non-operative treatments currently include, “medication optimization,” “activity

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modification," "bracing," and "active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ and hip including a home exercise program."

Colleagues and I have been reviewing the medical literature for high quality evidence that supports the efficacy of each of these interventions specifically in regards to the treatment of SIJ dysfunction/pain (not simply, "low back pain"). It appears that the strength of evidence of efficacy for chiropractic and osteopathic manipulative therapy for the treatment of SIJ dysfunction is at least as strong as for the other listed non-operative treatments.

So again, I recommend chiropractic and/or osteopathic manipulative therapy be added to our guideline as one of the non-operative interventions that must have been tried prior to qualifying for minimally invasive sacroiliac joint fusion surgery.

Note from HERC staff: there were no studies of chiropractic manipulation of the SI joint identified in MedLine on a January 7, 2019 search.

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Model Prioritization for Sacroiliiac Joint Dysfunction with Surgical Fusion

	Line 346	Line 527	HERC staff proposal	Kranenburg proposal
Category (Non-Fatal Condition)	7	7	7	7
Healthy Life Years (0-10)	5	4	4	6
Suffering (0-5)	4	3	3	5
Population effects (0-5)	0	0	0	0
Vulnerable population (0-5)	0	0	0	0
Tertiary prevention (0-5)	0	0	0	0
Effectiveness (0-5)	3	1	4	4
Need for service (0-1)	1	0.8	0.8	1
Net cost	2	2	2	
Score	780	112	560	960
Approximate line	346	527	418	330

Line 346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS
Line 527 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS

Possible similar line:
Line 356 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE

Note: line 346 has a guideline requiring neurological damage prior to authorizing surgery. This line would not be appropriate for SI joint fusion

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HERC staff recommendation:

1) Create a new line for SI joint fusion as shown below
    a. Leave ICD-10 M46.1 (Sacroiliitis, not elsewhere classified) on line 527 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS for mild cases
    b. Leave M46.1 on line 401 CONDITIONS OF THE BACK AND SPINE for medical care
    c. Chiropractic (CPT 98940- 98942) and osteopathic (CPT 98925- 98929) manipulation will pair on line 401 (medical back line)
2) Score as in staff proposal in table above (approximately line 418)
3) Modify GN161 as shown below

LINE: XXX
CONDITION: SEVERE SACROILIITIS
TREATMENT: SURGICAL THERAPY

ICD-10: ICD-10 M46.1 (Sacroiliitis, not elsewhere classified)

CPT: 27096 (Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed), 27279 (Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device), 98966-98969, 99051, 99060,99070,99078,99201-99215,99281-99285,99304-99337,99340-99404,99408-99449,99487-99490,99495,99496,99605-99607 (medical office visits, including ER and SNF)

HCPCS: G0260 (Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography), G0396-G0397 (alcohol and substance abuse screening), G0463-G0467,G0469,G0470 (FQHC care), G0490, G0511-G0513 (RFQHC care)

GUIDELINE NOTE 161, SACROILIAC ANESTHETIC INJECTIONS AND SACROILIAC JOINT FUSION

Line XXX,527

Sacroiliac joint (SIJ) injection (CPT 20610 and 27096, and HCPCS G0260) is included on ~~this line~~ these lines for diagnostic sacroiliac injections with anesthetic only, but not for therapeutic injections or corticosteroid injections. Injections are only covered for patients for whom SIJ fusion surgery is being considered.

SIJ fusion (CPT 27279) is included on ~~this~~ line XXX for patients who have all of the following:

A) Baseline score of at least 30% on the Oswestry Disability Index (ODI)
B) Undergone and failed a minimum six months of intensive non-operative treatment that must include non-opioid medication optimization and active therapy. Active therapy is defined as activity modification, chiropractic/osteopathic manipulative therapy, bracing, and/or active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ and hip including a home exercise program. Failure of conservative therapy is defined as less than a 50% improvement on the ODI.
C) Typically unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain.
D) Thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, i.e. at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine or PSIS) in the absence of tenderness of similar severity elsewhere (e.g. greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist.

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E) Positive response to at least three of six provocative tests (e.g. thigh thrust test, compression test, Gaenslen's test, distraction test, Patrick's sign, posterior provocation test).
F) Absence of generalized pain behavior (e.g. somatoform disorder) and generalized pain disorders (e.g. fibromyalgia).
G) Diagnostic imaging studies that include ALL of the following:
    1) Imaging (plain radiographs and a CT or MRI) of the SIJ that excludes the presence of destructive lesions (e.g. tumor, infection), fracture, traumatic sacroiliac joint instability, or inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion
    2) Imaging of the pelvis (AP plain radiograph) to rule out concomitant hip pathology
    3) Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain
    4) Imaging of the SIJ that indicates evidence of injury and/or degeneration
H) At least 75 percent reduction of pain for the expected duration of two anesthetics (on separate visits each with a different duration of action), and the ability to perform previously painful maneuvers, following an image-guided, contrast-enhanced intra-articular SIJ injection.

Otherwise, SIJ fusion is included on line 527.

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Donor Breast Milk Guideline Edits

Question: Should the Human Donor Breast Milk Guideline be further edited?

Question source: Renae Wentz, MD, HSD

Issue: Dr. Wentz has identified that the guideline as currently written could be construed to not be indicated for any infants, as the clause about "ongoing severe concerns with persistent diarrhea or malabsorption with improvement on breast milk compared to formula" may never be met in the outpatient setting, since infants fragile enough to still be triaged to receive HBM at hospital discharge with BW < 1500g or severe underlying gastrointestinal disease would not remain outpatient with additional ongoing persistent diarrhea/malabsorption.

Prioritized List Status (implemented January 1, 2019)

GUIDELINE NOTE 183 DONOR BREAST MILK FOR HIGH RISK INFANTS

Line 16, 34, 88, 101

Donor breast milk (T2101) is included on these lines for infants up to 6 months of age (adjusted for gestational age) who meet all of the following criteria:

- Low birth weight (<1500g) OR with severe underlying gastrointestinal disease
- Human donor milk was continued through neonatal hospital discharge for a clear medical indication
- Persistent outpatient medical need for human donor breast milk due to ongoing severe concerns with persistent diarrhea or malabsorption with improvement on breast milk compared to formula
- When maternal breast milk is not available, appropriate or sufficient to meet the infant's needs, despite lactation support for the mother.

Donor human milk may only be obtained through a milk bank with appropriate quality and infection control standards.

Recommendations:
Consider modifying the guideline note to:

GUIDELINE NOTE 183 DONOR BREAST MILK FOR HIGH RISK INFANTS

Line 16, 34, 88, 101

Donor breast milk (T2101) is included on these lines for infants up to 6 months of age (adjusted for gestational age) who meet all of the following criteria:

- Low birth weight (<1500g) OR with severe underlying gastrointestinal disease
- Human donor milk was continued through neonatal hospital discharge for a clear medical indication
- Persistent outpatient medical need for human donor breast milk (such as, but not limited to, ~~due to ongoing severe concerns with~~ persistent

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diarrhea or malabsorption with improvement on breast milk compared to formula)

- When maternal breast milk is not available, appropriate or sufficient to meet the infant's needs, despite lactation support for the mother.

Donor human milk may only be obtained through a milk bank with ~~appropriate quality and infection control standards.~~ accreditation from the Human Milk Banking Association of North America (HMBANA).

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Question: Should the guideline on the Diabetes Prevention Program be modified?

Question source: Public Health, HSD, CCO Medical Directors

Issue:
There is currently a Diabetes Prevention Program (DPP) Implementation Workgroup which involves OHA staff and representation from multiple CCOs. As this workgroup is making it through various issues, they have raised a number of concerns for HERC to address.

1) Currently, intensive lifestyle counseling for patients with obesity and overweight (with cardiac risk factors) is technically covered on Line 320. However, many OHP patients may not currently be accessing this benefit. In discussions with CCOs about implementing the DPP benefit, they have expressed interest in using DPP interventions in patients who are obese but do not necessarily meet prediabetes criteria as specified in the new DPP guideline. Also, public health has asked about using CDC criteria which allows people to participate in the program who have risk factors, but do not necessarily have lab confirmation of prediabetes. Therefore, there is interest in clarifying that patients with obesity are also eligible for DPP who may not necessarily meet laboratory criteria.
2) There was a CCO question about whether history of gestational diabetes needed to be within the prior year or any history of gestational diabetes would be appropriate.
3) Additional clarity about pediatric overweight/obesity in the guideline note itself is necessary

Prioritized List Status

Relevant diagnostic codes

Code	Code Description	Current List Placement
E66.01	Morbid (severe) obesity due to excess calories	320 OBESITY IN ADULTS AND CHILDREN; OVERWEIGHT STATUS IN ADULTS WITH CARDIOVASCULAR RISK FACTORS 659 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
E66.09	Other obesity due to excess calories	320
E66.1	Drug-induced obesity	320
E66.2	Morbid (severe) obesity with alveolar hypoventilation	320
E66.3	Overweight	320
E66.8	Other obesity	320
E66.9	Obesity, unspecified	320

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Code	Code Description	Current List Placement
R73.03	Prediabetes	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
Z68.1	Body mass index (BMI) 19.9 or less, adult	Informational Diagnosis File
Z68.20	Body mass index (BMI) 20.0-20.9, adult	Informational Diagnosis File
Z68.21	Body mass index (BMI) 21.0-21.9, adult	Informational Diagnosis File
Z68.22	Body mass index (BMI) 22.0-22.9, adult	Informational Diagnosis File
Z68.23	Body mass index (BMI) 23.0-23.9, adult	Informational Diagnosis File
Z68.24	Body mass index (BMI) 24.0-24.9, adult	Informational Diagnosis File
Z68.25	Body mass index (BMI) 25.0-25.9, adult	Informational Diagnosis File
Z68.26	Body mass index (BMI) 26.0-26.9, adult	Informational Diagnosis File
Z68.27	Body mass index (BMI) 27.0-27.9, adult	Informational Diagnosis File
Z68.28	Body mass index (BMI) 28.0-28.9, adult	Informational Diagnosis File
Z68.29	Body mass index (BMI) 29.0-29.9, adult	Informational Diagnosis File
Z68.30	Body mass index (BMI) 30.0-30.9, adult	320 OBESITY IN ADULTS AND CHILDREN; OVERWEIGHT STATUS IN ADULTS WITH CARDIOVASCULAR RISK FACTORS
Z68.31	Body mass index (BMI) 31.0-31.9, adult	320
Z68.32	Body mass index (BMI) 32.0-32.9, adult	320
Z68.33	Body mass index (BMI) 33.0-33.9, adult	320
Z68.34	Body mass index (BMI) 34.0-34.9, adult	320
Z68.35	Body mass index (BMI) 35.0-35.9, adult	320
Z68.36	Body mass index (BMI) 36.0-36.9, adult	320
Z68.37	Body mass index (BMI) 37.0-37.9, adult	320
Z68.38	Body mass index (BMI) 38.0-38.9, adult	320
Z68.39	Body mass index (BMI) 39.0-39.9, adult	320
Z68.41	Body mass index (BMI) 40.0-44.9, adult	320
Z68.42	Body mass index (BMI) 45.0-49.9, adult	320
Z68.43	Body mass index (BMI) 50-59.9, adult	320
Z68.44	Body mass index (BMI) 60.0-69.9, adult	320
Z68.45	Body mass index (BMI) 70 or greater, adult	320
Z68.51	Body mass index (BMI) pediatric, less than 5th percentile for age	Diagnostic Workup File (DWF)
Z68.52	Body mass index (BMI) pediatric, 5th percentile to less than 85th percentile for age	Informational Diagnosis File
Z68.53	Body mass index (BMI) pediatric, 85th percentile to less than 95th percentile for age	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
Z68.54	Body mass index (BMI) pediatric, greater than or equal to 95th percentile for age	3 320
Z86.32	Personal history of gestational diabetes	1 Pregnancy 3

Treatment codes

0403T	Preventive behavior change, intensive program of prevention of diabetes using a standardized diabetes prevention program curriculum, provided to individuals in a group setting, minimum 60 minutes, per day	Line 3
0488T	Preventive behavior change, online/electronic intensive program of prevention of diabetes using a standardized diabetes prevention program curriculum, provided to an individual, per 30 days	Line 3
99411	Preventive medicine counseling and/or risk factor reduction intervention(s) provided to individuals in a group setting (separate procedure); approximately 30 minutes	On >500 lines, including line 320.
99412	Group prevention counseling	On >500 lines, including line 320.
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; 5-8 patients	1 Pregnancy 8 Type1 DM 27 Type 2 DM
98969	Online assessment and management service provided by a qualified nonphysician health care professional to an established patient or guardian, not originating from a related assessment and management service provided within the previous 7 days, using the Internet or similar electronic communications network	On >600 lines, including line 320

G9873	First Medicare Diabetes Prevention Program (MDPP) core session was attended by an MDPP beneficiary under the MDPP Expanded Model (EM). A core session is an MDPP service that: (1) is furnished by an MDPP supplier during months 1 through 6 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for core sessions	Line 3
G9874	Four total Medicare Diabetes Prevention Program (MDPP) core sessions were attended by an MDPP beneficiary under the MDPP Expanded Model (EM). A core session is an MDPP service that: (1) is furnished by an MDPP supplier during months 1 through 6 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for core sessions.	Line 3
G9875	Nine total Medicare Diabetes Prevention Program (MDPP) core sessions were attended by an MDPP beneficiary under the MDPP Expanded Model (EM). A core session is an MDPP service that: (1) is furnished by an MDPP supplier during months 1 through 6 of the MDPP services period; (2) is approximately 1	Line 3

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	hour in length; and (3) adheres to a CDC-approved DPP curriculum for core sessions	
G9876	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 7-9 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary did not achieve at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 7-9.	Line 3
G9877	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 10-12 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary did not achieve at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 10-12.	Line 3
G9878	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 7-9 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary achieved at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 7-9.	Line 3
G9879	Two Medicare Diabetes Prevention Program (MDPP) core maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 10-12 under the MDPP Expanded Model (EM). A core maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 7 through 12 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary achieved at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at a core maintenance session in months 10-12	Line 3
G9880	The MDPP beneficiary achieved at least 5% weight loss (WL) from his/her baseline weight in months 1-12 of the MDPP services period under the MDPP Expanded Model (EM). This is a one-time payment available when a beneficiary first achieves at least 5% weight loss from baseline as measured by an in-person weight measurement at a core session or core maintenance session.	Line 3

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G9881	The MDPP beneficiary achieved at least 9% weight loss (WL) from his/her baseline weight in months 1-24 under the MDPP Expanded Model (EM). This is a one-time payment available when a beneficiary first achieves at least 9% weight loss from baseline as measured by an in-person weight measurement at a core session, core maintenance session, or ongoing maintenance session.	Line 3
G9882	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 13-15 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 13-15.	Line 3
G9883	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 16-18 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 16-18.	Line 3
G9884	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 19-21 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 19-21.	Line 3
G9885	Two Medicare Diabetes Prevention Program (MDPP) ongoing maintenance sessions (MS) were attended by an MDPP beneficiary in months (mo) 22-24 under the MDPP Expanded Model (EM). An ongoing maintenance session is an MDPP service that: (1) is furnished by an MDPP supplier during months 13 through 24 of the MDPP services period; (2) is approximately 1 hour in length; and (3) adheres to a CDC-approved DPP curriculum for maintenance sessions. The beneficiary maintained at least 5% weight loss (WL) from his/her baseline weight, as measured by at least one in-person weight measurement at an ongoing maintenance session in months 22-24.	Line 3
G9890	Bridge Payment: A one-time payment for the first Medicare Diabetes Prevention Program (MDPP) core session, core maintenance session, or ongoing maintenance session furnished by an MDPP supplier to an MDPP beneficiary during months 1-24 of the MDPP Expanded Model (EM) who has previously	Line 3

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	received MDPP services from a different MDPP supplier under the MDPP Expanded Model. A supplier may only receive one bridge payment per MDPP beneficiary.	
G9891	MDPP session reported as a line-item on a claim for a payable MDPP Expanded Model (EM) HCPCS code for a session furnished by the billing supplier under the MDPP Expanded Model and counting toward achievement of the attendance performance goal for the payable MDPP Expanded Model HCPCS code.(This code is for reporting purposes only).	Line 3

Line: 3

Condition: PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS (See Coding Specification Below) (See Guideline Notes 1,17,64,65,106,122,140,179,181)

Treatment: MEDICAL THERAPY

ICD-10: R73.03,Z00.00-Z00.01,Z00.110-Z00.5,Z00.70-Z00.8,Z01.00-Z01.10,Z01.110-Z01.118, Z01.411-Z01.42,Z08,Z11.1-Z11.4,Z11.51,Z12.11,Z12.2,Z12.31,Z12.4,Z13.1,Z13.220,Z13.31-Z13.39,Z13.41-Z13.6,Z13.820,Z13.88,Z20.1-Z20.7,Z20.810-Z20.89,Z23,Z29.11-Z29.12, Z29.14,Z29.8,Z39.1,Z68.53-Z68.54,Z71.41,Z71.7,Z76.1-Z76.2,Z80.0,Z80.41,Z86.32,Z87.891, Z91.81

CPT: 0403T,0488T,44392,44394,45333,45338,45384,45385,76706,77067,90378,90460-90472, 90620,90621,90630-90689,90696-90716,90723-90736,90739-90748,90750,90756,92002-92014,92551,93792,93793,96110,96127,96150-96161,98962-98969,99051,99060,99070, 99078,99173,99188,99201-99215,99281-99285,99341-99378,99381-99404,99408-99449, 99451,99452,99487-99491,99495-99498,99605-99607

HCPCS: D0191,D1206,G0008-G0010,G0068,G0071,G0104,G0105,G0121,G0248-G0250,G0296, G0297,G0396,G0397,G0438-G0445,G0463-G0468,G0490,G0511,G0513,G0514,G2010-G2012,G9873-G9891,H0049,H0050,S0285,S0610-S0613,S9443

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

Line: 320

Condition: OBESITY IN ADULTS AND CHILDREN; OVERWEIGHT STATUS IN ADULTS WITH CARDIOVASCULAR RISK FACTORS (See Guideline Notes 5,8,64,65)

Treatment: BEHAVIORAL INTERVENTIONS INCLUDING INTENSIVE NUTRITIONAL AND PHYSICAL ACTIVITY COUNSELING; BARIATRIC SURGERY

ICD-10: E66.01-E66.9,Z46.51,Z68.30-Z68.45,Z68.54,Z71.3,Z71.82

CPT: 43644,43645,43771-43775,43846-43848,93792,93793,96150-96155,97802-97804,98966-98969,99051,99060,99070,99078,99201-99215,99281-99285,99341-99378,99381-99404, 99408-99449,99451,99452,99487-99491,99495-99498

HCPCS: G0068,G0071,G0248-G0250,G0270,G0271,G0396,G0397,G0447,G0463-G0467,G0473, G0490,G0511,G0513,G0514,G2010-G2012,S2083

GUIDELINE NOTE 5, OBESITY AND OVERWEIGHT

Line 320

Medical treatment of overweight (with known cardiovascular risk factors) and obesity in adults is limited to intensive counseling on nutrition and physical activity, provided by health care professionals. Intensive

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counseling is defined as face-to-face contact more than monthly. A multidisciplinary team is preferred, but a single clinician could also deliver intensive counseling in primary care or other settings.

Intensive counseling visits are included on this line for 6 months. Intensive counseling visits may continue for an additional 6 months (up to 12 months) as long as there is evidence of continued weight loss or improvement in cardiovascular risk factors based on the intervention. Maintenance visits at the conclusion of the intensive treatment are included on this line no more than monthly after this intensive counseling period. The characteristics of effective behavioral interventions include: high intensity programs; multicomponent (including at a minimum diet and exercise), group-based commercial programs; Mediterranean diet; and the following sub-elements -- calorie counting, contact with a dietician, and comparison to peers.

Known cardiovascular risk factors in overweight persons for which this therapy is effective include: hypertension, dyslipidemia, prediabetes, or the metabolic syndrome. Treatment of prediabetes with the Diabetes Prevention Program (DPP) is addressed on Line 3 in Guideline Note 179.

Medical treatment of obesity in children is limited to comprehensive, intensive behavioral interventions. For treatment of children up to 12 years old, interventions may be targeted only to parents, or to both parents and children.

Pharmacological treatments and devices (e.g. gastric balloons, duodenal jejunal bypass liners, and vagus nerve blocking devices) for obesity are not intended to be included as services on this line or any other line on the Prioritized List.

GUIDELINE NOTE 179, DIABETES PREVENTION PROGRAM

Line 3

Prediabetes (R73.03) and personal history of gestational diabetes (Z86.32) are included on this line only for the Diabetes Prevention Program (DPP). The only programs included are CDC-recognized lifestyle change programs for DPP.

To be eligible for referral to a CDC-recognized lifestyle change program, patients must meet the following requirements:

- Be at least 18 years old and
- Be overweight (body mass index ≥25; ≥23 if Asian) and
- Have no previous diagnosis of type 1 or type 2 diabetes and
- Not have end-stage renal disease and
- Have a blood test result in the prediabetes range within the past year:
    - Hemoglobin A1C: 5.7%–6.4% or
    - Fasting plasma glucose: 100–125 mg/dL or
    - Two-hour plasma glucose (after a 75 gm glucose load): 140–199 mg/dL or
    - Be previously diagnosed with gestational diabetes

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<u>HERC Staff Summary</u>

The Diabetes Prevention Program (DPP) is currently actively being made available to OHP members, however, patients with obesity but not prediabetes currently have limited access to the covered intensive lifestyle treatment. CCOs are interested in having

this streamlined benefit across obese and prediabetic populations. DPP would be an appropriate form of intensive lifestyle treatment. Aligning the obesity line and DPP coverage will improve access and clarify HERC intent to cover intensive lifestyle treatment for obesity, as well as make the benefit easier for CCOs to administer.

HERC Staff Recommendations:

1) Enable DPP to also be provided as an alternative to intensive lifestyle counseling on Line 320 (obese patients and overweight with risk factors excluding prediabetes)
2) **Code changes**
    a. Add DPP codes to the obesity line 320
        i. Add G9873 – G9885, and G9890-G9891
        ii. Add 0403T and 0488T
    b. Remove Z68.53-Z68.54 from Line 3 for pediatric overweight/obesity (i.e. for 18-19 year olds). Place on line 320.
        i. Rationale: Prediabetes or history of gestational diabetes would be the primary diagnosis code, the other obesity codes are not on Line 3.
    c. Add Z68.25- Z68.29 (overweight BMI codes) to Line 320
        i. Advise HSD to remove from informational file
    d. Remove E66.01 Morbid (severe) obesity due to excess calories from line 659
        i. Rationale: this seems like a relic
3) **Modify the DDP Guideline Note as follows**

    GUIDELINE NOTE 179 DIABETES PREVENTION PROGRAM

    Line 3

    Prediabetes (R73.03) and personal history of gestational diabetes (Z86.32) are included on this line only for the Diabetes Prevention Program (DPP). The only programs included are CDC-recognized lifestyle change programs for DPP.

    To be eligible for referral to a CDC-recognized lifestyle change program, patients must meet the following requirements:

    1) Be at least 18 years old and
    2) Be overweight (body mass index ≥25; ≥23 if Asian; BMI percentile ≥85th percentile for 18-19 years old) and
    3) Have no previous diagnosis of type 1 or type 2 diabetes and
    4) Not have end-stage renal disease and
    5) Have a blood test result in the prediabetes range within the past year:
        a. Hemoglobin A1C: 5.7%–6.4% or
        b. Fasting plasma glucose: 100–125 mg/dL or
        c. Two-hour plasma glucose (after a 75 gm glucose load): 140–199 mg/dL OR
        d. Have a previous diagnosis of gestational diabetes

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4) Modify the Obesity and Overweight Guideline Note 5 as follows:

GUIDELINE NOTE 5, OBESITY AND OVERWEIGHT

Line 320

Medical treatment of overweight (with known cardiovascular risk factors) and obesity in adults is limited to intensive counseling on nutrition and physical activity, provided by health care professionals. Intensive counseling is defined as face-to-face contact more than monthly. A multidisciplinary team is preferred, but a single clinician could also deliver intensive counseling in primary care or other settings.

Intensive counseling visits are included on this line for 6 months. Intensive counseling visits may continue for an additional 6 months (up to 12 months) as long as there is evidence of continued weight loss or improvement in cardiovascular risk factors based on the intervention.

Maintenance visits at the conclusion of the intensive treatment are included on this line no more than monthly after this intensive counseling period. The characteristics of effective behavioral interventions include: high intensity programs; multicomponent (including at a minimum diet and exercise), group-based commercial programs; Mediterranean diet; and the following sub-elements -- calorie counting, contact with a dietician, and comparison to peers.

Known cardiovascular risk factors in overweight persons for which this therapy is effective include: hypertension, dyslipidemia, prediabetes, or the metabolic syndrome.

Treatment of prediabetes with the Diabetes Prevention Program (DPP) is addressed on Line 3 in Guideline Note 179. The DPP program can be used as an alternative to the intensive counseling as above, even in the absence of prediabetes as required by Guideline Note 179.

Medical treatment of obesity in children is limited to comprehensive, intensive behavioral interventions. For treatment of children up to 12 years old, interventions may be targeted only to parents, or to both parents and children.

Pharmacological treatments and devices (e.g. gastric balloons, duodenal jejunal bypass liners, and vagus nerve blocking devices) for obesity are not intended to be included as services on this line or any other line on the Prioritized List.

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Failure to Thrive in Children

Question: Should the ICD-10 code for failure to thrive in children (R62.51) be added to the Prioritized List to allow for pairing with treatments?

Question sources: various providers and CCOs, Hearings Division

Issue: Failure to thrive (child) (ICD-10 R62.51) is currently on the Diagnostic Procedures File. Codes in the "R" region of ICD10 are generally signs and symptoms. Failure to thrive needs diagnostic testing, such as labs or radiologic studies, to rule out various causes. However, when no cause is identified, "failure to thrive" is frequently used as a diagnosis to allow hospitalization for observed feeding (to rule out social causes), and for other treatments. Multiple hospitalizations using this code have apparently been denied in recent years, as well as procedures such as G tube placement. ICD10 P92.6 (Failure to thrive in newborn) is on line 18 FEEDING PROBLEMS IN NEWBORNS.

Failure to thrive in a child is defined as 'lack of expected normal physical growth' or 'failure to gain weight'. Common causes of failure to thrive in children are malnutrition secondary to psychosocial and caregiver factors, child abuse or neglect, malabsorption due to various GI conditions, and congenital or chronic medical conditions. Common treatments when no specific cause is identified might be special formula, feeding consultation, lactation support, PT/OT, etc. When a specific cause is identified (e.g. Crohn's disease, congenital heart disease), then that diagnosis can be used, and should pair with appropriate treatments on the Prioritized List.

Other payer policies

1) Aetna 2018: lists R62.51 as an acceptable diagnosis for use with treatments such as speech therapy, feeding clinic visits, psychotherapy, and medical nutrition therapy
2) Regence BCBS 2018: lists R62.51 as an acceptable diagnosis for pairing with various therapies

HERC staff recommendation:

1) Add ICD10 R62.51 to line 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
    a. Allows hospital care, office visits, feeding clinic visits, PT/OT and G tube placement

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Procalcitonin

Question: Should procalcitonin be removed from Line 660 and added to the Diagnostic Procedures File?

Question source: HERC Staff

Issue: Procalcitonin was last reviewed in December 2009 and was placed on the Never Covered File as a new CPT code. It has subsequently moved to Line 660 based on insufficient evidence of effectiveness. In recent years there has been a dramatic upsurge in use of procalcitonin based on its proposed ability to help distinguish bacterial infections in the setting of acute illness. It is an inexpensive test (~$25).

Current Prioritized List Status

Code	Code Description	Current Line Placement
84145	Procalcitonin (PCT)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

Evidence Summary:

Shuetz, 2017

https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD007498.pub3/full

1. Cochrane systematic review of procalcitonin to initiate or discontinue antibiotics in acute respiratory tract infections
2. 32 eligible RCTs, individual participant data from 26 trials including 6708 participants contributed to individual level meta-analysis
3. Results:
    a. Lower mortality - There were 286 deaths in 3336 procalcitonin-guided participants (8.6%) compared to 336 in 3372 controls (10.0%), (adjusted OR 0.83, 95% CI 0.70 to 0.99, P = 0.037). [although couldn't look at primary care trials]
    b. No difference in treatment failure - procalcitonin-guided participants (23.0% versus 24.9% in the control group, adjusted OR 0.90, 95% CI 0.80 to 1.01, P = 0.068).
    c. Reduction in antibiotic exposure and side effects - procalcitonin guidance was associated with a 2.4-day reduction in antibiotic exposure (5.7 versus 8.1 days, 95% CI -2.71 to -2.15, P < 0.001) and lower risk of antibiotic-related side effects (16.3% versus 22.1%, adjusted OR 0.68, 95% CI 0.57 to 0.82, P < 0.001).
    d. No difference in length of hospital stay and intensive care unit stay

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4. Conclusions: The use of procalcitonin to guide initiation and duration of antibiotic treatment results in lower risks of mortality, lower antibiotic consumption, and lower risk for antibiotic-related side effects in patients with acute respiratory infections.

Huang, 2017
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5700008/pdf/13613_2017_Article_338.pdf

1. Systematic review and metanalysis of procalcitonin to guide antibiotic therapy in the ICU setting
2. 13 trials enrolling 5136 patients. These studies used PCT in three clinical strategies: initiation, discontinuation, or combination of antibiotic initiation and discontinuation strategies.
3. Pooled analysis showed a PCT-guided antibiotic discontinuation strategy had fewer total days with antibiotics (MD - 1.66 days; 95% CI - 2.36 to - 0.96 days), longer antibiotic-free days (MD 2.26 days; 95% CI 1.40-3.12 days), and lower short-term mortality (RR 0.87; 95% CI 0.76-0.98), without adversely affecting other outcomes. Only a few studies reported data on other PCT-guided strategies for antibiotic therapies, and the pooled results showed no benefit in the predefined outcomes.
4. Conclusions: our meta-analysis produced evidence that among all the PCT-based strategies, only using PCT for antibiotic discontinuation can reduce both antibiotic exposure and short-term mortality in a critical care setting.

Andriolo, 2017
https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010959.pub2/full

1. Cochrane systematic review of procalcitonin evaluation for reducing mortality in adults with sepsis, severe sepsis or septic shock
2. 10 trials with 1215 participants.
3. Low-quality evidence showed no significant differences in mortality at longest follow-up (risk ratio (RR) 0.81, 95% confidence interval (CI) 0.65 to 1.01; I^2 = 10%; 10 trials; N = 1156), at 28 days (RR 0.89, 95% CI 0.61 to 1.31; I^2 = 0%; four trials; N = 316), at ICU discharge (RR 1.03, 95% CI 0.50 to 2.11; I^2 = 49%; three trials; N = 506) and at hospital discharge (RR 0.98, 95% CI 0.75 to 1.27; I^2 = 0%; seven trials; N = 805; moderate-quality evidence). However, mean time receiving antimicrobial therapy in the intervention groups was -1.28 days (95% CI to -1.95 to -0.61; I^2 = 86%; four trials; N = 313; very low-quality evidence). No primary study has analysed the change in antimicrobial regimen from a broad to a narrower spectrum.

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4. Authors' conclusions: Up-to-date evidence of very low to moderate quality, with insufficient sample power per outcome, does not clearly support the use of procalcitonin-guided antimicrobial therapy to minimize mortality, mechanical ventilation, clinical severity, reinfection or duration of antimicrobial therapy of patients with septic conditions.

Westwood, 2015 *https://www.ncbi.nlm.nih.gov/books/NBK327098/*

1. Systematic review and cost-effectiveness of procalcitonin in the Emergency Department
2. 18 studies (36 reports) were included in the systematic review. All but one of the ED studies were in patients with respiratory symptoms.
3. PCT algorithms were associated with reduced antibiotic duration [WMD -3.19 days, 95% confidence interval (CI) -5.44 to -0.95 days, I (2) = 95.2%; four studies], hospital stay (WMD -3.85 days, 95% CI -6.78 to -0.92 days, I (2) = 75.2%; four studies) and a trend towards reduced intensive care unit (ICU) stay (WMD -2.03 days, 95% CI -4.19 to 0.13 days, I (2) = 81.0%; four studies). PCT algorithms were associated with a reduction in the proportion of adults (RR 0.77, 95% CI 0.68 to 0.87; seven studies) and children (RR 0.86, 95% CI 0.80 to 0.93) receiving antibiotics, reduced antibiotic duration (two studies).
4. There were no differences for adverse clinical outcomes.
5. PCT testing was cost-saving for (1) adults with confirmed or highly suspected sepsis in an ICU setting; (2) adults with suspected bacterial infection presenting to the ED; and (3) children with suspected bacterial infection presenting to the ED.
6. Conclusions: the limited available data suggest that PCT testing may be effective and cost-effective when used to guide discontinuation of antibiotics in adults being treated for suspected or confirmed sepsis in ICU settings and initiation of antibiotics in adults presenting to the ED with respiratory symptoms and suspected bacterial infection.

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HERC Staff Summary

Procalcitonin is a commonly used test to determine the need for antibiotics in Emergency Departments and ICU settings, and, in acute respiratory conditions, appears to be associated with a mortality benefit and fewer unnecessary antibiotic days.

Recommendations:

1) Delete 84145 Procalcitonin from Line 660, removing the entry in Guideline Note 173
2) Recommend HSD add 84145 to the Diagnostic Procedures File

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

Line 660

The following Interventions are prioritized on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

~~84145~~	~~Procalcitonin (PCT)~~	~~Insufficient evidence of effectiveness~~	~~December 2009~~

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Fecal Calprotectin

Question: Should fecal calprotectin (CPT 83993) be moved to a covered line or the Diagnostic List?

Question source: Alison Little, CCO medical director

Issue: Fecal calprotectin is currently on line 660/GN173, but no rationale for this listing is given. No mention was found in any minutes regarding why this CPT code was added to the Excluded List. Dr. Little is requesting that it be considered for coverage, as "it is used in monitoring inflammatory bowel disease, and…is not expensive."

The main diseases that cause an increased excretion of fecal calprotectin are inflammatory bowel diseases, coeliac disease, infectious colitis, necrotizing enterocolitis, intestinal cystic fibrosis and colorectal cancer. Fecal calprotectin is regularly used as an indicator for inflammatory bowel diseases (IBD) during treatment and as a diagnostic marker. Inflammatory processes result in an influx of neutrophils into the bowel lumen. Since calprotectin comprises as much as 60% of the soluble protein content of the cytosol of neutrophils, it can serve as a marker for the level of intestinal inflammation.

Fecal calprotectin testing has been proposed as a noninvasive test to diagnose inflammatory bowel disease (IBD). Other potential uses are to evaluate response to treatment for patients with IBD and as a marker of relapse. Fecal calprotectin testing has been used to distinguish between organic and functional intestinal disease.

Evidence

1) **Holtman 2016,** systematic review and meta-analysis of fecal calprotectin in pediatric inflammatory bowel disease
   http://pediatrics.aappublications.org/content/pediatrics/137/1/e20152126.full.pdf
   a. N=19 studies (N=2806), all appear to be case control or cohort
   b. Symptoms (abdominal pain, diarrhea, rectal bleeding, and weight loss) had pooled sensitivities ranging from 0.48 to 0.82 and specificities ranging from 0.17 to 0.78.
   c. Of all the blood markers, C-reactive protein (CRP) (9 studies) and albumin (6 studies) had the best performance, with pooled sensitivities of 0.63 (0.51–0.73) and 0.48 (0.31–0.66), respectively, and specificities of 0.88 (0.80–0.93) and 0.94 (0.86–0.98).
   d. Assessment of fecal calprotectin (FCal) (10 studies) had a pooled sensitivity of 0.99 (0.92–1.00) and a specificity of 0.65 (0.54–0.74). One limitation was that none of the studies was conducted in nonreferred children.
   e. CONCLUSIONS: In children whose pediatrician is considering an endoscopy, symptoms are not accurate enough to identify low-risk patients in whom an endoscopy can be avoided. FCal, CRP, and albumin findings are potentially of clinical value, given their ability to select children at low risk (negative FCal test result) or high risk (positive CRP or albumin test result) for IBD.
2) **Kostakis 2013**, systematic review of fecal calprotecin in diagnosing pediatric inflammatory bowel disease
   a. N=34 studies, appeared to be case control or cohort studies
   b. Fecal calprotectin levels of patients with inflammatory bowel disease are much higher than those of healthy controls or patients with functional disorders or other gastrointestinal diseases.
   c. High sensitivity and positive likelihood ratio, low negative likelihood ratio, but moderate specificity.

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   d. 50 lg/g seems to be the most proper cutoff point for the fecal calprotectin test.
   e. Conclusions: The fecal calprotectin test could be used for supporting diagnosis or confirming relapse of inflammatory bowel disease in pediatric patients. A positive result could confirm the suspicion of either inflammatory bowel disease diagnosis or inflammatory bowel disease relapse, due to the high sensitivity of the test, but a negative result should not exclude these conditions, due to its moderate specificity.
3) **Van Rheenen 2012**, systematic review and meta-analysis of fecal calprotectin for diagnosing inflammatory bowel disease in children, adolescents, and adults https://www.bmj.com/content/bmj/341/bmj.c3369.full.pdf
   a. N=13 studies
      i. N=6 in adults (670 patietns)
      ii. N=7 in children and teenagers (371 patients)
   b. Inflammatory bowel disease was confirmed by endoscopy in 32% (n=215) of the adults and 61% (n=226) of the children and teenagers. In the studies of adults, the pooled sensitivity and pooled specificity of calprotectin was 0.93 (95% confidence interval 0.85 to 0.97) and 0.96 (0.79 to 0.99) and in the studies of children and teenagers was 0.92 (0.84 to 0.96) and 0.76 (0.62 to 0.86).
   c. Screening by measuring faecal calprotectin levels would result in a 67% reduction in the number of adults requiring endoscopy. The downside of this screening strategy is delayed diagnosis in 6% of adults because of a false negative test result.
   d. In the population of children and teenagers, 65 instead of 100 would undergo endoscopy. Nine of them will not have inflammatory bowel disease, and diagnosis will be delayed in 8% of the affected children.
   e. Conclusion: Testing for faecal calprotectin is a useful screening tool for identifying patients who are most likely to need endoscopy for suspected inflammatory bowel disease. The discriminative power to safely exclude inflammatory bowel disease was significantly better in studies of adults than in studies of children.
4) **Mao 2012**, systematic review and meta-analysis of fecal calprotectin for predicting relapse of inflammatory bowel disease
   a. N=6 studies (672 patients), prospective cohort or case control
   b. The pooled sensitivity and specificity of fecal calprotectin (FC) to predict relapse of quiescent IBD was 78% (95% confidence interval [CI]: 72–83) and 73% (95% CI: 68–77), respectively. The area under the summary receiver-operating characteristic (sROC) curve was 0.83 and the diagnostic odds ratio was 10.31 (95% CI: 5.05–21.06). The capacity of FC to predict relapse was comparable between ulcerative colitis (UC) and Crohn's disease (CD).
   c. Conclusions: As a simple and noninvasive marker, FC is useful to predict relapse in quiescent IBD patients.

Cost effectiveness

1) **Yang 2014**, cost effectiveness of fecal calprotectin in diagnosis of IBD
   a. In adults, FC screening saved $417/patient but delayed diagnosis for 2.2/32 patients with IBD, among 100 screened patients. In children, FC screening saved $300/patient but delayed diagnosis for 4.8/61 patients with IBD, among 100 screened patients. If endoscopic biopsy analysis remained the standard for diagnosis, direct endoscopic evaluation would cost an additional $18,955 in adults and $6,250 in children to avoid 1 false negative result from FC screening. Sensitivity analyses showed that cost effectiveness of FC screening varied with the sensitivity of the test and the pre-test

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probability of IBD in adults and children. Pre-test probabilities for IBD of ≤75% in adults and ≤65% in children made FC screening cost-effective, but cost ineffective if the probabilities were ≥85% and ≥78% in adults and children, respectively.

b. **CONCLUSIONS—**Screening adults and children to measure fecal levels of calprotectin is effective and cost-effective in identifying those with IBD on a per-case basis when the pretest probability is ≤75% for adults and ≤65% for children. The utility of the test is greater for adults than children. Increasing the FC cut-off level to ≥50 µg/g increases diagnostic accuracy without substantially increasing total cost.

Expert guidelines

1) *American College of Gastroenterology* http://gi.org/wp-content/uploads/2018/04/ajg201827.pdf
    a. Management of Crohn's disease in adults guideline, 2018
        i. Diagnosis of adults:
            1. In patients who have symptoms of active Crohn's disease, stool testing should be performed to include fecal pathogens, *Clostridium difficile* testing, and may include studies that identify gut inflammation such as a fecal calprotectin.
            2. Fecal calprotectin is a helpful test that should be considered to help differentiate the presence of IBD from irritable bowel syndrome (IBS) (strong recommendation, moderate level of evidence).
        ii. Monitoring disease activity:
            1. Fecal calprotectin and fecal lactoferrin measurements may have an adjunctive role in monitoring disease activity.
            2. Levels of >100 µ g/g indicate endoscopic recurrence with a sensitivity in the range of 89%. In patients with an infliximab-induced remission, fecal calprotectin of >160 µ g/g has a sensitivity of 91.7% and a specificity of 82.9% to predict relapse.
    b. Management of ulcerative colitis in adults, 2010
        i. Calprotectin not mentioned
        ii. Currently guideline is under revision

Other policies:

Wellmark BCBS 2017: experimental

Aetna 2018: Aetna considers fecal measurement of calprotectin medically necessary for the management of inflammatory bowel diseases (e.g., Crohn's disease, ulcerative colitis) and for distinguishing inflammatory bowel diseases from irritable bowel syndrome

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Fecal Calprotectin

HERC staff summary: Fecal calprotectin appears to be a useful test for ruling out inflammatory bowel disease and thus avoiding endoscopy in adults and in children. It also appears to have a role in monitoring disease relapse. It is recommended for use in expert guidelines. It appears to be cost effective as a screening tool to rule out IBS and the need for endoscopy.

HERC staff recommendations:

1) Recommend HSD add fecal calprotectin (CPT 83993) to the Diagnostic Procedures File
2) Remove the fecal calprotectin (CPT 83993) entry on line 660/GN173

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

Line 660

The following Interventions are prioritized on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

~~83993~~	~~Calprotectin, fecal~~		

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Pulmonary Rehabilitation

Question: Should a guideline limiting pulmonary rehabilitation be added to the Prioritized List?

Question source: Tuality Healthcare CCO

Issue: Pulmonary rehabilitation is on multiple lines on the Prioritized List with no limitations on coverage. Pulmonary rehabilitation is a broad program that helps improve the well-being of people who have chronic respiratory conditions such as COPD (chronic obstructive pulmonary disease), sarcoidosis, idiopathic pulmonary fibrosis, or cystic fibrosis. Pulmonary rehabilitation is a multi-disciplinary treatment that might include exercise training, nutritional counseling, education, breathing strategies, psychological counseling, etc. Pulmonary rehabilitation is normally an outpatient therapy, but may be provided in a patient's home.

From Tuality Healthcare:

> I wanted to inquire if we could possibly get a Pulmonary Rehab guideline note designed? Currently there is no such thing, although Medicare covers Pulmonary Rehab when it is "moderate to very severe" which has many different definitions according to different resources, so we're a bit unsure if we should be using the FEV, the mMRC or the CAT scores to determine this ranking. Also currently Medicare covers up to 36 sessions over the patient's lifetime, so should we be using the same guidelines? Any coverage guidance within this subject would be incredibly helpful.

Current Prioritized List status:
G0237 (Therapeutic procedures to increase strength or endurance of respiratory muscles, face to face, one on one, each 15 minutes (includes monitoring)), G0238 (Therapeutic procedures to improve respiratory function, other than described by G0237, one on one, face to face, per 15 minutes (includes monitoring)), G0239 (Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring)), and S9437 (Pulmonary rehabilitation program, non-physician provider, per diem) are on the Ancillary Procedures File.

G0424 (Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day) is on lines 9 ASTHMA, 58 BRONCHIECTASIS,223 OCCUPATIONAL LUNG DISEASES, 234 ADULT RESPIRATORY DISTRESS SYNDROME; ACUTE RESPIRATORY FAILURE; RESPIRATORY CONDITIONS DUE TO PHYSICAL AND CHEMICAL AGENTS, 241 CONDITIONS REQUIRING HEART-LUNG AND LUNG TRANSPLANTATION, 283 CHRONIC OBSTRUCTIVE PULMONARY DISEASE; CHRONIC RESPIRATORY FAILURE.

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Evidence

1) **Puhan 2016**, Cochrane review of pulmonary rehabilitation for COPD
https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD005305.pub4/epdf/full
    a. N=20 studies (1477 patients)
    b. Eight studies involving 810 participants contributed data on hospital readmissions. Moderate-quality evidence indicates that pulmonary rehabilitation reduced hospital readmissions (pooled odds ratio (OR) 0.44, 95%confidence interval (CI) 0.21 to 0.91), but results were heterogenous (I2 = 77%).
    c. Six studies including 670 participants contributed data on mortality. The quality of evidence was low, and the meta-analysis did not show a statistically significant effect of rehabilitation on mortality (pooled OR 0.68, 95% CI 0.28 to 1.67). Again, results were heterogenous (I2 = 59%).
    d. Hospital readmissions and mortality studies newly included in this update showed, on average, significantly smaller effects of rehabilitation than were seen in earlier studies.
    e. High-quality evidence suggests that pulmonary rehabilitation after an exacerbation improves health-related quality of life.
    f. Five studies involving 278 participants explicitly recorded adverse events, four studies reported no adverse events during rehabilitation programmes and one study reported one serious event.
    g. **Authors' conclusions** Overall, evidence of high quality shows moderate to large effects of rehabilitation on health-related quality of life and exercise capacity in patients with COPD after an exacerbation. Some recent studies showed no benefit of rehabilitation on hospital readmissions and mortality and introduced heterogeneity as compared with the last update of this review. Such heterogeneity of effects on hospital readmissions and mortality may be explained to some extent by the extensiveness of rehabilitation programmes and by the methodological quality of the included studies.
2) **Dowman 2014,** Cochrane review of pulmonary rehabilitation for interstitial lung disease
https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD006322.pub3/epdf/full
    a. N=9 studies
    b. No adverse effects of pulmonary rehabilitation were reported.
    c. Pulmonary rehabilitation improved the six-minute walk distance with weighted mean difference (WMD) of 44.34 meters (95% confidence interval (CI) 26.04 to 62.64 meters) vs -0.4 to 17 meters for control patients [note: clinically meaningful improvement for this test is defined as a >30 meter gain] and improved oxygen consumption (VO2) peak with WMD of 1.24 mL/kg/min (95% CI 0.46 to 2.03 mL/kg/min) vs -0.02 to 0.4 ml/kg/min for controls.
    d. Quality of life improved following pulmonary rehabilitation for all participants on a variety of measures (SMD 0.59, 95% CI 0.20 to 0.98)
    e. Two studies reported longer-term outcomes, with no significant effects of pulmonary rehabilitation on clinical variables or survival at three or six months.
    f. **Authors' conclusions:** Pulmonary rehabilitation seems to be safe for people with ILD. Improvements in functional exercise capacity, dyspnoea and quality of life are seen immediately following pulmonary rehabilitation. Because of inadequate reporting of methods and small numbers of included participants, the quality of evidence was low to moderate. Little evidence was available regarding longer-term effects of pulmonary rehabilitation.

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Expert guidelines

1) **ACCP/AACVPR 2007,** evidence based guideline on pulmonary rehabilitation https://journal.chestnet.org/article/S0012-3692(16)30215-X/pdf
    a. A program of exercise training of the muscles of ambulation is recommended as a mandatory component of pulmonary rehabilitation for patients with COPD. Grade of recommendation, 1A
    b. Pulmonary rehabilitation improves the symptom of dyspnea in patients with COPD: Grade of recommendation, 1A
    c. Pulmonary rehabilitation improves health related quality of life in patients with COPD. Grade of recommendation, 1A
    d. Pulmonary rehabilitation reduces the number of hospital days and other measures of health-care utilization in patients with COPD. Grade of recommendation, 2B
    e. Pulmonary rehabilitation is cost-effective in patients with COPD. Grade of recommendation, 2C
    f. There is insufficient evidence to determine whether pulmonary rehabilitation improves survival in patients with COPD. No recommendation is provided.
    g. There are psychosocial benefits from comprehensive pulmonary rehabilitation programs in patients with COPD. Grade of recommendation, 2B
    h. Six to twelve weeks of pulmonary rehabilitation produces benefits in several outcomes that decline gradually over 12 to 18 months. Grade of recommendation, 1A. Some benefits, such as HRQOL, remain above control levels at 12 to 18 months. Grade of recommendation, 1C
    i. Longer pulmonary rehabilitation programs (beyond 12 weeks) produce greater sustained benefits than shorter programs. Grade of recommendation, 2C
    j. Maintenance strategies following pulmonary rehabilitation have a modest effect on long-term outcomes. Grade of recommendation, 2C
    k. Education should be an integral component of pulmonary rehabilitation. Education should include information on collaborative self-management, and the prevention and treatment of exacerbations. Grade of recommendation, 1B
    l. Pulmonary rehabilitation is beneficial for patients with some chronic respiratory diseases other than COPD. Grade of recommendation, 1B
2) **British Thoracic Society 2013**, guideline on pulmonary rehabilitation in adults https://www.brit-thoracic.org.uk/document-library/clinical-information/pulmonary-rehabilitation/bts-guideline-for-pulmonary-rehabilitation/
    a. As a minimum, efficacy of pulmonary rehabilitation programmes needs to be regularly assessed by demonstrating clinically important improvements in exercise capacity, dyspnoea and health status. (Grade B)
    b. Patients with a Medical Research Council (MRC) Dyspnoea score of 3–5 who are functionally limited by breathlessness should be referred for outpatient pulmonary rehabilitation. (Grade A)
    c. Patients with a MRC dyspnoea score of 2 who are functionally limited by breathlessness should be referred for pulmonary rehabilitation. (Grade D)
    d. Patients with a MRC dyspnoea score of 5 who are housebound should not routinely be offered supervised pulmonary rehabilitation within their home. (Grade B)

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e. Patients with unstable cardiac disease or locomotor difficulties that preclude exercise (eg, severe arthritis or severe peripheral vascular disease) should not be referred for pulmonary rehabilitation.
f. Pulmonary rehabilitation programmes should be a minimum of twice-weekly supervised sessions. (Grade D)
g. Pulmonary rehabilitation programmes of 6–12 weeks are recommended. (Grade A)
h. Pulmonary rehabilitation programmes including the attendance at a minimum of 12 supervised sessions are recommended, although individual patients can gain some benefit from fewer sessions. (Grade A)
i. Repeat pulmonary rehabilitation should be considered in patients who have completed a course of pulmonary rehabilitation more than 1 year previously. The likely benefits should be discussed and willing patients referred. (Grade B)
j. Earlier repeat pulmonary rehabilitation should be considered in individuals with accelerated physiological decline or if additional benefits on a shorter timescale would be clinically valuable. (Grade D)
k. It is unlikely that if the patient completed the pulmonary rehabilitation course originally and failed to gain a benefit, they would benefit a second time round, unless circumstances such as an exacerbation interrupted the initial programme.

3) **Canadian Thoracic Society 2010**, guideline on pulmonary rehabilitation https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2933771/pdf/crj17159.pdf
   a. Length of rehabilitation program:
      i. based on limited evidence from six studies and consensus of the expert panel
      ii. it is recommended that longer PR programs, beyond six to eight weeks duration, be provided for COPD patients. (GRADE: 2B)
   b. Which patients benefit from pulmonary rehabilitation?
      i. based on evidence from five studies and consensus of the expert panel.
      ii. Evidence supports PR for patients with moderate, severe and very severe COPD (GRADE: 1C)
      iii. There are insufficient data to make a recommendation regarding patients with mild COPD
      iv. It is uncertain whether prescribing PR to all patients regardless of disease severity is cost effective
   c. Should patients start PR within one month of an acute exacerbation of COPD?
      i. It is strongly recommended that COPD patients undergo pulmonary rehabilitation within one month following an AECOPD due to evidence supporting improved dyspnea, exercise tolerance and health related quality of life compared with usual care (GRADE 1B)
      ii. Pulmonary rehabilitation within one month following an AECOPD is also recommended due to evidence supporting reduced hospital admissions and mortality compared with usual care (GRADE 2C)

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<u>Other coverage policies</u>

1) **CMS 2010**, NCD for pulmonary rehabilitation
   a. Pulmonary rehabilitation is covered if is it a physician–supervised, comprehensive PR program for patients with moderate to very severe COPD. Medicare will pay for up to two (2) one-hour sessions per day, for up to 36 lifetime sessions (in some cases, up to 72

lifetime sessions) of PR. The PR program must include the following mandatory components:

i. Physician-prescribed exercise;
ii. Education or training;
iii. Psychosocial assessment;
iv. Outcomes assessment; and
v. An individualized treatment plan.

2) **NICE 2016**, management of COPD https://www.nice.org.uk/guidance/qs10/resources/chronic-obstructive-pulmonary-disease-in-adults-pdf-2098478592709
   a. People with stable COPD and exercise limitation due to breathlessness are referred to a pulmonary rehabilitation programme.
      i. Rationale: Pulmonary rehabilitation programmes improve a person's exercise capacity, quality of life, symptoms and levels of anxiety and depression
   b. People admitted to hospital for an acute exacerbation of COPD start a pulmonary rehabilitation programme within 4 weeks of discharge.
   c. Programmes comprise individualised exercise programmes and education, and:
      i. are at least 6 weeks in duration and include a minimum of twice-weekly supervised sessions
      ii. include supervised, individually tailored and prescribed, progressive exercise training including both aerobic and resistance training
      iii. include a defined, structured education programme.
   d. Pulmonary rehabilitation is not suitable for people with unstable cardiac disease, locomotor or neurological difficulties precluding exercise such as severe arthritis or peripheral vascular disease, and people in a terminal phase of an illness or with significant cognitive or psychiatric impairment.

3) Aetna 2018
   a. Aetna considers entry into a medically supervised outpatient pulmonary rehabilitation program medically necessary when *all* of the following criteria are met:
      i. Member has chronic pulmonary disease (including alpha-1 antitrypsin deficiency, asbestosis, asthma, emphysema, chronic airflow obstruction, chronic bronchitis, cystic fibrosis, fibrosing alveolitis, pneumoconiosis, pulmonary alveolar proteinosis, pulmonary fibrosis, pulmonary hemosiderosis, radiation pneumonitis), or other conditions that affect pulmonary function such as ankylosing spondylitis, bronchopulmonary dysplasia, Guillain-Barre' syndrome or other infective polyneuritis, muscular dystrophy, myasthenia gravis, paralysis of diaphragm, sarcoidosis, or scoliosis; *and*
      ii. Member has dyspnea at rest or with exertion; *and*
      iii. Member has a reduction in exercise tolerance that restricts the ability to perform activities of daily living and/or work; *and*
      iv. Symptoms persist despite appropriate medical management; *and*
      v. Member does not have a recent history of smoking or has quit smoking for at least 3 months; *and*
      vi. Member has a moderate to severe functional pulmonary disability as evidenced by *either* of the following:
         1. A maximal pulmonary exercise stress test under optimal bronchodilatory treatment which demonstrates a respiratory limitation to exercise with a maximal oxygen uptake (VO2max) equal to or less than 20 ml/kg/min, or about 5 metabolic equivalents (METS); *or*

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2. Pulmonary function tests showing that either the forced expiratory volume in one second (FEV1), forced vital capacity (FVC), FEV1/FVC ratio, or diffusion capacity for carbon monoxide (Dlco) is less than 60 % of that predicted; *and*

vii. Member is physically able, motivated and willing to participate in the pulmonary rehabilitation program and be a candidate for self-care post program; *and*

viii. Member does not have *any* concomitant medical condition that would otherwise imminently contribute to deterioration of pulmonary status or undermine the expected benefits of the program (e.g., symptomatic coronary artery disease, congestive heart failure, myocardial infarction within the last 6 months, dysrhythmia, active joint disease, claudication, malignancy).

b. Aetna considers pulmonary rehabilitation medically necessary for persons receiving a medically necessary lung transplantation

c. Aetna considers repeat pulmonary rehabilitation programs not medically necessary. However, exceptions may be made for patients undergoing a repeat pulmonary rehabilitation program in connection with lung transplantation or lung volume reduction surgery.

d. Aetna considers pre-operative pulmonary rehabilitation in persons undergoing surgery for lung cancer experimental and investigational because the effectiveness of this approach has not been established.

e. Pulmonary rehabilitation is *not* considered medically necessary in persons who have very severe pulmonary impairment as evidenced by dyspnea at rest, difficulty in conversation (one-word answers), inability to work, cessation of most of all usual activities making them housebound and often limiting them to bed or chair with dependency upon assistance from others for most ADL. According to available guidelines, persons with very severe pulmonary impairment are not appropriate candidates for pulmonary rehabilitation.

f. A typical course of pulmonary rehabilitation extends for up to 6 weeks or 36 hours of therapy.

g. Coverage of pulmonary rehabilitation may be subject to applicable limits on short-term rehabilitation.

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<u>CCO feedback to proposed guideline:</u>

1) The only comment received was that some CCOs do not PA pulmonary rehabilitation because it is underutilized. The guideline was felt be appropriate.

Pulmonary Rehabilitation

HERC staff summary

Pulmonary rehabilitation programs have evidence of benefit for increased quality of life and increased exercise ability in patients with a variety of chronic respiratory illnesses. There is mixed or insufficient evidence of effectiveness for decreasing hospitalizations and improving mortality.

Most expert guideline and other payer policies recommend pulmonary rehabilitation for moderate or severe respiratory disease for patients without severe comorbid conditions or who are not housebound. Pulmonary rehabilitation must be a multidisciplinary program including exercise and education. Most recommendations are for a minimum of 2 sessions per week for 6-12 weeks. US policies generally limit pulmonary rehabilitation to 36 hours. Repeat pulmonary rehabilitation programs should be limited to those patients who successfully completed a previous program more than one year prior, particularly if that patient has lung surgery; although there is no evidence of benefit of repeat programs.

HERC staff recommendations

1) Add pulmonary rehabilitation HCPCS codes to lines with chronic pulmonary disease diagnoses
    a. HCPCS codes:
        i. G0237 (Therapeutic procedures to increase strength or endurance of respiratory muscles, face to face, one on one, each 15 minutes (includes monitoring))
        ii. G0238 (Therapeutic procedures to improve respiratory function, other than described by G0237, one on one, face to face, per 15 minutes (includes monitoring))
        iii. G0239 (Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring))
        iv. S9437 (Pulmonary rehabilitation program, non-physician provider, per diem) are on the Ancillary Procedures File.
        v. Note: G0424 is already on the lines below
    b. Lines:
        i. 9 ASTHMA
        ii. 58 BRONCHIECTASIS
        iii. 223 OCCUPATIONAL LUNG DISEASES
        iv. 234 ADULT RESPIRATORY DISTRESS SYNDROME; ACUTE RESPIRATORY FAILURE; RESPIRATORY CONDITIONS DUE TO PHYSICAL AND CHEMICAL AGENTS
        v. 241 CONDITIONS REQUIRING HEART-LUNG AND LUNG TRANSPLANTATION
        vi. 283 CHRONIC OBSTRUCTIVE PULMONARY DISEASE; CHRONIC RESPIRATORY FAILURE.
2) Add a new guideline for pulmonary rehabilitation as shown below

GUIDELINE NOTE XXX, PULMONARY REHABILITATION

Lines 9,58,234,241,283

Pulmonary rehabilitation is included on these lines only for patients with all of the following:

1) moderate to severe chronic pulmonary disease with dyspnea with exertion that reduces their ability to perform activities of daily living despite appropriate medical management, *and*
2) moderate to severe pulmonary disability defined as either
    a. A maximal pulmonary exercise stress test under optimal bronchodilatory treatment which demonstrates a respiratory limitation to exercise with a maximal oxygen

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uptake (VO2max) equal to or less than 20 ml/kg/min, or about 5 metabolic equivalents (METS); *or*

b. Pulmonary function tests showing that either the forced expiratory volume in one second (FEV1), forced vital capacity (FVC), FEV1/FVC ratio, or diffusion capacity for carbon monoxide (Dlco) is less than 60 % of that predicted; *and*

3) physically able, motivated and willing to participate in the pulmonary rehabilitation program and be a candidate for self-care post program; *and*
4) no contraindications to pulmonary rehabilitation, including unstable cardiac disease, locomotor or neurological difficulties precluding exercise, significant cognitive or psychiatric impairment, or housebound due to the severity of disease.

Pulmonary rehabilitation is only covered for

1) A multidisciplinary program with includes supervised exercise therapy, patient education, and smoking cessation (if applicable).
2) A minimum of 2 session per week for 6-12 weeks.

Repeat pulmonary rehabilitation programs should be limited to those patients who successfully completed a previous program more than one year prior and who have had a significant change in their health status.

Portions of the pulmonary rehabilitation program that include services in GUIDELINE NOTE 6, REHABILITATIVE AND HABILITATIVE THERAPIES are included in the visit totals in that guideline.

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Errata
March 2019

1) The USPSTF recommendation date in GN106 was updated to reflect changes in effect as of January 1, 2018, in accordance to ACA requirements.

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Lines 3,619

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, 2018.
   1) http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/
   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 on December 20, 2016. Available at https://www.hrsa.gov/womens-guidelines-2016/index.html as of 3/6/2019.

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.

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Consent Agenda Issues—March 2019

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
Q66.21	Congenital metatarsus primus varus	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS. 540 DEFORMITIES OF FOOT	ICD10 Q66.21 is a foot deformity where the first metatarsal bone is rotated and angled away from the second metatarsal bone. This predisposes patients to develop bunions. It is not treated by itself; the bunion, if it develops, would be treated. Q66.21 is currently on line 359. Bunion surgery as well as ICD-10 Q22.1 (Hallux valgus (acquired)) are on line 540.	Remove Q66.21 from line 359 Add Q66.21 to line 540
28292	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with resection of proximal phalanx base, when performed, any method	356 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE	CPT 28292 is on both lines 365 and line 540. All other bunionectomy codes (i.e. 28295-28299) are only on line 540.	Remove 28292 from line 356
R33.8	Other retention of urine	Diagnostic Workup File (DWF) Line 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION	While a diagnostic code, sometimes urinary retention may not require further workup and just needs ongoing management with interventions like Foley catheters and/or bladder training. By placement on DWF rather than being on a line, it is impeding chronic management of urinary retention.	Add R33.8 on Line 327 Keep R33.8 on the Diagnostic Workup File
H04.55 H04.56	Acquired stenosis of nasolacrimal duct Stenosis of right lacrimal punctum	393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN	GN134 specifies when nasolacrimal duct obstruction can be treated on line 393. However, line 393 is missing several ICD10 codes for nasolacrimal duct obstruction.	Add the H04.55 and H04.56 code series to line 393

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Consent Agenda Issues—March 2019

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
44186	Laparoscopy, surgical; jejunostomy (eg, for decompression or feeding)	157 CANCER OF COLON, RECTUM, SMALL INTESTINE AND ANUS	CPT 44186 is on various lines for cancers of the upper GI tract, but not line 157. Similar code 44186 is on line 157.	Add 44186 to line 157

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Straightforward Guideline Note Changes
March 2019

1) An additional CPT code for tympanostomy tubes that appears on line 389 needs to be added to Guideline Note 29
    a. CPT 69433 (Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia)

GUIDELINE NOTE 29, TYMPANOSTOMY TUBES IN ACUTE OTITIS MEDIA

Line 389

Tympanostomy tubes (CPT 69433, 69436) are only included on this line as treatment for:

A) recurrent acute otitis media (three or more well-documented and separate episodes in six months or four or more well-documented and separate episodes in the past 12 months with at least one episode in the past six months) in patients who have unilateral or bilateral middle ear effusion at the time of assessment for tube candidacy, or
B) patients with complicating conditions (immunocompromised host, meningitis by lumbar puncture, acute mastoiditis, sigmoid sinus/jugular vein thrombosis by CT/MRI/MRA, cranial nerve paralysis, sudden onset dizziness/vertigo, need for middle ear culture, labyrinthitis, or brain abscess).

Patients with craniofacial anomalies, Down's syndrome, cleft palate, permanent hearing loss of 25dB or greater independent of otitis media with effusion, and patients with speech and language delay may be considered for tympanostomy if unresponsive to appropriate medical treatment or having recurring infections (without needing to meet the strict "recurrent" definition above).

Removal of retained tympanostomy tubes requiring anesthesia (CPT code 69424) or as an office visit, is included on Line 422 as a complication, pairing with ICD-10-CM H74.8.

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.

2) When Diagnostic Guideline D1 was amended to remove the cancer-related tests, there was a reference to section F1 that was not corrected to be section E1 (former section E1 was removed to become the new cancer-related genetic testing guideline)

DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE

A) Genetic tests are covered as diagnostic, unless they are listed below in section ~~F1~~ E1 as excluded or have other restrictions listed in this guideline. To be covered, initial screening (e.g. physical exam, medical history, family history, laboratory studies, imaging studies) must indicate that the chance of genetic abnormality is > 10% and results would do at least one of the following:
    1) Change treatment,
    2) Change health monitoring,
    3) Provide prognosis, or
    4) Provide information needed for genetic counseling for patient; or patient's parents, siblings, or children

…

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E) Related to other tests with specific CPT codes:
   1) Certain genetic tests have not been found to have proven clinical benefit.

3) There is an "or" missing in GN36.

GUIDELINE NOTE 36, ADENOTONSILLECTOMY FOR INDICATIONS OTHER THAN OBSTRUCTIVE SLEEP APNEA

Lines 42,47,368,548

Tonsillectomy/adenotonsillectomy is an appropriate treatment for patients with:

A) Five documented attacks of strep tonsillitis in a year or 3 documented attacks of strep tonsillitis in each of two consecutive years where an attack is considered a positive culture/screen and where an appropriate course of antibiotic therapy has been completed; or
B) Peritonsillar abscess requiring surgical drainage; or,
C) Unilateral tonsillar hypertrophy in adults; unilateral tonsillar hypertrophy in children with other symptoms suggestive of malignancy.

ICD-10-CM J35.1 and J35.3 are included on Line 368 only for 1) unilateral tonsillar hypertrophy in adults and 2) unilateral tonsillar hypertrophy in children with other symptoms suggestive of malignancy. Bilateral tonsillar hypertrophy and unilateral tonsillar hypertrophy in children without other symptoms suggestive of malignancy are included only on Line 548.

See Guideline Note 118 for diagnosis and treatment of obstructive sleep apnea in children.

4) The new SI joint surgery line approved for the Biennial Review list effective 1/1/2020 needs references to guideline notes 6, 64, and 65.

LINE: XXX
CONDITION: SEVERE SACROILIITIS
TREATMENT: SURGICAL THERAPY

Attach GUIDELINE NOTE 6, REHABILITATIVE AND HABILITATIVE THERAPIES, GUIDELINE NOTE 64, PHARMACIST MEDICATION MANAGEMENT, and GUIDELINE NOTE 65, TELEPHONE AND EMAIL CONSULTATIONS

5) The new line for hidradenitis suppurativa approved for the Biennial review list 1/1/2020 needs references to guideline notes 64 and 65.

Line: XXX
CONDITION: MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

Attach GUIDELINE NOTE 64, PHARMACIST MEDICATION MANAGEMENT, and GUIDELINE NOTE 65, TELEPHONE AND EMAIL CONSULTATIONS

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Pulmonary Rehabilitation

Question: Should a guideline limiting pulmonary rehabilitation be added to the Prioritized List?

Question source: VbBS

Issue: Pulmonary rehabilitation was discussed at the January 2019 VbBS meeting. Based on a review of the evidence and expert guidelines, the VbBS agreed with the staff recommendation to add a new pulmonary rehabilitation guideline, but requested further staff research into 1) the indications for repeat pulmonary rehabilitation (such as lung reduction surgery or lung transplant), and 2) whether a total number of sessions per week or total number of hours allowed should be added to the guideline based on other expert guidelines.

Pulmonary rehabilitation is currently is on multiple lines on the Prioritized List with no limitations on coverage. Pulmonary rehabilitation is a broad program that helps improve the well-being of people who have chronic respiratory conditions such as COPD (chronic obstructive pulmonary disease), sarcoidosis, idiopathic pulmonary fibrosis, or cystic fibrosis. Pulmonary rehabilitation is a multi-disciplinary treatment that might include exercise training, nutritional counseling, education, breathing strategies, psychological counseling, etc. Pulmonary rehabilitation is normally an outpatient therapy, but may be provided in a patient's home.

Current Prioritized List status:

HCPCS code	Code Description	Current Placement
G0237	Therapeutic procedures to increase strength or endurance of respiratory muscles, face to face, one on one, each 15 minutes	Ancillary Procedures File
G0238	Therapeutic procedures to improve respiratory function, other than described by G0237, one on one, face to face, per 15 minutes	Ancillary Procedures File
G0239	Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals	Ancillary Procedures File
G0424	Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session	9,58,223,234,241,283
S9473	Pulmonary rehabilitation program, non-physician provider, per diem	Ancillary Procedures File

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Pulmonary Rehabilitation

Expert guidelines on length of pulmonary rehabilitation

1) ACCP/AACVPR 2007: a minimum of 6 to 12 weeks. Longer pulmonary rehabilitation programs (beyond 12 weeks) produce greater sustained benefits than shorter programs. (GRADE: 2C)
2) British Thoracic Society 2013: Pulmonary rehabilitation programmes of 6–12 weeks are recommended.
3) Canadian Thoracic Society 2010: it is recommended that longer PR programs, beyond six to eight weeks duration, be provided for COPD patients. (GRADE: 2B)
4) NICE 2016: at least 6 weeks in duration and include a minimum of twice-weekly supervised sessions

Other payer guidelines on number of sessions/hours of pulmonary rehab

1) CMS 2010: Medicare will pay for up to two (2) one-hour sessions per day, for up to 36 lifetime sessions (in some cases, up to 72 lifetime sessions) of PR [pulmonary rehabilitation]
2) Aetna 2019: typical course of pulmonary rehabilitation extends for up to 6 weeks or 36 hours of therapy

Expert guidelines on repeat pulmonary rehabilitation

1) ACCP/AACVPR 2007: although repeated pulmonary rehabilitation interventions spaced 1 year apart led to significant short-term gains similar to those seen following an initial 8-week outpatient program, no additive, long-term physiologic benefits were noted in one study
1) British Thoracic Society 2013: Repeat pulmonary rehabilitation should be considered in patients who have completed a course of pulmonary rehabilitation more than 1 year previously.

Other payer guidelines on repeat pulmonary rehabilitation

1) Aetna 2019: Aetna considers repeat pulmonary rehabilitation programs not medically necessary. However, exceptions may be made for patients undergoing a repeat pulmonary rehabilitation program in connection with lung transplantation or lung volume reduction surgery.

<u>HERC staff summary</u>

The consensus among experts and other payers is that 36 hours of pulmonary rehabilitation is a standard recommendation, although additional clinical benefit may be gained from longer rehabilitation programs. There is no evidence that repeat pulmonary rehabilitation leads to significant additional long-term benefits. Other payers allow repeat pulmonary rehabilitation in extraordinary circumstances such as lung transplantation or lung volume reduction surgery.

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HERC staff recommendations

1) Add pulmonary rehabilitation HCPCS codes to lines with chronic pulmonary disease diagnoses
    a. HCPCS codes:
        i. G0237 (Therapeutic procedures to increase strength or endurance of respiratory muscles, face to face, one on one, each 15 minutes (includes monitoring))
        ii. G0238 (Therapeutic procedures to improve respiratory function, other than described by G0237, one on one, face to face, per 15 minutes (includes monitoring))
        iii. G0239 (Therapeutic procedures to improve respiratory function or increase strength or endurance of respiratory muscles, two or more individuals (includes monitoring))
        iv. S9473 (Pulmonary rehabilitation program, non-physician provider, per diem)
        v. Note: G0424 is already on the lines below
    b. Lines:
        i. 9 ASTHMA
        ii. 58 BRONCHIECTASIS
        iii. 223 OCCUPATIONAL LUNG DISEASES
        iv. 234 ADULT RESPIRATORY DISTRESS SYNDROME; ACUTE RESPIRATORY FAILURE; RESPIRATORY CONDITIONS DUE TO PHYSICAL AND CHEMICAL AGENTS
        v. 241 CONDITIONS REQUIRING HEART-LUNG AND LUNG TRANSPLANTATION
        vi. 283 CHRONIC OBSTRUCTIVE PULMONARY DISEASE; CHRONIC RESPIRATORY FAILURE
2) Add a new guideline for pulmonary rehabilitation as shown below

GUIDELINE NOTE XXX, PULMONARY REHABILITATION

Lines 9,58,223,234,241,283

Pulmonary rehabilitation is included on these lines only for patients with all of the following (1-4):

1) Moderate to severe chronic pulmonary disease with dyspnea with exertion that reduces their ability to perform activities of daily living despite appropriate medical management
2) Moderate to severe pulmonary disability defined as either
    a. A maximal pulmonary exercise stress test under optimal bronchodilatory treatment which demonstrates a respiratory limitation to exercise with a maximal oxygen uptake (VO2max) equal to or less than 20 ml/kg/min, or about 5 metabolic equivalents (METS); *or*
    b. Pulmonary function tests showing that either the forced expiratory volume in one second (FEV1), forced vital capacity (FVC), FEV1/FVC ratio, or diffusion capacity for carbon monoxide (DlCO) is less than 60 % of that predicted
3) Physically able, motivated and willing to participate in the pulmonary rehabilitation program and be a candidate for self-care post program
4) No contraindications to pulmonary rehabilitation, including unstable cardiac disease, locomotor or neurological difficulties precluding exercise, significant cognitive or psychiatric impairment, or housebound due to the severity of disease.

Pulmonary rehabilitation is only covered for:

1) A multidisciplinary program with includes supervised exercise therapy, patient education, and smoking cessation (if applicable).
2) Up to 36 total sessions.

Repeat pulmonary rehabilitation programs should be limited to those patients who have had a subsequent lung reduction surgery or lung transplantation.

VbBS Issue Summaries from 3-14-2019

Non-invasive Testing for Liver Fibrosis Guideline Update

Question: How should the guideline on non-invasive testing for liver fibrosis be updated given the change in coverage of hepatitis C treatments, regardless of level of liver fibrosis?

Question source: HERC Staff, P&T Staff

Issue: As of March 1, 2019, FFS is modifying its coverage criteria for direct acting antivirals (DAAs) to cover treatment regardless of fibrosis level. Because of the hepatitis C risk corridor, this will impact the entire OHP population.

There is a HERC Coverage Guidance and Guideline Note on appropriate diagnostic testing for liver fibrosis to guide treatment for hepatitis C. Given that specific levels of fibrosis will no longer be necessary to determine treatment, elements of this guideline are no longer necessary.

Clinically, now that F2 and F3 are no longer important criteria for a change in management, the major criteria that would change management is when a person develops F4 level disease, as this can change the length of indicated treatment for hepatitis C, or can change monitoring (such as screening for hepatocellular carcinoma). Ultrasound and serum biomarkers are commonly used for identification of cirrhosis and routinely guide this change in management. Other common conditions that can lead to cirrhosis include nonalcoholic fatty liver disease and nonalcoholic fatty liver steatohepatitis (NASH) and do not necessarily have an effective treatment beyond weight loss and avoidance of hepatotoxins. Intensive serial monitoring of liver fibrosis in these situations is therefore unlikely to yield significant improvements in health.

MR elastography is an expensive test that was only to be used in case of indeterminant results and unavailability of other tests. Access to this test no longer seems as necessary given that the critical impact to the patient (access to DAA treatment) would no longer be dependent on specific fibrosis scores. The cost-benefit of this test is likely significantly lowered.

Additional drugs will be on the market in the next few years for other causes of liver fibrosis/cirrhosis, for which distinguishing levels of fibrosis may still be important, making elements of this guideline possibly still useful. Some medical directors have expressed ongoing interest in having relevant components of the guideline remain in place, just modified given the DAA changes.

Excerpts from email conversation with Dr. Atif Zaman

> For F3 disease and receives DAA, consider monitoring fibrosis in 1 to 2 years to verify fibrosis has not progressed to F4.
>
> What about with non-hep C disease, like NASH? How often would you follow up to monitor progression to F4? No one knows the answer to this unfortunately. Typically is

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a NASH patient (or other etiology) with F1/2 and no follow up imaging is done unless there are signs of ongoing inflammation (ie liver enzymes rise of platelet count starts dropping). But this really can't be codified, since there is no evidence yet.

From Dr. Barry Schlanksy (email conversations)

Regarding HCV, I agree with Atif that F3 patients with SVR should undergo some sort of post-treatment monitoring, though there is no clear evidence-based approach to this. There is evidence that such patients have an HCC risk, albeit lower than HCV patients with F4/cirrhosis, and some centers perform biannual ultrasound-based liver cancer screening in this group. Another approach would be to perform a FibroScan 1-2 years after SVR as Atif suggested. Cat, I agree with your suggestion to permit annual noninvasive testing (especially VCTE) in F3 patients with HCV (including those who achieved SVR already).

The second question is the utility of noninvasive fibrosis testing in non-HCV chronic liver disease. The largest subgroup is NASH, but noninvasive fibrosis testing is frequently used for other chronic liver diseases as well. The most evidence for the various testing modalities is in NAFLD/NASH and hepatitis B. I disagree with the statement in the guideline that there is no recommendation for fibrosis assessment in NAFLD/NASH because there are no effective treatments at this time (there are effective treatments that are not pharmacologic, including lifestyle and risk factor modification/weight loss, bariatric surgery, etc). There is likely significant practice variation in how such fibrosis staging tests are used, but a common approach is to surveil patients with no or early fibrosis infrequently (or not at all), whereas those with F3/advanced fibrosis (but not yet cirrhosis) might be surveilled more often (e.g. q1-2 years, not just a single time as for HCV after SVR, because the disease process remains active and has not been 'cured'). Would it be possible to retain the coverage of noninvasive fibrosis testing no more than every 3 years for those who are <F3, along with the up to annual testing for F3?

Regarding repeat FibroScan for patients with <F3, I agree that there are no data to support subsequent fibrosis staging. Especially for patients who have developed moderate fibrosis (F2), it is common practice to repeat a FibroScan testing at some interval as the underlying disease process (NASH) has no cure and progression is therefore expected. Some providers may feel that such testing is not necessary and follow things like the liver tests or platelet count instead, however there is abundant evidence that elevation or normalization of liver tests do not correlate with liver fibrosis in NASH, and the platelet count only falls once the liver disease is very advanced. I believe a prudent strategy is to allow repeat FibroScan but at a less frequent interval than for F3 (e.g. q3 or q5 years). Regarding whether such a practice would change management - stability or progression in fibrosis after such a longer interval can

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provide useful information about the disease trajectory (for example, patients who remain F2 after 3-5 years may be offered more reassurance, whereas an F2 patient who progresses to F3 may be advised to pursue more aggressive NASH treatment, whether a more concerted effort at weight loss or referral for bariatric surgery or a clinical trial for pharmacologic therapy). I appreciate that there may be a difference of opinion here, and support whatever the HERC committee decides for this subgroup.

Finally, regarding MRE, the ultrasound based elastography techniques (VCTE, SWE) have a significant failure rate, especially in more obese patients (many of whom have NAFLD/NASH), and MRE does not. If a VCTE/SWE failure occurs and one suspects a patient may have aggressive disease/advanced fibrosis (in NAFLD, this assessment is based on risk factors such as older age, DM2, obesity, and high FIB-4, APRI, or NAFLD Fibrosis Score), and cirrhosis is not identified on routine imaging (ultrasound/CT/MRI), the only options to stage fibrosis are liver biopsy or MRE. The cost of liver biopsy (the procedure and pathology fees) is likely similar or higher than MRE, and biopsy is invasive. I believe that MRE still has an important role for staging such patients and would avoid a significant number of liver biopsies and associated (rare) procedural complications

For MRE, I agree that it has little benefit over other non-invasive fibrosis testing in NASH and it is not justified as a first-line test as an alternative to ultrasound-based elastography. It should be reserved for patients in whom ultrasound-based elastography fails as an alternative to liver biopsy. I agree that if the MRE shows fibrosis, it brings up the question of whether there is a role for subsequent MRE to monitor disease progression. MRE is a considerably more expensive and resource intensive test relative to FibroScan - although there are no data, I do not think MRE should be used for subsequent monitoring of fibrosis. Although the serum tests, including liver tests and platelet count, are less accurate than elastography in assessing (and monitoring) fibrosis progression, in this subgroup who cannot undergo FibroScan, lab monitoring and standard imaging (e.g. ultrasound) should be used despite their acknowledged deficiencies. I agree with and support your proposed MRE guideline.

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<u>Clinical background (from Coverage Guidance):</u>
Traditionally, staging of chronic hepatitis C infection was done by examining histologic specimens from liver biopsies of the liver for evidence of fibrosis. The METAVIR fibrosis stage is the most commonly used measure for assessing the histologic degree of hepatic fibrosis:

- F0 = No fibrosis
- F1 = Portal fibrosis without septa
- F2 = Portal fibrosis with few septa

- F3 = Portal fibrosis with numerous septa without cirrhosis
- F4 = Cirrhosis

Progression from fibrosis to cirrhosis is associated with complications of end-stage liver disease including portal hypertension, portosystemic encephalopathy, and hepatocellular carcinoma.

Current Prioritized List Status

GUIDELINE NOTE 76, DIAGNOSTIC TESTING FOR LIVER FIBROSIS TO GUIDE TREATMENT OF HEPATITIS C IN NON-CIRRHOTIC PATIENTS

Line 199

Given that a fibrosis score of ≥F2 is the threshold for antiviral treatment of Hepatitis C, the following are included on this line:

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

Blood tests (only if imaging tests are unavailable):
- Enhanced Liver Fibrosis (ELF™)
- Fibrometer™
- FIBROSpect® II
- FibroSure® (FibroTest®) or ActiTest®

If a fibrosis score of ≥F3 is the threshold for antiviral treatment of Hepatitis C, one or more of the following are included on this line:

Imaging tests:
- Transient elastography (FibroScan®)
- Acoustic radiation force impulse imaging (ARFI)
- Shear wave elastography (SWE)

Magnetic resonance elastography is included on this line for ≥F2 or ≥F3 only when at least one imaging test (FibroScan, ARFI, and SWE) has resulted in indeterminant results, a second one is similarly indeterminant, contraindicated or unavailable, and MRE is readily available.

The following tests are not included on this line (or any other line):
- Real time tissue elastography
- Hepascore (FibroScore)

Noninvasive tests are covered no more often than once per year.

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

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Updated discussion of MR elastography at the November 2018 VbBS/HERC meeting.

1) Magnetic resonance elastography
    a. CPT codes
        i. **76391** Magnetic resonance (eg, vibration) elastography
    b. Definition: Magnetic resonance elastography is a phase-contrast-based magnetic resonance imaging (MRI) technique that can directly visualize and quantitatively measure propagating acoustic strain waves in tissue subjected to harmonic mechanical excitation. The data acquired allows the calculation of local quantitative values of shear modulus and the generation of images that depict tissue elasticity or stiffness. MR elastography has mostly been studied in liver disease, although sporadic reports of evaluation of other conditions were found in the literature.
    c. Similar code CPT 91200 (Liver elastography, mechanically induced shear wave (eg, vibration), without imaging, with interpretation and report) is on line 199 CHRONIC HEPATITIS; VIRAL HEPATITIS
    d. Evidence
        i. **Singh 2017, https://www.gastrojournal.org/article/S0016-5085(17)30325-6/pdf** technical review of elastography for evaluation of liver disease
            1. MR elastography (MRE) vs vibration-controlled transient elastography (VCTE)
                a. Key Question 11. In adults with chronic HCV, is the overall diagnostic performance of MRE superior to VCTE for detection of cirrhosis?
                    i. Key message. In adults with HCV, MRE has little to no increased diagnostic accuracy in identifying cirrhosis in patients who truly have cirrhosis over VCTE, but has lower diagnostic accuracy in ruling out cirrhosis in patients who do not have cirrhosis, over VCTE (Very low quality of evidence).
                b. Question 12. In adults with non-alcoholic fatty liver disease (NAFLD), is the overall diagnostic performance of MRE superior to VCTE for detection of cirrhosis?
                    i. Key message. In adults with NAFLD, MRE has little to no increased diagnostic accuracy in identifying cirrhosis in patients who truly have cirrhosis over VCTE, but has considerably higher diagnostic accuracy in

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ruling out cirrhosis in patients who do not have cirrhosis, over VCTE (Very low quality of evidence).

ii. The technical report notes that there is limited consensus on when fibrosis assessment (regardless of modality) should be performed in patients suspected of having NAFLD, as there are very limited treatment options available to favorably modify the natural history of patients with NAFLD.

ii. **Singh 2015**, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4333001/pdf/nihms638933.pdf systematic review and meta analysis of MR elastography for staging liver fibrosis

1. N=12 retrospective studies (607 patients)
2. Mean AUROC values (and 95% confidence intervals) for diagnosis of any (≥stage 1), significant (≥stage 2), or advanced fibrosis (≥stage 3), and cirrhosis, were 0.84 (0.76–0.92), 0.88 (0.84–0.91), 0.93 (0.90–0.95), and 0.92 (0.90–0.94), respectively. Similar diagnostic performance was observed in stratified analysis based on sex, obesity, and etiology of CLD. The overall rate of failure of MRE was 4.3%.
3. Conclusion—Based on pooled analysis of data from individual participants, MRE has high accuracy for diagnosis of significant or advanced fibrosis and cirrhosis, independent of BMI and etiology of CLD. Prospective studies are warranted to better understand the diagnostic performance of MRE.

e. HERC staff summary: MR elastography does not add to the accuracy of standard liver elastography for the detection of cirrhosis in patients with hepatitis C. Based on very low quality of evidence, MR elastography may be superior to standard liver elastography for ruling out cirrhosis in non-alcoholic fatty liver disease, but there is no standard recommendation to conduct a fibrosis assessment in NAFLD as there is no effective treatment for that condition at this time. However, GN76, based on the hepatitis C coverage guidance, includes limited coverage for MR elastography of the liver.

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Evidence excerpts for distinguishing F4, from HERC Coverage Guidance

Table 2: Diagnostic Operating Characteristics of MRE

Fibrosis Stage	AUROC (95% CI)	Sensitivity	Specificity	Positive LR	Negative LR
Any: ≥F1	0.84 (0.76 - 0.92)	0.73	0.79	3.48	0.34
Significant: ≥F2	0.88 (0.84 - 0.91)	0.79	0.81	4.16	0.26
Advanced: ≥F3	0.93 (0.90 - 0.95)	0.85	0.85	5.67	0.18
Cirrhosis: F4	0.92 (0.90 - 0.94)	0.91	0.81	4.79	0.11

Table 3: Diagnostic Operating Characteristics of Transient Elastography

Fibrosis Stage	AUROC (95% CI)	Sensitivity	Specificity	Positive LR	Negative LR
Significant: ≥F2	0.89 (0.86 - 0.91)	0.76	0.86	5.43	0.28
Advanced: ≥F3	0.92 (0.89 - 0.94)	0.88	0.91	9.7	0.13
Cirrhosis: F4	0.94 (0.92 - 0.96)	0.85	0.91	9.4	0.16

Table 4: AUROC of Acoustic Radiation Force Impulse (ARFI) Imaging Tests

Fibrosis Stage	AUROC – HCV only studies (95% CI)	AUROC – Mixed studies (95% CI)
Significant: ≥F2	0.88 (0.81 - 0.96)	0.83 (0.80 - 0.86)
Advanced: ≥F3	0.93 (0.89 - 0.97)	0.87 (0.85 - 0.90)
Cirrhosis: F4	0.92 (0.85 - 0.99)	0.91 (0.89 - 0.93)

Table 8. Diagnostic Operating Characteristics for Shear Wave Elastography

Fibrosis Stage	AUROC (95% CI)	Sensitivity	Specificity	Positive LR	Negative LR
Significant: ≥F2	0.88 (0.85 - 0.91)	0.85	0.81	4.47	0.18
Advanced: ≥F3	0.94 (0.92 - 0.96)	0.90	0.81	4.73	0.12
Cirrhosis: F4	0.92 (0.89 - 0.94)	0.87	0.88	7.25	0.15

Table 9. Diagnostic Operating Characteristics for Real-Time Tissue Elastography

Fibrosis Stage	AUROC (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)	Positive LR (95% CI)	Negative LR (95% CI)
Significant: ≥F2	0.69 (NR)	0.79 (0.75 - 0.83)	0.76 (0.68 - 0.82)	3.29 (NR)	0.27 (NR)
Advanced: ≥F3	0.86 (NR)	0.82 (0.75 - 0.88)	0.81 0.72 - 0.88)	4.31 (NR)	0.22 (NR)
Cirrhosis: F4	0.72 (NR)	0.74 (0.63 - 0.82)	0.84 0.79 - 0.88)	4.6 (NR)	0.30 (NR)

Table 6: Studies of Blood Tests for Liver Fibrosis

Test	Number of studies	Strength of evidence	Fibrosis (≥F2) AUROC median (range)	Cirrhosis AUROC median (range)
Platelet count	18	Moderate	0.71 (0.38 - 0.94)	0.89 (0.64 - 0.99)
Hyaluronic acid	8	Moderate	0.75 (0.65 - 0.88)	0.90 (0.80 - 0.97)
Age-platelet index	11	Moderate	0.74 (0.64 - 0.79)	0.86 (0.64 - 0.91)
AST-platelet ratio index	7	High	0.77 (0.58 - 0.95)	0.84 (0.54 - 0.97)
AST-ALT ratio	32	High	0.59 (0.50- 0.82)	0.72 (0.52 - 0.91)
Bonacini index	12	Moderate	0.66 (0.58 - 0.71)	0.74 (0.61 - 0.91)
ELF™	8	Moderate	0.81 (0.72 - 0.87)	0.88 (0.78 - 0.91)
FIB-4	19	Moderate	0.74 (0.61 - 0.81)	0.87 (0.83 - 0.92)
FibroIndex	9	Moderate	0.76 (0.58 - 0.86)	0.86 (0.78 - 0.92)
Fibrometer™	8	Moderate	0.82 (0.78 - 0.85)	0.91 (0.89 - 0.94)
FIBROSpect® II	7	Low	0.86 (0.77 - 0.90)	NR
FibroTest®	32	High	0.79 (0.70 - 0.89)	0.86 (0.71 - 0.92)
Forns index	22	High	0.76 (0.60 - 0.86)	0.87 (0.85 - 0.91)
GUCI	5	Low	NR	0.82 (0.78 - 0.86)
Hepascore®	12	High	0.79 (0.69 - 0.82)	0.89 (0.88 - 0.94)
Lok index	10	Moderate	NR	0.80 (0.61 - 0.91)
Pohl index	12	Low	0.52 (0.52 - 0.53)	0.65 (0.64 - 0.66)

Guidelines from others

AASLD, 2018
https://www.aasld.org/sites/default/files/NAFLD%20Guidance%202018.pdf

- The Diagnosis and Management of Nonalcoholic Fatty Liver Disease: Practice Guidance From the American Association for the Study of Liver Diseases
- NAFLD is diagnosed by imaging findings
- The most important histological feature of NAFLD associated with long-term mortality is fibrosis; specifically, zone 3 sinusoidal fibrosis plus periportal fibrosis (stage 2) to advanced (bridging fibrosis [stage 3] or cirrhosis [stage 4]).
- In the recent meta-analysis, HF progression in patients with histological NASH at baseline showed a mean annual fibrosis progression rate of 0.09 (95% CI, 0.06-0.12).
- Incidentally discovered hepatic steatosis.. "the natural history and optimal diagnostic and management strategies for this patient population have not been investigated."
- The utility of noninvasively quantifying HS in patients with NAFLD in routine clinical care is limited.
- The commonly investigated noninvasive tools for the presence of advanced fibrosis in NAFLD include clinical decision aids (e.g., NAFLD fibrosis score, FIB-4 index, aspartate aminotransferase [AST] to platelet ratio index [APRI]), serum biomarkers (Enhanced Liver Fibrosis [ELF] panel, Fibrometer, FibroTest, and Hepascore), or imaging (eg, TE, MR elastography [MRE], acoustic radiation force impulse imaging, and supersonic shear wave elastography)
- Guidance statements (selected)
    - 4. Routine Screening for NAFLD in high-risk groups attending primary care, diabetes, or obesity clinics is not advised at this time because of uncertainties surrounding diagnostic tests and treatment options, along with lack of knowledge related to long-term benefits and cost-effectiveness of screening.
    - 5. There should be a high index of suspicion for NAFLD and NASH in patients with type 2 diabetes. Clinical decision aids such as NFS or fibrosis-4 index (FIB-4) or vibration controlled transient elastography (VCTE) can be used to identify those at low or high risk for advanced fibrosis (bridging fibrosis or cirrhosis).
    - 11. In patients with NAFLD, MetS [metabolic syndrome] predicts the presence of SH, and its presence can be used to target patients for a liver biopsy.
    - 12. NFS (age, BMI, hyperglycemia, platelet count, albumin, and AST/ALT ratio) or FIB-4 index are clinically useful tools for identifying NAFLD patients with higher likelihood of having bridging fibrosis (stage 3) or cirrhosis (stage 4).
    - 13. Vibration controlled transient elastography (VCTE) or MRE are clinically useful tools for identifying advanced fibrosis in patients with NAFLD.

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- 14. Liver biopsy should be considered in patients with NAFLD who are at increased risk of having SH and/or advanced fibrosis.
- 15. The presence of MetS, NFS or FIB-4, or liver stiffness measured by VCTE or MRE may be used for identifying patients who are at risk for SH and/or advanced fibrosis.
- 16. Liver biopsy should be considered in patients with suspected NAFLD in whom competing etiologies for HS and the presence and/or severity of coexisting CLDs cannot be excluded without a liver biopsy.
- 19. Pharmacological treatments aimed primarily at improving liver disease should generally be limited to those with biopsy-proven NASH and fibrosis.
- 40. Patients with NASH cirrhosis should be screened for gastroesophageal varices according to the AASLD and ACG practice guidelines.(262)
- 41. Patients with cirrhosis suspected because of NAFLD should be considered for HCC screening according to the AASLD practice guidelines.(263)
- 42. Current evidence does not support routine screening and surveillance for HCC in patients with noncirrhotic NASH.

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Washington Medicaid
https://www.hca.wa.gov/assets/billers-and-providers/WA-Apple-Health-HepatitisC-Clinical-Policy.pdf

HCA-accepted diagnostic tests and scores to stage liver fibrosis

Metavir Score	Biopsy	Fibroscan	Elastography (ARFI/PSWE)	FibroSure	APRI	Other Imaging
F4	F4	≥ 12.5 kPa	≥ 2.34 m/s	≥ 0.75	≥ 2.0	Cirrhosis
F3	F3	9.6 – 12.4 kPa	2.01 – 2.33 m/s	0.58 – 0.74	1.5 – 1.9	
F2	F2	7.1 – 9.5 kPa	1.38 – 2.0 m/s	0.49 – 0.57	1.0 – 1.4	
F1	F1	≤ 7.0 kPa	≤ 1.37 m/s	0.23 - 0.48	≤ 0.9	
F0	F0			≤ 0.22		

HERC Staff Summary
The guideline on noninvasive diagnostic testing for liver fibrosis needs to be updated given that it specifically addresses treatment with DAAs based on a specific fibrosis level, which is no longer applicable for the OHP population. However, the guideline still has value in understanding which tests are most effective at distinguishing different levels of fibrosis, particularly for F4, which may lead to changes in a variety of chronic liver disease populations.

The following imaging tests have reasonable ability (sensitivity and specificity ≥ 0.8) to distinguish F4 (sensitivity, specificity):
- MR elastography (0.91, 0.81)
- Transient elastography (0.85, 0.91)
- Acoustic radiation force impulse (ARFI) (0.92, 0.91)
- Shear wave elastography (0.87, 0.88)

The following test is not as good for identifying F4:
- Real-time tissue elastography (0.74, 0.84)

The following blood tests have reasonable AUROC for distinguishing cirrhosis (*proprietary):
- Platelet count (0.89)
- Hyaluronic acid (0.90)
- Age-platelet index (0.86)
- AST-platelet ratio (0.84)
- ELF* (0.88)
- FIB-4 (0.87)
- FibroIndex (0.86)
- Fibrometer* (0.91)
- FibroTest* (0.86)
- Forns index (0.87)

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- GUCI (0.82)
- Hepascore* (0.89)
- Lok index (0.80)

The following blood tests have poor AUROC for distinguishing cirrhosis:

- AST-ALT ratio (0.72)
- Bonacini index (0.74)
- FIBROSpect II* (unavailable)
- Pohl index (0.65)

Given that there are a variety of good quality non-proprietary blood tests, additional expense associated with proprietary blood tests is not warranted.

MRE is currently allowed in limited circumstances; however, with the changes in coverage to hepatitis C treatment, MRE does not offer additional benefit and has a markedly increased cost compared to alternatives.

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HERC Staff Recommendations:

1) **Retire the Coverage Guidance** *Noninvasive liver testing for liver fibrosis in patients with hepatitis C.*

2) **Modify guideline note 76 as follows:**

~~**GUIDELINE NOTE 76, DIAGNOSTIC TESTING FOR LIVER FIBROSIS TO GUIDE TREATMENT OF HEPATITIS C IN NON-CIRRHOTIC PATIENTS**~~

~~*Line 199*~~

~~Given that a fibrosis score of ≥F2 is the threshold for antiviral treatment of Hepatitis C, the following are included on this line:~~

~~Imaging tests:~~

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

~~Blood tests (only if imaging tests are unavailable):~~

- ~~Enhanced Liver Fibrosis (ELF™)~~
- ~~Fibrometer™~~
- ~~FIBROSpect® II~~
- ~~FibroSure® (FibroTest®) or ActiTest®~~

~~If a fibrosis score of ≥F3 is the threshold for antiviral treatment of Hepatitis C, one or more of the following are included on this line:~~

~~Imaging tests:~~

- ~~Transient elastography (FibroScan®)~~
- ~~Acoustic radiation force impulse imaging (ARFI)~~
- ~~Shear wave elastography (SWE)~~

~~Magnetic resonance elastography is included on this line for ≥F2 or ≥F3 only when at least one imaging test (FibroScan, ARFI, and SWE) has resulted in indeterminant results, a second one is similarly indeterminant, contraindicated or unavailable, and MRE is readily available.~~

~~The following tests are not included on this line (or any other line):~~

- ~~Real time tissue elastography~~
- ~~Hepascore (FibroScore)~~

~~Noninvasive tests are covered no more often than once per year.~~

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

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

Line 199

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

Non-proprietary blood tests

Imaging tests:

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

The following tests are not included on this line (or any other line):

- Real time tissue elastography
- Proprietary blood tests

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

3) **Consider 2 options for MR elastography**

OPTION 1: Move MR elastography to Line 500 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS

a. While MR elastography was added as a 2nd or 3rd line test in the Coverage Guidance and current Prioritized List guideline, this was based on the significant impact of potentially receiving DAAs compared to not receiving DAAs for which this test may be the final arbiter. However, current decisions about exact liver fibrosis levels are no longer quite as critical since the DAA decision is no longer applicable. Given that, having this test available when multiple other cheaper and equally effective imaging and blood tests are available, or requiring delay or repetition of a test at a one year follow up is much less consequential, and it is not clear that the benefits outweigh the considerable cost of MR elastography.

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

Line 500

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Procedure Code	Intervention Description	Rationale	Last Review
76391	Magnetic resonance (eg, vibration) elastography	Less expensive alternatives are available	March, 2019

OPTION 2 Add coverage for MR elastography to Guideline Note 76 above to allow coverage in limited circumstances

Magnetic resonance elastography is included on this line for patients when ALL of the following apply:

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

Repeat MR elastography is not indicated.

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Hepatitis C Direct-Acting Antivirals (Effective March 1, 2019)

Goals:

Approve use of cost-effective treatments supported by the medical evidence.
Provide consistent patient evaluations across all hepatitis C treatments.
Ensure appropriate patient regimen based on disease severity, genotype, and patient comorbidities.

Length of Authorization:

- 8-16 weeks

Requires PA:

All direct-acting antivirals for treatment of Hepatitis C

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the request for treatment of chronic Hepatitis C infection (B18.2)?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness.
3. Is expected survival from non-HCV-associated morbidities more than 1 year?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness.

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Approval Criteria		
4. Has <u>all</u> of the following pre-treatment testing been documented: a. Genotype testing in past 3 years is required if the patient has cirrhosis, <u>any</u> prior treatment experience, and if prescribed a regimen which is not pan-genotypic; b. Baseline HCV RNA level in past 6 months; c. Current HBV status of patient d. Pregnancy test in past 30 days for a woman of child-bearing age; <u>and</u> e. History of previous HCV treatment and outcome f. Presence or absence of cirrhosis as clinically determined (e.g., clinical, laboratory, or radiologic evidence)? Note: Direct-acting antiviral agents can re-activate hepatitis B in some patients. Patients with history of HBV should be monitored carefully during and after treatment for flare-up of hepatitis. Prior to treatment with a DAA, all patients should be tested for HBsAG, HBsAb, and HBcAB status. HIV testing is also recommended, and modification of HIV or HCV treatment regimens may be necessary if there are significant drug-drug interactions.	**Yes:** Record results of each test and go to #5 Note: If the patient has HIV or HBV co-infection, it is highly recommended that a specialist be consulted prior to treatment. Currently treatment is not recommended during pregnancy due to lack of safety and efficacy data	**No**: Pass to RPh. Request updated testing.
5. Which regimen is requested?	Document and go to #6	
6. Does the patient have clinical, radiologic or laboratory evidence of complications of cirrhosis (ascites, portal hypertension, hepatic encephalopathy, hepatocellular carcinoma, esophageal varices)?	**Yes:** Go to #7 .	**No:** Go to #8
7. Is the regimen prescribed by, OR is the patient in the process of establishing care with or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness. Recommend prescriber document referral to a specialist prior to initiating treatment.

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Approval Criteria		
8. Is there attestation that the patient and provider will comply with case management to promote the best possible outcome for the patient and adhere to monitoring requirements required by the Oregon Health Authority, including measuring and reporting of a post-treatment viral load? Case management includes assessment of treatment barriers and offer of patient support to mitigate potential barriers to regimen adherence as well as facilitation of SVR12 evaluation to assess treatment success.	**Yes**: Go to #9	**No:** Pass to RPh. Deny; medical appropriateness.
9. Is the prescribed drug: a) Elbasvir/grazoprevir for GT 1a infection; or b) Daclatasvir + sofosbuvir for GT 3 infection?	**Yes**: Go to #10	**No:** Go to #11
10. Has the patient had a baseline NS5a resistance test that documents a resistant variant to one of the agents in #16? Note: Baseline NS5A resistance testing is required.	**Yes:** Pass to RPh; deny for appropriateness	**No:** Go to #11 Document test and result.
11. Does the prescribed regimen include a NS3/4a protease inhibitor (elbasvir, glecaprevir, simeprevir, paritaprevir, voxilaprevir)?	**Yes:** Go to #12	**No:** Go to #13
12. Does the patient have moderate-severe hepatic impairment (Child-Pugh B or Child-Pugh C)?	**Yes:** Pass to RPh; deny for appropriateness	**No:** Go to #13
13. Is the prescribed regimen for the retreatment after failure of a DAA due to noncompliance or loss of follow-up?	**Yes:** Pass to RPh; Deny and refer to medical director for review	**No:** Go to #14

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Approval Criteria		
14. Is the prescribed drug regimen a recommended regimen based on the patient's genotype, treatment status (retreatment or treatment naïve) and cirrhosis status (see **Table 1**)?	**Yes:** Approve for 8-16 weeks based on duration of treatment indicated for approved regimen	**No:** Pass to RPh. Deny; medical appropriateness.

Table 1: Recommended Treatment Regimens for Chronic Hepatitis C.

Treatment History	Cirrhosis Status	Recommended Regimen
Genotype 1		
DAA-Treatment naive	Non-cirrhotic	EBV/GZR x 12 weeks** SOF/VEL x 12 weeks G/P x 8 weeks
	Compensated Cirrhosis	EBV/GZR x 12 weeks** SOF/VEL x 12 weeks G/P x 12 weeks
	Decompensated Cirrhosis	SOF/VEL + RBV x 12 week
Treatment experienced (Prior PEG/RBV)	Non-cirrhotic	EBV/GZR x 12 weeks** SOF/VEL x 12 weeks G/P x 8 weeks
	Compensated cirrhosis	EBV/GRZ 12weeks** SOF/VEL x 12 weeks G/P x 12 weeks
Treatment Experienced (Prior sofosbuvir)	Non-cirrhotic or compensated cirrhosis	SOF/VEL x 12 weeks G/P x 12 weeks
Treatment Experienced (Prior NS3A/4A inhibitor)	Non-cirrhotic or compensated cirrhosis	SOF/VEL x 12 weeks EBV/GZR + RBV x 12 weeks** G/P x 12 weeks
Treatment Experienced (prior NS5A-containing regimen)	Non-cirrhotic or compensated cirrhosis	G/P x 16 weeks
Genotype 2		
Naïve	Non-cirrhotic	SOF/VEL x 12 weeks G/P x 8 weeks
	Compensated cirrhosis	SOF/VEL x 12 weeks G/P x 12 weeks
	Decompensated	SOF/VEL + RBV x 12 weeks
Treatment Experienced (prior PEG/RBV)	Non-cirrhotic	SOF/VEL x 12 weeks G/P x 8 weeks
	Compensated cirrhosis	SOF/VEL x 12 weeks

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		G/P x 12 weeks
Treatment Experienced (SOF + RBV)	Non-cirrhotic or compensated cirrhosis	SOF/VEL x 12 weeks G/P x 12 weeks
Treatment Experienced (prior NS5A-containing regimen)	Non-cirrhotic or compensated cirrhosis	SOF/VEL/VOX x 12 weeks
Genotype 3		
Naïve	Non-cirrhotic	SOF/VEL X 12 weeks G/P x 8 weeks
	Compensated cirrhosis	SOF/VEL + RBV x 12 weeks G/P x 12 weeks
	Decompensated Cirrhosis	SOF/VEL + RBV x 12 weeks
Treatment Experienced (prior PEG/RBV only)	Non-cirrhotic or compensated cirrhosis	SOF/VEL x 12 weeks G/P x 16 weeks
Treatment Experienced (SOF + RBV)	Non-cirrhotic or compensated cirrhosis	G/P x 16 weeks
Experienced (prior NS5A-containing regimen)	Non-cirrhotic or compensated cirrhosis	SOF/VEL/VOX x 12 weeks
Genotype 4		
Treatment Naïve	Non-cirrhotic	SOF/VEL x 12 weeks EBV/GZR x 12 weeks G/P x 8 weeks
	Compensated cirrhosis	SOF/VEL x 12 weeks EBV/GZR x 12 weeks G/P x 12 weeks
	Decompensated Cirrhosis	SOF/VEL + RBV x 12 week
Treatment Experienced (prior PEG/RBV only)	Non-cirrhotic	SOF/VEL x 12 weeks EBV/GZR x 12 weeks G/P x 8 weeks
	Compensated cirrhosis	SOF/VEL x 12 weeks EBV/GZR x 12 weeks G/P x 12 weeks
Treatment Experienced (prior NS5A-containing regimen OR sofosbuvir)	Non-cirrhotic or compensated cirrhosis	SOF/VEL/VOX x 12 weeks
Genotype 5/6		
Treatment Naïve or Experienced (prior PEG-IFN/RBV only)	Non-cirrhotic	SOF/VEL x 12 weeks G/P x 8 weeks
	Compensated cirrhosis	SOF/VEL x 12 weeks G/P x 12 weeks
	Decompensated cirrhosis	SOF/VEL + RBV x 12 weeks
Experienced (prior NS5A-containing regimen OR sofosbuvir)	Non-cirrhotic or compensated cirrhosis	SOF/VEL/VOX x 12 weeks

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Abbreviations: CTP = Child-Turcotte-Pugh; DAA = direct acting antiviral; EBV/GZR = elbasvir/grazoprevir; G/P = glecaprevir and pibrentasvir; PEG = pegylated interferon; RAV = resistance-associated variant; RBV = ribavirin; SOF = sofosbuvir; SOF/VEL = sofosbuvir/velpatasvir; SOF/VEL/VOX = sofosbuvir/velpatasvir/voxilaprevir **No baseline NS5A RAVs. For genotype 1a patients with baseline NAS5A RAVs, extend duration to 16 weeks. ±Evidence is insufficient if the addition of RBV may benefit subjects with GT3 and cirrhosis. If RBV is not used with regimen, then baseline RAV testing should be done prior to treatment to rule out the Y93 polymorphism.
^ Rarely, genotyping assays may indicate the presence of a mixed infection (e.g., genotypes 1a and 2). Treatment data for mixed genotypes with direct-acting antivirals are limited. However, in these cases, a pangenotypic regimen is appropriate.
Ribavirin-containing regimens are absolutely contraindicated in pregnant women and in the male partners of women who are pregnant. Documented use of two forms of birth control in patients and sex partners for whom a ribavirin containing regimen is chosen is required.
Regimens other than glecaprevir/pibrentasvir (G/P;) and elbasvir/grazoprevir (EBV/GZR) should not be used in patients with severe renal impairment (GRF < 30 mL/min) or end stage renal disease requiring dialysis.
All regimens containing a protease inhibitor (elbasvir, glecaprevir, simeprevir, paritaprevir, voxilaprevir) should not be used in patients with moderate to severe hepatic impairment (CTP B and C).
There is limited data supporting DAA regimens in treatment- experienced patients with decompensated cirrhosis. These patients should be handled on a case by case basis with the patient, prescriber, and CCO or FFS medical director.

P&T Review: *11/18; 9/18 (MH); 1/18; 9/17; 9/16; 1/16; 5/15; 3/15; 1/15; 9/14; 1/14*
Implementation: *TBD; 1/1/2019; 3/1/2018; 1/1/2018; 2/12/16; 4/15; 1/15*

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Hysterectomy Guidelines Review

Questions:

1) Should the requirement for laboratory confirmed anemia be removed from several of the hysterectomy guidelines for all procedures? If not, should it be removed for endometrial ablation procedures (see #3 below)?
2) Should the menstrual bleeding disorders guideline be clarified as to whether it applies to post-menopausal bleeding?
3) Should the guideline around endometrial ablation be changed to make it easier to qualify for this procedure as it is less invasive than hysterectomy?

Question sources:

1) Various CCOs and hearings cases
2) CCO hearings case
3) Dr. Michael Adler, OB/Gyn and HERC member

Issues:

The hysterectomy guidelines were reviewed as part of the 2012 ICD-10 OB/Gyn review, and various modifications were made. Since that review, there have been several additional changes made to these guidelines as described below. Various questions have been raised recently regarding these guidelines, and HERC staff felt that they should best be reviewed en masse.

1) The hysterectomy guidelines require proof of anemia as a qualification for hysterectomy. Originally, this requirement was a hemoglobin level of <10. This was modified a few years ago to allow a hemoglobin level of <11 if the patient was taking iron. However, many CCOs and HSD review providers have told HERC staff that it is difficult to obtain documentation of the hemoglobin level, and that many providers do not allow their patients to drop to a low hemoglobin level before instituting various therapies such as oral iron. Many CCOs and HSD reconsiderations allow hysterectomies for patients without documented anemia when they otherwise qualify under the guidelines. The question has been raised from several sources about whether this criteria should be removed due to the difficulty in its administration.
2) The guideline on menstrual bleeding states that "Endometrial ablation or hysterectomy for abnormal uterine bleeding in premenopausal women may be indicated…" Recently, a case came to hearings in which a patient had post-menopausal bleeding and the question was whether GN44 MENSTUAL BLEEDING DISORDERS should apply. The previous intent of the commission was that postmenopausal bleeding should have a diagnostic work up for the cause, and then treated based on that cause. The rationale was that postmenopausal bleeding by definition could not be significant enough to cause anemia, and was always considered pathologic until proven otherwise.
3) GN44 MENSTUAL BLEEDING DISORDERS currently requires the same criteria for a patient to qualify for a hysterectomy as for endometrial ablation. Endometrial ablation is a procedure in which the lining of the uterus is treated in such a way (heat, cryotherapy, etc.) as to minimize the ability of the lining to bleed. It is considered less invasive than a hysterectomy.
    a. From Dr. Adler: As a practicing OBGYN and Commissioner of the HERC, I feel the restrictions for an OHP patient to obtain an endometrial ablation are onerous and not in the best health interests of the patient. To my knowledge, this decision regarding endometrial ablation restrictions was based upon a review of published data over 6 years ago. To that end, I would request that the Value Based Benefits Subcommittee of the HERC review the current cost and health benefits of an endometrial ablation vs. less effective medical therapy. As a practicing OBG, I find it easier to have a hysterectomy

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authorized for menorrhagia than an endometrial ablation; and to me, this is counter intuitive and potentially harmful to a patient.

In addition, I think Line 5 should be stricken re: sonohysteroscopy, hysteroscopy, and hysterosalpingography. These are expensive unnecessary procedures and a hysteroscopy is routinely performed at the time of endometrial ablation procedure. I think it is reasonable to substitute the above procedures with a pelvic ultrasound as part of the preoperative work up. Additionally, with the hysteroscopy at the time of the endometrial ablation, minor endometrial pathologies will be cured with the accompanying endometrial curettage and the destruction of endometrium occurring from the ablation.

b. HSC/HERC history: endometrial ablation was added to the menstrual bleeding disorders line in 1998. Endometrial cryoablation was added to this line as a new CPT code in 2004.

<u>Other payer policies</u>

1) **Regence BCBS 2018**, endometrial ablation
    a. Endometrial ablation, with or without hysteroscopic guidance, may be considered **medically necessary** when the clinical records document all of the following criteria (i-iv) are met:
        i. There is a diagnosis of abnormally heavy uterine bleeding in a patient who is not post-menopausal; *and*
        ii. Hysteroscopy, sonohysterography (SIS), or pelvic ultrasound has been performed and report is provided; and
        iii. Clinical documentation confirms counseling regarding hormonal treatment options has been addressed (see Policy Guidelines); *and*
        iv. Endometrial sampling or dilation and curettage (D&C) has been performed or is planned according to any of the following:
            1. Endometrial sampling or D&C has been performed and report is provided. The histopathology report is provided showing absence of endometrial hyperplasia or uterine cancer; or
            2. Endometrial sampling or D&C has been performed and report is provided. The histopathology report is provided, but inadequate tissue was obtained for diagnosis; or
            3. Cervical stenosis precludes endometrial sampling, and D&C is planned concomitantly with ablation
2) **Aetna 2018**, endometrial ablation policy
    a. Aetna considers endometrial ablation medically necessary for women who meet *all* of the following selection criteria:
        i. Menorrhagia unresponsive to (or with a contraindication to) *either*:
            1. Dilation and curettage; *or*
            2. Hormonal therapy or other pharmacotherapy;

        (Note: The degree of severity and persistence of the menorrhagia and the failure of prior treatment should be such that the member would otherwise be a candidate for a hysterectomy; these alternative less invasive approaches should have been attempted in the past year or to stop residual menstrual bleeding

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after androgen treatment in a female to male transgender person who meet criteria for gonadectomy in CPB 0615 - Gender Reassignment Surgery)

and

b. Endometrial sampling or D&C has been performed within the year prior to the procedure to exclude cancer, pre-cancer or hyperplasia, and the results of the histopathological report have been reviewed before the ablation procedure is scheduled (should be done in the past year); *and*
c. Structural abnormalities (fibroids, polyps) that require surgery or represent a contraindication to an ablation procedure have been excluded (this is almost always done by ultrasound in the past year); *and*
d. Pap smear and gynecologic examination have excluded significant cervical disease. (Note: The Pap smear should be up to date so not necessarily within the past year).

CCO feedback:

There was near unanimous support for continuing to include a hemoglobin level as a criterion for hysterectomy. Most CCOs reported having no difficulty in obtaining the lab results from their providers.

The CCO medical directors were in favor of removing hemoglobin level as a criteria for endometrial ablation as this procedure does not require hospitalization, is less invasive, and is frequently used as a way of avoiding hysterectomy.

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HERC staff summary

1) Hemoglobin documentation requirement: review of other payer policies finds that this is not a requirement. However, the CCOs are in favor of continuing this requirement.
2) Applicability of GN44 to postmenopausal bleeding
    a. Postmenopausal bleeding is by definition abnormal. Postmenopausal women by definition should not meet the criteria for profuse bleeding lasting more than 7 days or occurring at less than 21 day intervals. Hysterectomy should be done if indicated by the underlying pathology or through the exceptions review process.
3) Requirements for endometrial ablation: review of other payer policies finds that they generally have the same requirements as in GN44. CCO medical directors are in favor of removing the hemoglobin criteria for this procedure.

HERC staff recommendations:

1) Modify GN44 as shown below
    a. Removes the requirement for documented hemoglobin level for endometrial ablation
    b. Discuss other changes to the hemoglobin requirement such as increasing the hemoglobin level required
2) Make no changes to the other hysterectomy guidelines (see Appendix A)

GUIDELINE NOTE 44, MENSTRUAL BLEEDING DISORDERS

Line 420

Endometrial ablation or hysterectomy for abnormal uterine bleeding in premenopausal women may be indicated when all of the following are documented (A-C):

A) Patient history of (1, 2, 3, 4, and 5):
    1) Excessive uterine bleeding evidence by (a, b and c):
        a) Profuse bleeding lasting more than 7 days or repetitive periods at less than 21-day intervals
        b) Anemia due to acute or chronic blood loss (hemoglobin less than 10 or hemoglobin less than 11 g/dL if use of iron is documented) for hysterectomy. No documented hemoglobin level is required for endometrial ablation procedures.
        c) Bleeding causes major impairment or interferes with quality of life
    2) Failure of hormonal treatment for a six-month trial period or contraindication to hormone use (oral contraceptive pills or patches, progesterone-containing IUDs, injectable hormone therapy, or similar)
    3) No current medication use that may cause bleeding, or contraindication to stopping those medications
    4) Endometrial sampling performed
    5) For hysterectomy, no evidence of treatable intrauterine conditions or lesions by (a, b or c):
        a) Sonohysterography
        b) Hysteroscopy
        c) Hysterosalpingography

        For endometrial ablation, a pre-operative ultrasound should be performed
B) Negative preoperative pregnancy test result unless patient has been previously sterilized
C) Nonmalignant cervical cytology, if cervix is present

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Appendix A: Current guidelines

GUIDELINE NOTE 39, ENDOMETRIOSIS AND ADENOMYOSIS

Lines 1,395

B) Hysterectomy, with or without adnexectomy, for endometriosis may be appropriate when all of the following are documented (1-4):
   1) Patient history of (a and b):
      a) Prior detailed operative description or histologic diagnosis of endometriosis
      b) Presence of pain for more than 6 months with negative effect on patient's quality of life
   2) Failure of a 3-month therapeutic trial with both of the following (a and b), unless there are contraindications to use:
      a) Hormonal therapy (i or ii):
         i) Oral contraceptive pills or patches, progesteronecontaining IUDs, injectable hormone therapy, or similar
         ii) Agents for inducing amenorrhea (e.g., GnRH analogs or danazol)
      b) Nonsteroidal anti-inflammatory drugs
   3) Nonmalignant cervical cytology, if cervix is present
   4) Negative preoperative pregnancy test result unless patient is postmenopausal or has been previously sterilized

C) Hysterectomy, with or without adnexectomy, for adenomyosis may be appropriate when all of the following are documented (1-5):
   1) Patient history of dysmenorrhea, pelvic pain or abnormal uterine bleeding for more than six months with a negative effect on her quality of life.
   2) Failure of a six-month therapeutic trial with both of the following (a and b), unless there are contraindications to use:
      a) Hormonal therapy (i or ii):
         i) Oral contraceptive pills or patches, progesteronecontaining IUDs, injectable hormone therapy, or similar
         ii) Agents for inducing amenorrhea (e.g., GnRH analogs or danazol)
      b) Nonsteroidal anti-inflammatory drugs
   3) One of the following (a or b):
      a) Endovaginal ultrasound suspicious for adenomyosis (presence of abnormal hypoechoic myometrial echogenicity or presence of small myometrial cysts)
      b) MRI showing thickening of the junctional zone > 12mm
   4) Nonmalignant cervical cytology, if cervix is present
   5) Negative preoperative pregnancy test unless patient is postmenopausal or has been previously sterilized

GUIDELINE NOTE 40, UTERINE LEIOMYOMA

Line 403

Hysterectomy, myomectomy, or uterine artery embolization for leiomyomata may be indicated when all of the following are documented (A-D):

A) One of the following (1 or 2):
   1) Patient history of 2 out of 3 of the following (a, b and c):
      a. Leiomyomata enlarging the uterus to a size of 12 weeks or greater gestation
      b. Pelvic discomfort cause by myomata (i or ii or iii):
         i) Chronic lower abdominal, pelvic or low backpressure

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ii) Bladder dysfunction not due to urinary tract disorder or disease
iii) Rectal pressure and bowel dysfunction not related to bowel disorder or disease
c. Rapid enlargement causing concern for sarcomatous changes of malignancy

2) Leiomyomata as probable cause of excessive uterine bleeding evidenced by (a, b, c and d):
a. Profuse bleeding lasting more than 7 days or repetitive periods at less than 21-day intervals
b. Anemia due to acute or chronic blood loss (hemoglobin less than 10 or hemoglobin less than 11 g/dL if use of iron is documented)
c. Documentation of mass by sonography
d. Bleeding causes major impairment or interferes with quality of life

B) Nonmalignant cervical cytology, if cervix is present
C) Assessment for absence of endometrial malignancy in the presence of abnormal bleeding
D) Negative preoperative pregnancy test result unless patient is postmenopausal or has been previously sterilized

GUIDELINE NOTE 44, MENSTRUAL BLEEDING DISORDERS

Line 420

Endometrial ablation or hysterectomy for abnormal uterine bleeding in Premenopausal women may be indicated when all of the following are documented (A-C):

D) Patient history of (1, 2, 3, 4, and 5):
1) Excessive uterine bleeding evidence by (a, b and c):
a) Profuse bleeding lasting more than 7 days or repetitive periods at less than 21-day intervals
b) Anemia due to acute or chronic blood loss (hemoglobin less than 10 g/dL or hemoglobin less than 11 g/dL if use of iron is documented)
c) Bleeding causes major impairment or interferes with quality of life
2) Failure of hormonal treatment for a six-month trial period or contraindication to hormone use (oral contraceptive pills or patches, progesterone-containing IUDs, injectable hormone therapy, or similar)
3) No current medication use that may cause bleeding, or contraindication to stopping those medications
4) Endometrial sampling performed
5) No evidence of treatable intrauterine conditions or lesions by (a, b or c):
a) Sonohysterography
b) Hysteroscopy
c) Hysterosalpingography

E) Negative preoperative pregnancy test result unless patient has been previously sterilized
F) Nonmalignant cervical cytology, if cervix is present

GUIDELINE NOTE 50, PELVIC ORGAN PROLAPSE SURGERY

Line 464

Hysterectomy, cystocele repair, and/or other surgery for pelvic organ prolapse may be indicated when all of the following are documented (A-E):

A) Patient history of symptoms of pelvic prolapse such as:
1) Complaints of the pelvic organs prolapsing at least to the introitus, and one or more of the following:
a) Low back discomfort or pelvic pressure, or
b) Difficulty in defecating, or

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c) Difficulty in voiding

B) For hysterectomy
   1) Nonmalignant cervical cytology, if cervix is present, and
   2) Assessment for absence of endometrial malignancy in the presence of abnormal bleeding

C) Physical examination is consistent with patient's symptoms of pelvic support defects indicating either symptomatic prolapse of the cervix, enterocele, cystocele, rectocele or prolapse of the vaginal vault

D) Negative preoperative pregnancy test unless patient is postmenopausal or has been previously sterilized

E) Patient required to have 3 months of alternative therapy (e.g., pessaries or physical therapy, including bladder training, pelvic floor exercises and/or biofeedback, as available). If limited coverage of physical therapy is available, patients should be taught pelvic floor exercises by their treating provider, physical therapist or trained staff, and have documented consistent practice of these techniques over the 3 month period.

GUIDELINE NOTE 55, PELVIC PAIN SYNDROME

Line 529

D) Diagnostic MRI may be indicated for evaluation of pelvic pain to assess for Adenomyosis and to assist in the management of these challenging patients when all of the following are documented:
   1) Patient history of dysmenorrhea, pelvic pain or abnormal uterine bleeding for more than six months with a negative effect on her quality of life.
   2) Failure of a six-month therapeutic trial with both of the following (a and b), unless there are contraindications to use:
      a) Hormonal therapy (i or ii):
         i) Oral contraceptive pills or patches, progesterone-containing IUDs, injectable hormone therapy, or similar
         ii) Agents for inducing amenorrhea (e.g., GnRH analogs or danazol)
      b) Nonsteroidal anti-inflammatory drugs
   3) An endovaginal ultrasound within the past 12 months that shows no other suspected gynecological pathology if diagnostic MRI shows > 12mm thickening of the junctional zone, the presumptive diagnosis of adenomyosis is fulfilled. See Guideline Note 39.

B) Hysterectomy for chronic pelvic pain in the absence of significant pathology may be Indicated when all of the following are documented (1-7):
   1) Patient history of:
      a) No treatable conditions or lesions found on laparoscopic examination
      b) Pain for more than 6 months with negative effect on patient's quality of life
   2) Failure of a six-month therapeutic trial with both of the following (a and b), unless there are contraindications to use:
      a) Hormonal therapy (i or ii):
         i) Oral contraceptive pills or patches, progesterone-containing IUDs, injectable hormone therapy, or similar
         ii) Agents for inducing amenorrhea (e.g., GnRH analogs or danazol)
      b) Nonsteroidal anti-inflammatory drugs
   3) Evaluation of the following systems as possible sources of pelvic pain:
      a) Urinary
      b) Gastrointestinal
      c) Musculoskeletal

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4) Evaluation of the patient's psychologic and psychosexual status for nonsomatic cause of symptoms
5) Nonmalignant cervical cytology, if cervix is present
6) Assessment for absence of endometrial malignancy in the presence of abnormal bleeding
7) Negative preoperative pregnancy test unless patient is postmenopausal or as been previously sterilized

GUIDELINE NOTE 59, DYSMENORRHEA

Line 555

Hysterectomy for dysmenorrhea may be indicated when all of the following are documented (A-G):

A) Patient history of:
   1) No treatable conditions or lesions found on laparoscopic examination
   2) Pain for more than 6 months with negative effect on patient's quality of life
B) Failure of a six-month therapeutic trial with both of the following (1 and 2), unless there are contraindications to use:
   1) Hormonal therapy (a or b):
      a) Oral contraceptive pills or patches, progesterone-containing IUDs, injectable hormone therapy, or similar
      b) Agents for inducing amenorrhea (e.g., GnRH analogs or danazol)
   2) Nonsteroidal anti-inflammatory drugs
C) Evaluation of the following systems as possible sources of pelvic pain:
   1) Urinary
   2) Gastrointestinal
   3) Musculoskeletal
D) Evaluation of the patient's psychologic and psychosexual status for nonsomatic cause of symptoms
E) Nonmalignant cervical cytology, if cervix is present
F) Assessment for absence of endometrial malignancy in the presence of abnormal bleeding

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Posterior Urethral Valves

Question: Should posterior urethral valves be paired with surgical correction when not causing hydronephrosis?

Question source: Dr. Daniel Hirselj at NW Urology

Issue: Posterior urethral valves are congenital obstructive membranes that develop in the urethra in males. The valve can cause obstruction which can lead to hydronephrosis and kidney damage. In less severe cases, the valves can cause urinary tract infections, urinary incontinence, and difficulty with urination. In more severe cases, they cause hydronephrosis and even renal failure.

Currently the treatment for posterior urethral valves (CPT 52400 Cystourethroscopy with incision, fulguration, or resection of congenital posterior urethral valves, or congenital obstructive hypertrophic mucosal folds) is on three lines: 49 CONGENITAL HYDRONEPHROSIS, 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION, and 329 CANCER OF PROSTATE GLAND.

Dr. Hirselj is requesting that CPT 52400 pair with ICD-10 Q64.2 (Congenital posterior urethral valves) which is on line 87 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM.

On review of the literature, it appears that very mild cases of posterior urethral valves do not require specific therapy. However, generally the diagnosis of posterior urethral valves is made after a child has symptoms that require a voiding cystourethrogram or other diagnostic testing. There has been no previous HSC/HERC review of this topic identified in a search of the minutes. Currently, if the posterior urethral valves cause hydronephrosis, then the surgery would be covered using diagnosis code ICD10 Q62.0 (Congenital hydronephrosis) on line 49.

HERC staff recommendation

1) Add CPT 52400 (Cystourethroscopy with incision, fulguration, or resection of congenital posterior urethral valves, or congenital obstructive hypertrophic mucosal folds)) to line 87 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM

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Breast MRI for Breast Cancer Screening in Breast Cancer Survivors

Question: How should diagnostic guideline D6 and GN26 be modified to internally agree with each other regarding when a woman with a personal history of breast cancer should have breast MRI covered for screening for future breast cancers?

Question source: HSD claims reconsideration

Issue: GN26 BREAST CANCER SURVEILLANCE specifies the follow up testing for women with a history of breast cancer, which does not include breast MRI. When GN26 was written, Diagnostic Guideline D6 BREAST CANCER SCREENING IN ABOVE-AVERAGE RISK WOMEN simply stated that breast MRI was not covered for breast cancer screening. At that point, the two guidelines were internally consistent and based on NCCN guidelines. Diagnostic Guideline D6 was subsequently modified in 2017 based on a coverage guidance, allowing breast MRI screening for women with >20% lifetime risk of breast cancer and for women with both a personal history of breast cancer and a family history of breast cancer.

HSD recently had a case of a women with a personal history of breast cancer and a paternal aunt with breast cancer. Their question was whether the breast MRI was covered according to the clause in Diagnostic Guideline D6 or whether it was not covered according to the GN26 specification that no testing other than mammography was covered.

Kevin Olson from the HERC and an oncologist was consulted. He felt that surveillance and screening are two separate entities and that the two guidelines should continue to have their current requirements.

NCCN 2018, breast cancer screening

1) Recommend annual breast MRI recommended for women with a lifetime risk of 20% or greater
2) Insufficient evidence to recommend for or against MRI for women with a personal history of breast cancer, including DCIS

HERC staff recommendations:

1) Modify diagnostic Guideline D6 as shown below
2) Modify GN26 as shown below
    a. Clarifies that breast MRI is covered with a lifetime risk of >20%

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

Annual screening mammography and annual screening MRI without computer-aided detection (CAD) are covered only for women at above-average risk of breast cancer. This coverage, beginning at 30 years of age, includes women who have one or more of the following:

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

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For women with a history of high dose chest radiation (≥ 20 Gray) before the age of 30, annual screening MRI without computer-aided detection (CAD) and annual screening mammography are covered beginning 8 years after radiation exposure or at age 25, whichever is later.

For women with both a personal history and a family history of breast cancer which give a greater than 20% lifetime risk of breast cancer, annual mammography, annual breast MRI without computer-aided detection (CAD) and annual breast ultrasound are covered.

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

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

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

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

GUIDELINE NOTE 26, BREAST CANCER SURVEILLANCE

Line 191

A) History and physical exam is indicated every 3 to 6 months for the first three years after primary therapy, then every 6-12 months for the next 2 years, then annually thereafter.
B) Mammography is indicated annually, and patients treated with breast conserving therapy, initial mammogram of the affected breast should be 6 months after completion of radiotherapy.
C) No other surveillance testing is indicated

For ongoing screening for a new breast cancer, see Diagnostic Guideline D6 BREAST CANCER SCREENING IN ABOVE-AVERAGE RISK WOMEN.

VbBS Issue Summaries from 3-14-2019

Tonsillectomy Guideline March 2019

Question: should the tonsillectomy guideline be modified to match the 2019 American Academy of Otolaryngology-Head and Neck Surgery guideline?

Question source: HERC staff

Issue: The AAO-HNS has just published an updated set of recommendations regarding when tonsillectomy should be performed for recurrent strep tonsillitis. The revised AAO-HNS guidelines are stricter that the current Prioritized List guideline.

AAO-HNS 2019 Clinical Practice Guideline: Tonsillectomy in Children (Update)
https://journals.sagepub.com/doi/pdf/10.1177/0194599818801757

1) Strong recommendation based on systematic reviews of randomized controlled trials with limitations and observational studies with a preponderance of benefit over harm: (1) Clinicians should recommend watchful waiting for recurrent throat infection if there have been <7 episodes in the past year, <5 episodes per year in the past 2 years, or <3 episodes per year in the past 3 years.
2) Recommendation based on randomized controlled trials and observational studies with a preponderance of benefit over harm: tonsillectomy be considered for children with >1 peritonsillar abscess (previous guideline recommended tonsillectomy with a "history of peritonsillar abscess")
    a. The role of tonsillectomy in managing peritonsillar abscess remains controversial, but the threshold for surgery is lowered when a child with recurrent throat infection develops or has a history of peritonsillar abscess. When peritonsillar abscess is treated with needle aspiration or incision and drainage, the need for subsequent tonsillectomy is about 10% to 20%. This rate may not merit routine tonsillectomy unless a patient also has a history of frequent prior throat infections, especially when culture positive for GABHS. Some authors advocate ''quinsy'' tonsillectomy, which is performed in the setting of an active peritonsillar abscess, especially if general anesthesia is required for drainage (eg, uncooperative child) and there is a history of tonsil disease

HERC staff recommendation:

1) Modify GN36 as shown below

GUIDELINE NOTE 36, ADENOTONSILLECTOMY FOR INDICATIONS OTHER THAN OBSTRUCTIVE SLEEP APNEA

Lines 42,47,368,548

Tonsillectomy/adenotonsillectomy is an appropriate treatment for patients with:

A) ~~Five~~ Seven documented attacks of strep tonsillitis in a year or ~~3~~ 5 documented attacks of strep tonsillitis in each of two consecutive years or 3 documented attacks of strep tonsillitis per year in each of the three consecutive years where an attack is considered a positive culture/screen and where an appropriate course of antibiotic therapy has been completed;
B) ~~Peritonsillar abscess requiring surgical drainage~~ A history of two or more peritonsillar abscesses OR when general anesthesia is required for the surgical drainage of a peritonsillar abscess and tonsillectomy is performed at the time of the surgical drainage; or,
C) Unilateral tonsillar hypertrophy in adults; unilateral tonsillar hypertrophy in children with other symptoms suggestive of malignancy.

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ICD-10-CM J35.1 and J35.3 are included on Line 368 only for 1) unilateral tonsillar hypertrophy in adults and 2) unilateral tonsillar hypertrophy in children with other symptoms suggestive of malignancy. Bilateral tonsillar hypertrophy and unilateral tonsillar hypertrophy in children without other symptoms suggestive of malignancy are included only on Line 548.

See Guideline Note 118 for diagnosis and treatment of obstructive sleep apnea in children.

VbBS Issue Summaries from 3-14-2019

Embolization of Vascular Malformations

Question: When should embolization of venous and arteriovenous malformations (AVMs) be covered?

Question source: Nina Lara, Primary Health

Issue: There are two CPT codes for embolization of arteriovenous and venous malformations that are currently only on unfunded lines. The ICD-10 code for AVMs is on a different, covered line. There was a case brought to Primary Health requesting pairing of embolization with a venous malformation.

An AVM is an abnormal connection (or usually multiple small connections) between an artery and vein. They are classified in four stages:

Schobinger Classification	
Type 1	Quiescent - stable
Type 2	Growing
Type 3	Symptomatic: pain, bleeding or functional problems
Type 4	Decompensating, high output cardiac failure

A venous malformation is an abnormally developed blood vessel with varying degrees of communication with normal veins. They typically cause pain and swelling. Some types of venous malformations are varicose veins or varices; there are very rare cases of large malformations that might cause functional issues.

Current Prioritized List status

CPT Code	**Code Description**	**Current Lines**
37241	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)	545 SUBLINGUAL, SCROTAL, AND PELVIC VARICES 625 BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES
37242	… arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)	545, 625
ICD-10 Code		
Q27.3X	Arteriovenous malformation of vessel (does not include intracranial AVMs)	305 DISORDERS OF ARTERIES, OTHER THAN CAROTID OR CORONARY
Q27.8	Other specified congenital malformations of peripheral vascular system	305

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HERC staff recommendations:

1) Do not add CPT 37241 (Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles)) to any additional lines as venous malformations typically only cause pain and swelling rather than functional issues. The rare venous malformation that causes functional issues can be reviewed as an exception.
2) Add CPT 37242 (Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)) to line 305 DISORDERS OF ARTERIES, OTHER THAN CAROTID OR CORONARY
3) Add the new guideline below to line 305

GUIDELINE NOTE XXX, EMBOLIZATION OF ARTERIAL MALFORMATIONS

Line 305

Vascular embolization or occlusion of arterial or arteriovenous malformations is included on this line only for Schobinger Class 3 or 4 lesions.

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Injections for Plantar Fasciitis

Question: Should procedure codes for injections into the plantar fascia be paired with plantar fasciitis?

Question source: Hearings Division

Issue: Plantar fasciitis (ICD-10 M72.2 Plantar fascial fibromatosis) is currently on line 537 LESION OF PLANTAR NERVE; PLANTAR FASCIAL FIBROMATOSIS, and does not pair with the procedure code for injections into the plantar fascia (CPT 20550 Injection(s); single tendon sheath, or ligament, aponeurosis (eg, plantar "fascia")). CPT 20550 appears on multiple funded lines. There was a recent case that went to the Hearings Division regarding the pairing of these codes. No previous review of this topic was found in old minutes.

Various treatments involving injections into the plantar fascia are currently utilized in practice. The most common injection is corticosteroids, but platelet rich plasma and dehydrated amniotic membrane are also injected in some practices.

Evidence

1) **David 2017**, Cochrane review of corticosteroid injections for plantar heel pain https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD009348.pub2/epdf/full
    a. N=39 studies (2492 patients)
        i. Most studies were small (median=59 patients)
        ii. Follow up ranged from 1 month to 2 years
        iii. With one exception, trials were assessed at high risk of bias in one or more domains, mostly relating to lack of blinding,
    b. N=8 trials (724 patients)) compared steroid injection versus placebo or no treatment.
        i. Steroid injection may lead to lower heel pain visual analogue scores (VAS) (0 to 100; higher scores = worse pain) in the short-term (< 1 month) (MD -6.38, 95% CI -11.13 to - 1.64; 350 participants; 5 studies; I^2 = 65%; low quality evidence). Based on a minimal clinically significant difference (MCID) of 8 for average heel pain, the 95% CI includes a marginal clinical benefit. This potential benefit was diminished when data were restricted to three placebo-controlled trials. Steroid injection made no difference to average heel pain in the medium-term (1 to 6 months follow-up) (MD -3.47, 95% CI -8.43 to 1.48; 382 participants; 6 studies; I^2 = 40%; low quality evidence). There was very low quality evidence for no effect on function in the medium-term and for an absence of serious adverse events (219 participants, 4 studies). No studies reported on other adverse events, such as post-injection pain, and on return to previous activity.
    c. The available evidence for other comparisons was rated as very low quality. We are therefore very uncertain of the estimates for the relative effects on people with heel pain of steroids compared with other interventions (tibial nerve block, orthoses, oral NSAIDs, intensive PT, laser therapy, radiation therapy, locally injectable NSAID, platelet-rick plasma injections, botulinum toxin injections, cryopreserved human amniotic membrane injection
    d. We are also uncertain about the estimates from trials testing different techniques of local steroid injection: ultrasonography-guided versus palpation-guided (5 trials); and scintigraphy-guided versus palpation-guided (1 trial).

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e. An exploratory analysis involving pooling data from 21 trials reporting on adverse events revealed two ruptures of plantar fascia (reported in 1 trial) and three injection site infections (reported in 2 trials) in 699 participants allocated to steroid injection study arms. Five trials reported a total of 27 participants with less serious short-term adverse events in the 699 participants allocated steroid injection study arms.

f. **Authors' conclusions** We found low quality evidence that local steroid injections compared with placebo or no treatment may slightly reduce heel pain up to one month but not subsequently. The available evidence for other outcomes of this comparison was very low quality. Where available, the evidence from comparisons of steroid injections with other interventions used to treat heel pain and of different methods of guiding the injection was also very low quality. Although serious adverse events relating to steroid injection were rare, these were under-reported and a higher risk cannot be ruled out.

Expert guidelines

1) **American College of Foot and Ankle Surgeons 2018**: Clinical Consensus Statement Diagnosis and Treatment of Adult Acquired Infracalcaneal Heel Pain
    a. The panel determined that the following statements are appropriate
        i. Corticosteroid injections are safe and effective in the treatment of plantar fasciitis.
            1. In a recent Cochrane review and meta-analysis of 3 RCTs, David et al concluded that local steroid injections compared with placebo or no treatment might slightly reduce heel pain for ≤1 month but not subsequently. The panel was of the same opinion and admitted to using injectable steroids for the acute relief of symptoms, recognizing that these are not disease modifying and have little lasting effect beyond the first 4 weeks.
    b. The panel determined that the following statements were uncertain—neither appropriate nor inappropriate.
        i. Other injection techniques (e.g., amniotic tissue, platelet-rich plasma, botulinum toxin, needling, and prolotherapy) are safe and effective in the treatment of plantar fasciitis.
            1. Although other injection techniques are emerging for the treatment of plantar fasciitis, they have been supported only by low quality studies consisting of case series, retrospective comparative studies, or small trials, lacking long-term follow-up data. Rather than speculate on the value of these injection therapies, the panel thought that further investigation is needed to assess how these will compare with the more conventional treatment protocols.

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Injections for Plantar Fasciitis

HERC staff summary:
Based on low quality evidence, corticosteroid injections for plantar fasciitis have a non-clinically significant impact on short term (<1 month) pain, but not on function. There are limited adverse events reports. Other injections (amniotic tissue, platelet-rich plasma, botulinum toxin, etc.) have very low quality of evidence which does not allow determination of their effectiveness and are not recommended by experts.

HERC staff recommendation:

1) Add CPT 20550 to line 537, with the coding specification below
    a. "CPT 20550 only appears on this line for corticosteroid injections."
    b. The treatment is appropriate to the condition, but has limited evidence of effectiveness

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Screening for Eye Complications for Patients on High Risk Medications

Question: How can screening for eye complications for patients on high risk medications be represented on the Prioritized List?

Question source: Oregon Eye Specialists, PC; HERC staff

Issue: Many medications have possible eye injury or disease as a complication. Oregon Eye Specialists contacted OHA about their inability to get screening eye exams and tests covered for patients on Plaquenil for rheumatoid arthritis or lupus. It was noted during the 2019 CPT code review that eye tests to look for complications of other types of drug induced retinopathy were similarly not being covered due to lack of pairing.

During the 2019 CPT code review, one issue that was found was that there is no specific ICD-10 code for eye complications due to medications. One code commonly used to order various tests to monitor high-risk medications, ICD-10 Z79.899 (Other long term (current) drug therapy), is on the Diagnostic Workup File whereas all of the ophthalmology visit and testing codes are on lines. HERC staff has identified one ICD-10 code being allowed by private insurers for such testing, H36 (Retinal disorders in diseases classified elsewhere). H36 is currently on line 652 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY.

The specific tests being requested by Oregon Eye Associates [CPT 92134 (retinal spectral domain optical coherence tomography (SD-OCT)); CPT 92082-3 (Humphrey visual fields); and CPT 92250 (fundus autofluorescence)] are on a variety of ophthalmology lines.

HERC staff recommendations:

1) Add ICD-10 H36 (Retinal disorders in diseases classified elsewhere) to line 360 CHORIORETINAL INFLAMMATION
    a. All appropriate CPT codes are on this line
2) Adopt a new guideline note for line 360 as shown below

GUIDELINE NOTE XXX, SCREENING FOR OPHTHALMOLOGIC COMPLICATIONS OF HIGH-RISK MEDICATIONS

Lines 360, 632

ICD-10 H36 (Retinal disorders in diseases classified elsewhere) is included on Line 360 only for ophthalmologic examinations and testing to screen for complications of high-risk medications. ICD-10 H36 is included on Line 632 for all other indications.

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Shoulder Arthroplasty for Rotator Cuff Disease

Question: Should shoulder arthroplasty no longer be paired with various non-traumatic rotator cuff conditions?

Question source: Doug Carr, CCO medical director

Issue: A recent evidence-based guideline strongly recommended against shoulder arthroplasty for shoulder impingement syndrome, also known as rotator cuff disease, based on a lack of evidence of benefit and an evidence of possible harm. This surgery is currently paired with a variety of rotator cuff conditions on line 417 DISORDERS OF SHOULDER, INCLUDING SPRAINS/STRAINS GRADE 4 THROUGH 6.

Patients who have subacromial pain for more than 3 months without a history of trauma usually receive a diagnosis of subacromial pain syndrome (SAPS), shoulder impingement, or rotator cuff disease. Each of these labels describe similar clinical presentations, but there is inconsistency about how they are defined and overlap between these diagnoses. These conditions are generally coded with ICD-10 M75.4 (Impingement syndrome of shoulder). This diagnosis does not include adhesive capsulitis ("frozen shoulder") or glenohumeral osteoarthritis.

First line treatment options for SAPS include simple analgesia such as Tylenol, non-steroidal anti-inflammatory drugs (NSAIDs), glucocorticoid injections, and exercise therapy. Subacromial decompression surgery is a second line treatment option for patients with more longstanding symptoms. Such surgery includes removal of the subacromial bursa (bursectomy) and removal of bone from the under surface of the acromion (acromioplasty), which is usually done laparoscopically.

Current Prioritized List status:

Code	**Code description**	**Placement**
CPT 29826	Arthroscopy, shoulder, surgical; decompression of subacromial space with partial acromioplasty, with coracoacromial ligament (ie, arch) release, when performed Note: this is an add-on code	356 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE 417 DISORDERS OF SHOULDER, INCLUDING SPRAINS/STRAINS GRADE 4 THROUGH 6 441 MALUNION AND NONUNION OF FRACTURE
M75.0	Adhesive capsulitis of shoulder	417
M75.1	Rotator cuff tear or rupture	417
M75.4	Impingement syndrome of shoulder	417
M75.5	Bursitis of shoulder	417
M75.6	Shoulder lesion, unspecified	417

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Evidence

1) **Vandvik 2019**, systematic review and expert guideline on surgical decompression for subacromial pain syndrome
    a. Two trials included placebo surgery and were at low risk of bias. At one year after treatment, they showed that surgery did not have meaningful benefit over placebo surgery:
        i. High certainty evidence for little or no effect on
            1. Pain (mean difference −0.26 (95% confidence interval −0.84 to 0.33), MID 1.5) [MID=mean clinically important difference]
            2. Function (mean difference 2.8 (−1.4 to 6.9), MID 8.3)
            3. Health related quality of life (mean difference −0.03 points (−0.11 to 0.06), MID 0.07)
        ii. Moderate certainty evidence for little or no global perceived effect (risk ratio 1.10 (0.94 to 1.30))
        iii. Low certainty evidence for little or no effect on return to work (risk ratio 1.05 (0.89 to 1.23))
        iv. Similar results were seen at six months, two years, and at five year follow-up, with the latter supported by low certainty evidence due to imprecise estimates from unblinded trials
    b. Harms:
        i. There were around 12 more frozen shoulders per 1000 patients undergoing subacromial decompression surgery, based on the two placebo controlled trials (low certainty evidence).
        ii. Based on one large prospective cohort registry study from the United States: the risk of serious harms after mixed shoulder arthroscopic procedures was 0.5% (95% confidence interval 0.4% to 0.7%) during years 2006-11 and 0.6% (0.5% to 0.7%) during 2011-13. Reported harms included events such as major bleeding, deep infections, serious anesthetic complications, venous thromboembolism, and peripheral nerve injury.
    c. **Recommendation** The guideline panel makes a strong recommendation against surgery.

Expert input

Susan Williams, MD, orthopedic surgeon

29826 is an add-on code which means it cannot be used by itself. It cannot be the only reason a patient is having a surgery. The reason it was changed to an add-on code (from a stand-alone code) was because of the studies that show that decompression for impingement syndrome alone was not effective. 29826 is used as an add-on code in addition to arthroscopic rotator cuff repair. In order to perform a rotator cuff repair, and if the area of tear is from a bone spur, then subacromial decompression is indicated.

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HERC staff summary:
A new evidence-based, GRADE informed guideline strongly recommends against decompressive surgery for non-traumatic rotator cuff conditions. A variety of laparoscopic shoulder surgeries appear on line 417, paired with these types of conditions. Other shoulder conditions, such as traumatic rotator cuff tears and shoulder arthritis, also appear on line 417 and are not included in the recommendation against surgery. Expert input confirms that decompressive surgery is not indicated for non-traumatic rotator cuff conditions, but is used as part of rotator cuff surgery.

HERC staff recommendations:

1) Add the new guideline below to lines containing CPT 29826 (Arthroscopy, shoulder, surgical; decompression of subacromial space with partial acromioplasty, with coracoacromial ligament (ie, arch) release, when performed)
    a. Lines 356 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE, 417 DISORDERS OF SHOULDER, INCLUDING SPRAINS/STRAINS GRADE 4 THROUGH 6, and 441 MALUNION AND NONUNION OF FRACTURE

GUIDELINE NOTE XXX, SHOULDER DECOMPRESSION SURGERY

Lines 356,417,441

CPT 29826 is only included on these lines as a component of rotator cuff repair surgery. CPT 29826 is not included on this line for pairing with shoulder impingement syndrome or adhesive capsulitis of shoulder.

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Guideline Note 172 and 173 Modifications

Question: Should Guideline Notes 172 and 173 have certain entries clarified?

Question source: Several CCOs

Issue: A CCO has reviewed GN172 and GN173 and found numerous instances in which the codes in these guidelines also appear on covered lines, which is causing issues with their claims processing systems. GN172 and GN173 are the guidelines for non-cost effective or non-effective interventions. In several cases, the GN172/GN173 entry has wording added to clarify that the codes are there for certain uses, and the codes appear on covered lines for other uses. However, HERC staff agree with the CCO reviewer that in several cases, the code duplication is confusing or unnecessary and the clarification on coverage could better be handled in alternative ways.

There were also several mistakes found in these guidelines that required correction.

Specific questions/issues:

1) When Yttrium 90 was reviewed and added to the liver cancer line in November 2018, the CPT and HCPCS codes for Y90 were left in GN173 to represent use in cancers other than hepatocellular carcinoma or colorectal cancer metastatic to the liver. Wording was added to the code description to try to make this distinction clear. HERC staff recommend removing the GN173 entry for Y90 and just leave the codes on the liver cancer line. They will not pair with other types of cancer, and this will reduce confusion and issues with claims processing.
2) Continuous blood glucose monitoring was reviewed in August 2017, at which time it was added to line 8 with a guideline. The CPT codes for continuous blood glucose monitoring (CPT 95250-95251) are also used for retrospective professional glucose monitoring, which was found to have limited evidence of clinical utility. This indication was added to GN172, with wording to indicate that it was there for retrospective monitoring. Again, this is confusing for CCOs. There is already a coding specification on line 8 which makes this distinction clear: "CPT 95250 and 95251 are included on this line for services related to real-time continuous glucose monitoring but not retrospective (professional) continuous glucose monitoring." HERC staff recommend removing this entry from GN172.
3) CPT 64568 (Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator) is on 2 covered lines (174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS and 440 TRIGEMINAL AND OTHER NERVE DISORDERS) and on line 660. The line 660 entry has wording to reflect that this code is in GN173 for "hypoglossal nerve stimulation for treatment of obstructive sleep apnea." There is a guideline note attached to the sleep apnea line where this restriction can be placed to limit confusion. HERC staff recommend moving the restriction to GN27 and removing from GN173.
4) CPT 81246 mistakenly appears in GN173.
5) CPT 88120 and 88121 (Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes) appear on line 271 CANCER OF BLADDER AND URETER when they are used for Uravysion testing which is clearly not included on line 271 in GUIDELINE NOTE 148, BIOMARKER TESTS OF CANCER TISSUE: "For bladder cancer, Urovysion testing is included on Line 660." HERC staff recommend removing these CPT codes from line 271.
6) CPT 90869 (Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management) was mistakenly

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not removed from GN173 when it was reviewed and added to line 7 MAJOR DEPRESSION, RECURRENT; MAJOR DEPRESSION, SINGLE EPISODE, SEVERE with a specific guideline as below.

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.

7) CPT 95012 (Nitric oxide expired gas determination) was added to line 9 in March 2018, but the entry to GN173 was not removed.

HERC staff recommendations:

1) Remove CPT 88120 and 88121 (Cytopathology, in situ hybridization (eg, FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes) from line 271 CANCER OF BLADDER AND URETER
2) Modify GN 27 as shown below

GUIDELINE NOTE 27, SLEEP APNEA

Line 203

CPAP is covered initially when all of the following conditions are met:

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

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

Mandibular advancement devices (oral appliances) are covered for those for whom CPAP fails or is contraindicated.

Surgery for sleep apnea in adults is not included on this line (due to lack of evidence of efficacy). Surgical codes are included on this line only for children who meet criteria according to Guideline Note 118 OBSTRUCTIVE SLEEP APNEA DIAGNOSIS AND TREATMENT FOR CHILDREN.

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Hypoglossal nerve stimulation for treatment of obstructive sleep apnea is not included on this line due to insufficient evidence of effectiveness and evidence of harm.

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.

3) Modify GN 172 as shown below

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

Line 500

The following interventions are prioritized on Line 500 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS:

Procedure Code	Intervention Description	Rationale	Last Review
~~95250 95251~~	~~Retrospective (professional) continuous glucose monitoring~~	~~Limited evidence of clinical utility~~	~~August, 2017~~

4) Modify GN173 as shown below

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

Line 660

The following Interventions are prioritized on Line 660 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
~~64568~~	~~Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator for hypoglossal nerve stimulation for treatment of obstructive sleep apnea~~	~~Insufficient evidence of effectiveness and evidence of harm~~	~~May, 2018~~
~~79445~~	~~Radiopharmaceutical therapy, by intra-arterial particulate administration for use in treating cancers other than primary hepatocellular carcinoma or colorectal cancer metastatic to the liver~~	~~No evidence of effectiveness~~	~~March, 2018~~

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~~C2616~~ ~~S2095~~	~~Brachytherapy source, non-stranded, yttrium-90, per source in treating cancers other than primary hepatocellular carcinoma or colorectal cancer metastatic to the liver.~~ ~~Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres, in treating cancers other than primary hepatocellular carcinoma or colorectal cancer metastatic to the liver~~		
81232~~, 81246~~	5-fluorouracil/5-FU and capecitabine drug metabolism	Insufficient evidence of effectiveness	November, 2017
~~90869~~	~~Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment~~	~~No evidence of effectiveness~~	~~December, 2012~~
~~95012~~	~~Nitric oxide expired gas determination~~		~~August 2015~~

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Value-based Benefits Subcommittee: Chronic Pain Reprioritization

March 14, 2019

Oregon Health Authority

Agenda

- Background
- Evidence summary
- Options for HERC consideration
  - Revised proposal
  - No action
- Public testimony
- Discussion and decision

Status quo

- All 5 of the conditions under consideration are “below the line” currently
- No treatments (e.g. cognitive behavioral therapy, PT) are available for patients with these conditions, unless they have another funded condition
- Medications (e.g. gabapentin, opioids) may be covered for patients with these conditions if their CCO does not prior authorize that drug
  - Current guideline calls out non-coverage of opioids for fibromyalgia
- Many CCOs have conducted initiatives to taper patients off opioids for these conditions as “below the line”

Conditions

ICD-10 Code	Description
G89.21	Chronic pain due to trauma
G89.28	Other chronic postprocedural pain
G89.29	Other chronic pain
G89.4	Chronic pain syndrome
M79.7	Fibromyalgia

No proposal today to change coverage requirements for other conditions associated with chronic pain other than these five conditions and consideration for adjusting the back pain taper requirement

Decision 1: Create new line?

- Review evidence, scoring, cost

Impact if funded

- Adds non-pharmacologic treatments and non-opioid pharmacologic treatments
- Adds explicit chronic opioid coverage if guideline is followed
- Taper plan for fibromyalgia and prescribing outside guideline

Impact if unfunded

- No change in noncoverage for any of these conditions
- Patients may continue to receive opioids if they have another funded painful condition (other than back pain), no PA requirement, or receiving through exception
- Still need to address back pain taper

Treatment	Effect	Level of Evidence
Tai Chi	Small but clinically significant short term benefit in pain and function	Low
Yoga	Inconsistent evidence	Low
Exercise	Non-clinically significant improvement in pain (S) and function (S,I)	Low to Moderate
Acupuncture	Small, non-clinically significant improvement in function (S,I)	Low
Interdisciplinary rehab	Clinically meaningful improvement in function in the short, intermediate, and long term	Low
Mindfulness	No clear improvement in function or pain	Moderate
Massage/PT	Small, non-clinically significant impact on short term function; insufficient evidence of impact on pain	Low
CBT	Small, non-clinically significant effects on pain, function and mood immediately post-treatment but not intermediate or long term	Low
Pain Education	No improvement in pain or function	Low

Drug	Effect	Level of Evidence
Milnacipran (Savella)	Improves pain and function by 30% or more (NNT 5-11)	Low
Duloxetine (Cymbalta)	Improves pain and function by 30% or more (NNT 5-11)	Low
Pregabalin (Lyrica)	Improves pain 30-50% (NNT 7-22)	Low
opioids	Small, non-clinically significant short-term improvement in pain and functioning Insufficient evidence of benefit for long-term prescribing	High Insufficient

Harms of Therapies

Therapy	Harms
Non-pharmaceutical therapies (eg PT, CBT)	Few if any
Non-opioid medications (eg pregabalin, duloxetine)	Sedation, weight gain, nausea
Opioids	Constipation, fatigue, dependence, overdose, opioid induced hyperalgesia, death

MED report on opioid tapering

- Overall quality of the evidence is very low
- Findings suggested that pain, function, and quality of life might improve during and after opioid discontinuation or dose reduction
- Scant evidence on harms associated with tapering strategies

Options for HERC Consideration

- ***OPTION: Do not reprioritize chronic pain syndrome, fibromyalgia and related conditions due to lack of evidence of effectiveness of available treatment modalities. Consider readdressing the prioritization of these conditions as part of the 2022 or 2024 Biennial Review.***
  - Rationale:
    - Low level of evidence of small, non-clinically significant effectiveness of various therapies
    - Wait for studies on back line changes
  - Impact:
    - Continued HERC intent of non-coverage for various treatments and medications (including opioids) for these 5 conditions

Options for HERC Consideration

- ***OPTION: Adopt the CPTF informed proposal from January with consideration of VbBS/HERC staff suggested edits***
  - ***Rationale:*** Chronic pain patients would have access to alternative therapies to opioids (physical treatments, pharmaceutical options). The Chronic Pain Taskforce felt these were beneficial treatments in their expert opinion.
  - ***Impact:*** New coverage would be created for nonpharmacologic and pharmacologic treatments for patients with these specific chronic pain conditions, including new coverage of long-term opioid therapy if patients meet certain criteria. This will have cost implications which will require actuarial analysis.

	Current HERC status	Future status with modified CPTF proposal
Fibromyalgia		
Opioids	Not covered	Covered, with required taper
Non-opioid medications	Not covered	Covered
Non-medication therapies	Not covered	Covered
Chronic pain syndrome		
Opioids	Not covered	Covered, within statewide guidelines
Non-opioid medications	Not covered	Covered
Non-medication therapies	Not covered	Covered
Back pain		
Chronic opioids	Covered for acute and subacute, not covered generally for chronic	No change. Improves tapering language to be more individualized.
Non-opioid medications	Covered	Covered
Non-medication therapies	Covered	Covered

New Line

- ***Create a new line for five chronic pain conditions including fibromyalgia for the 2020 Biennial Review***

CONDITION: FIBROMYALGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS

TREATMENT: LIMITED PHYSICAL MODALITIES, COGNITIVE BEHAVIORAL THERAPY, MEDICAL THERAPY

Diagnoses:

- Chronic pain due to trauma
- Other chronic postprocedural pain
- Other chronic pain
- Chronic pain syndrome
- Fibromyalgia

Procedures:

- Standard outpatient codes
- Psychotherapy (for CBT/ACT)
- Physical therapy
- Occupational therapy
- Acupuncture
- Health and behavior assessment

New Guideline with VBBS/Staff Suggested Changes

GUIDELINE NOTE XXX, TREATMENT OF FIBROMYALGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS

Line XXX

Chronic pain syndrome (ICD-10 G89.4), chronic pain due to trauma (ICD-10 G89.21), other chronic postprocedural pain (ICD-10 G89.28), other chronic pain (ICD-10 G89.29), and fibromyalgia (ICD-10 M79.7) are included on Line XXX when symptoms have been present for at least 3 months.

The following treatments are included on Line XXX:

- Office evaluation, consultation and education.
- Pain education, if done, should include but not be limited to sleep, nutrition, stress reduction/mood, exercise, and knowledge of pain as a biopsychosocial phenomenon. All providers with primary responsibility for managing fibromyalgia, chronic pain syndrome and related conditions ~~patients~~ should be trained in pain science (e.g., a contemporary understanding of the central and peripheral nervous system in chronic pain), motivational interviewing, culturally sensitive care, and trauma informed care. Care should be multidisciplinary and focus on active therapies.

Guideline continued

- Cognitive behavioral therapy (CBT). The necessity for CBT should be re-evaluated every 90 days and coverage will only be continued if there is documented evidence of decreasing depression or anxiety symptomatology, improved ability to work/function, increased self-efficacy, or other clinically significant, objective improvement.
- The following therapies, when available, may be provided: adaptive and restorative yoga, tai chi, mindfulness training, massage, supervised exercise therapy (land based and aquatic), intensive interdisciplinary rehabilitation. HCPCS S9451 is only included on Line XXX for the provision of yoga or supervised exercise therapy.

Guideline continued

- A total of 30 visits per year of any combination of the following therapies when available and medically appropriate. These therapies are only included on these lines if provided by a provider licensed to provide the therapy and when there is documentation of measurable clinically significant progress toward the therapy plan of care goals and objectives using evidence-based objective tools. Once the pre-determined goals of care have been achieved, an additional two visits may be authorized for maintenance therapy to maintain these improvements. These 30 visits count toward the visit totals in GUIDELINE NOTE 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE if the patient has comorbid back or spine conditions.
  - Rehabilitative therapy (physical and/or occupational therapy), if provided according to Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES. Rehabilitation services provided under this guideline also count towards visit totals in Guideline Note 6. CPT 97124 is included in this category.
  - Acupuncture

Guideline continued

- Non-opioid medications are only included on Line XXX if all of the following apply:
  - The patient is also being treated with active therapy (e.g., physical therapy, CBT) or is continuing maintenance of self-management strategies learned from such therapy.
  - The benefit of non-opioid medication is re-evaluated at least every 90 days and medications are only continued if there is documented evidence of initial improvement of function of at least fifteen percent as compared to baseline based on a validated tool (e.g., Pain average, interference with Enjoyment of life, and interference with General activity" (PEG) Assessment Scale, Oswestry, Oswestry, SF-MPQ, MSPQ), and function is maintained thereafter. Less frequent monitoring may be appropriate for certain medications after safety and efficacy are established.
- Short term opioid therapy (<90 days) is included on these lines only for chronic pain syndrome (ICD-10 G89.4), chronic pain due to trauma (ICD-10 G89.21), other chronic postprocedural pain (ICD-10 G89.28), and other chronic pain (ICD-10 G89.29), and only when prescribed in alignment with the Oregon Opioid Prescribing Guideline (2017-2018 version) [link]

Guideline continued

- Long-term opioid therapy (>90 days) is included on these lines only for chronic pain syndrome (ICD-10 G89.4), chronic pain due to trauma (ICD-10 G89.21), other chronic postprocedural pain (ICD-10 G89.28), and other chronic pain (ICD-10 G89.29) when all of the following criteria are met:
  - In alignment with the Oregon Opioid Prescribing Guidelines (2017-2018 version)
    - No illicit drug use or active substance use disorder (excluding tobacco)
    - The patient has been prescribed the patient pain education module through OPMC when it becomes available
    - Verification that the patient is not high risk for opioid misuse or abuse
      - Appropriate risk assessment has been performed (e.g., Opioid Risk Assessment Tool)
      - PDMP checked at least annually and shows no aberrant behavior
      - Urine drug testing is performed at least once per year and is appropriate

Guideline continued

- Prescribing criteria
  - Initial functional improvement has been documented of at least 30%, and function is maintained throughout the prescribing period
  - When prescribed with nonpharmacologic treatment options for managing pain
  - Careful reassessment of the evidence of individual benefits and risks should be undertaken for dosages > 50 MED. Dosages >90 MED should be avoided or carefully justified. When dosages > 50 MED are prescribed, naloxone should also be prescribed to the patient.
  - Patient and provider have assessed the relative risks and benefits of therapy and agree benefits outweigh risks, and have completed a material risk notice https://www.oregon.gov/omb/OMBForms1/material-risk-notice.pdf
  - No additional opioids are prescribed for flares of the chronic pain condition, although opioids may be prescribed separately for other acute injuries or surgeries as clinically appropriate
  - Comorbid mental health disorders are appropriately addressed

Guideline continued

- Opioid therapy is not included on this line for the following conditions/situations due to the evidence for harm:
  - When prescribed for fibromyalgia
  - For patients who fail to meet the guideline requirements regarding opioids above who have chronic pain syndrome, chronic pain due to trauma, other chronic postprocedural pain, and other chronic pain conditions included on this line

Guideline continued

- If a patient is already receiving chronic opioid therapy for these conditions/situations, then tapering is indicated. Opioid tapering should be done on an individualized basis which includes a taper goal of zero. Tapering should be unidirectional with a shared goal set by the patient and provider, generally with a 5-10% decrease monthly, and can be paused or slowed if the prescriber believes this is medically appropriate 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 opioid use disorder, treatment is included on Line 4 SUBSTANCE USE DISORDER.

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Actuarial Analysis of Creation of New Chronic Pain Line Above Funding Line

- Preliminary estimate of $10.8-$16.2 million per year total funds starting in 2020
- Approximately 89,700 individuals with paid claims in 2017 with at least one of the five diagnoses in proposal (didn't necessarily receive paid service for those diagnosis)
- About 62,900 of those also have diagnosis on back line who would already qualify for new benefits
- Therefore, an estimated 26,800 would be able to receive additional services
- Of 39,600 of these individuals currently receiving opioids, 12,900 with at least 120-day supply (majority of the others with 14 days or less)

Line Scoring

	Line 401	Line XXX	Line 528
Category (Non-Fatal Condition)	7	7	7
Healthy Life (0-10)	5	TBD	4
Suffering (0-5)	3	TBD	3
Population effects (0-5)	0	0	0
Vulnerable population (0-5)	0	0	0
Tertiary prevention (0-5)	2	TBD	0
Effectiveness (0-5)	3	TBD	1
Need for service (0-1)	0.8	TBD	0.8
Net cost	2	2	2
Score	432	TBD	112
Approximate line	401	TBD	528

HLY Score	Line Examples
5	Arthritis, back conditions
4	Migraine, persistent depression
Tertiary Prevention	
2	Strep throat, back conditions
1	Anxiety, Vestibular conditions
0	Arthritis, migraines
Effectiveness	
3	Back conditions, anxiety, arthritis
2	Peripheral nerve disorder, prostate disorders
1	Pelvic pain syndrome, colitis

Line 528 Revision

Line:	**528**
Condition:	~~FIBROMYALGIA,~~ CHRONIC FATIGUE SYNDROME~~, AND RELATED DISORDERS~~ (See Guideline Notes 64,65~~,135~~)
Treatment:	MEDICAL THERAPY
ICD-10:	~~G89.21,G89.28-G89.29,G89.4,M79.7,~~R53.82
CPT:	90785,90832-90840,90846-90853,93792,93793,98966-98969,99051, 99060,99070,99078,99201-99215,99281-99285,99341-99378,99381-99404,99408-99449,99487-99490,99495-99498,99605-99607
HCPCS:	G0248-G0250,G0396,G0397,G0463-G0467,G0490,G0511,G0513, G0514

Other Proposed Changes

- Back conditions guideline note edits (GN 56)
  - Wording changes to tie into new chronic pain line/guideline
  - Deletion of obsolete table
- Opioids for back condition guideline note edits (GN 60)
  - Removes “flare” as indication for short-term opioids
  - Tapering section revised to exactly match the section in the new chronic pain line guideline, with staff suggested edits
    - See wording on next slide
- Acupuncture guideline note edit (GN 92)
  - Adds entry for new line
- Delete fibromyalgia guideline note (GN 135)

Opioids for Back Conditions Guideline: Taper Paragraph

Transitional coverage for patients on long-term opioid therapy ~~as of July 1, 2016~~:

For patients ~~on covered chronic~~ receiving long-term opioid therapy (>90 days) for conditions of the back and spine ~~as of July 1, 2016, opioid medication is included on these lines only from July 1, 2016 to December 31, 2016. During the period from January 1, 2017 to December 31, 2017~~, continued coverage of opioid medications requires an individual treatment plan which includes a taper plan ~~developed by January 1, 2017 which includes a taper with an end to opioid therapy no later than January 1, 2018~~. Opioid tapering should be done on an individualized basis and include a taper goal to zero. Tapering should be unidirectional with a shared goal set by the patient and provider, generally with a 5-10% decrease monthly and can be paused or slowed if the prescriber believes this is medically appropriate based on the patient's overall status. Taper plans ~~must~~ should include nonpharmacological treatment strategies for managing the patient's pain ~~based on Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE~~. During the taper, behavioral health conditions need to be regularly assessed and appropriately managed.

Opioids for Back Conditions Guideline: Taper Paragraph Revisions Continued

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 ~~dependence and/or addiction related to their opioids~~ opioid use disorder, treatment is ~~available~~ included on Line 4 SUBSTANCE USE DISORDER.

Discussion and Decision

Reprioritization of Certain Chronic Pain Conditions
March 2019

WORK TO DATE AND INTERVAL INPUT

The Chronic Pain Taskforce met multiple times in 2017 and 2018. The in-process CPTF proposal was reviewed at the August 2018 and January 2019 VbBS meetings. The current proposal was informed by evidence and multiple stakeholder perspectives, including extensive public testimony, input from partners in public health, the CCOs, and various experts.

January VBBS meeting

At the January 2019 VbBS meeting, HERC staff presented proposed Prioritized List changes regarding coverage of certain chronic pain conditions, as informed by the Chronic Pain Taskforce and extensive public comment to date. HERC staff were directed to work on several sections of the proposal and bring it back for further consideration at the March 2019 VbBS and HERC meetings.

VbBS and HERC concerns to be addressed by HERC staff included:

1) Clarification of wording for the portion of the proposed new guideline regarding pain education:
    a. …. All providers ~~seeing~~ managing *[staff to propose improved wording here]* chronic pain patients should be trained in pain science (e.g., a contemporary understanding of the central and peripheral nervous system in chronic pain)…
2) Clarifications or modifications to the section of the proposed new guideline referring to opioid prescribing:
    a. Clarification regarding what (if any) circumstances would allow co-prescribing opioids with benzodiazepines
    b. Consideration for adding a requirement for co-prescribing naloxone for patients prescribed over 50 MED of opioids
    c. Suggestion to group provider qualifications together and patient requirements together for improved clarity.
3) Clarify or modify the section of the proposed new guideline referring to opioid tapering:
    a. Remove the title of the section as it is confusing
    b. Clarify that the opioid taper requirement in fibromyalgia is for "when prescribed for fibromyalgia."
    c. Clarify whether "evidence of harm" should be removed from the section when referring to opioid use in fibromyalgia

Additional Stakeholder Feedback

Since the January 2019 VbBS meeting, HERC staff have received feedback from the CCO Pharmacy Directors during their monthly public meetings. A summary of CCO Pharmacy Directors input includes:

1) High level of concern that the overall effect of this proposal would be to increase access to opioids
2) Appreciation of the VbBS/HERC goal to reduce opioid reliance for these conditions by offering alternative treatments, but unanimous concern that the other services and medications proposed for these conditions will have costs that outweigh any benefits
3) Many CCOs have implemented opioid controls for prescribing related to a broad range of conditions. There was general concern that the current proposed new guideline wording would require coverage of a second taper when the CCOs have already covered a taper for a patient.
4) Concern about the ability to track whether a provider or patient has completed the required pain education component of the opioid portion of the guideline

5) The high cost of the non-opioid medications used to treat fibromyalgia.
    a. *Note: Per OHA Pharmacy Team, duloxetine and amitriptyline are mental health carve-out drugs covered by FFS. Gabapentin is currently frequently covered without prior authorization. The only high cost drug added for coverage for fibromyalgia in this proposal would be pregabalin [Lyrica], which could have a substantial financial impact on the CCOs. However, pregabalin is scheduled to become generic in mid-2019, which could substantially reduce the cost of this drug over the next few years. A new drug, milnacipran (brand name Savella), has received FDA approval for treatment of fibromyalgia but has only very limited use to date.*
6) The proposed new guideline as written would add a significant prior authorization burden for CCOs, providers and patients
7) Concern that the magnitude of benefit and level of evidence for all of the drugs used to treat fibromyalgia is low.

EVIDENCE SUMMARY

HERC staff have summarized the overall level of evidence for the various treatment modalities proposed for the new line. This should be taken into consideration when discussing prioritization of the proposed new line. This evidence has been previously reviewed by the CPTF and VbBS; however, two of the reviewed articles [AHRQ 2018, Cochrane 2017] have been updated and are included in the abstracts below.

Evidence for Non-Pharmacologic Therapies

1) **Exercise (including Tai Chi)**
    a. AHRQ 2018 https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/nonpharma-chronic-pain-cer-209.pdf
        i. Tai Chi and quigong
            1. Over the short-term, two trials of mind-body practices reported slight improvement in function for qigong compared with waitlist (MD −7.5, 95% CI −13.3 to −1.68) and for tai chi compared with attention control (MD −23.5, 95% CI −30 to −17) based on 0 to 100 scale total FIQ score; Significantly more participants in the tai chi group also showed clinically meaningful improvement on total FIQ (RR 1.6, 95% CI 1.1 to 2.3) consistent with a slight effect (SOE: low).
            2. Note: minimum clinically important difference (MCID) in the 100 point FIQ scale is 14% change
            3. Qigong and tai chi were associated with moderately greater improvement in pain (0-10 scale) compared with waitlist and attention control in the short term (2 trials, pooled MD −1.54, 95% CI −2.67, −0.41, I2=75%). Significantly more participants in the tai chi group also showed clinically meaningful improvement on VAS pain (RR 2.0, 95% CI 1.1 to 3.8) consistent with a slight effect (SOE: low).
            4. Note: MCID for VAS pain scale is 1.0-1.4
            5. No evidence in the intermediate or long term.
            6. Data for harms were insufficient.
        ii. Exercise
            1. Exercise improved function short term (7 trials, pooled MD −7.61 on a 0 to 100 scale, 95% CI −12.78 to −2.43, I2= 59.9%) (SOE: low) and intermediate term (8 trials, pooled MD −6.04, 95% CI −9.05 to −3.03, I2=0%) (SOE: moderate). There were no clear effects in the long term (3 trials, pooled MD −4.33, 95% CI −10.18 to 1.52, I2=0%) (SOE: low).
                a. Note: minimum clinically important difference (MCID) in the 100 point FIQ scale is 14% change
            2. Exercise had a slightly greater effect on VAS pain (0 to 10 scale) compared with usual care, attention control, or no treatment short term (6 trials, pooled MD −0.89, 95% CI −1.32 to −0.46, I2=0%), but there were no clear effects at intermediate term (7 trials, pooled MD −0.41, 95% CI −0.87 to 0.05, I2=9.5%) or long term (4 trials, pooled MD −0.18, 95% CI −0.77 to 0.42, I2=0%) (SOE: moderate for all time frames).
                a. Note: MCID for VAS pain scale is 1.0-1.4

3. Data on harms were insufficient.

b. Cochrane review 2017 (Geneen) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5461882/
   i. Conclusions: The evidence in this overview suggests that the broad spectrum of physical activity and exercise interventions assessed here (aerobic, strength, flexibility, range of motion, and core or balance training programmes, as well as yoga, Pilates, and tai chi) are potentially beneficial, though the evidence for benefit is low quality and inconsistent.

c. Cochrane review 2018 (Geneen 2017b) https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD011279.pub3/full
   i. N=264 studies (19,642 participants)
   ii. Pain conditions included rheumatoid arthritis, osteoarthritis, fibromyalgia, low back pain, intermittent claudication, dysmenorrhoea, mechanical neck disorder, spinal cord injury, postpolio syndrome, and patellofemoral pain.
   iii. Interventions included aerobic, strength, flexibility, range of motion, and core or balance training programmes, as well as yoga, Pilates, and tai chi.
   iv. The quality of evidence was low due to participant numbers (most included studies had fewer than 50 participants in total), length of intervention and follow-up (rarely assessed beyond three to six months).
   v. Pain severity: several reviews noted favourable results from exercise but results were inconsistent across interventions and followup
   vi. Physical function: significantly improved as a result of the intervention in 14 reviews, though even these statistically significant results had only small-to-moderate effect sizes
   vii. Psychological function and quality of life**:** had variable results, results were either favourable to exercise (generally small and moderate effect size, with two reviews reporting significant, large effect sizes for quality of life), or showed no difference between groups.
   viii. **Authors' conclusions** The quality of the evidence examining physical activity and exercise for chronic pain is low. There were some favourable effects in reduction in pain severity and improved physical function, though these were mostly of small to-moderate effect, and were not consistent across the reviews.

2) Acupuncture

a. AHRQ 2018 https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/nonpharma-chronic-pain-cer-209.pdf
   i. Acupuncture was associated with slightly greater improvements in function based on 0 to 100 FIQ Total Score compared with sham acupuncture in the short term (2 trials, pooled MD −8.63, 95% CI −12.12 to −5.13, I2=0%) and intermediate term (2 trials, pooled MD −9.41, 95% CI −13.96 to −4.85, I2=27.4%) (SOE: moderate).
      1. Note: minimum clinically important difference (MCID) in the 100 point FIQ scale is 14% change
   ii. There was no clear effect of acupuncture on pain (0 to 10 scale) versus sham acupuncture in the short term (3 trials, pooled MD −0.13, 95% CI −1.06 to 0.79, I2=72%) or intermediate term (3 trials, pooled MD −0.53, 95% CI −1.15 to 0.09, I2=45.5%) (SOE: low).
   iii. No data on long-term effects were reported.
   iv. Discomfort & bruising were the most common adverse events. (SOE: moderate).

3) **Mindfulness therapy**
    a. AHRQ 2018 https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/nonpharma-chronic-pain-cer-209.pdf
        i. No clear short-term effects of mindfulness-based stress reduction (MBSR) were seen on function compared with waitlist or attention control (MD 0 to 0.06 on a 0-10 scale) in two trials (one fair and one poor quality) (SOE: moderate).
        ii. No clear short-term effects of MBSR on pain (MD 0.1 on a 0-100 VAS pain scale in one poor quality trial; MD −1.38 to −1.59 on the affective and −0.28 to −0.71 on the sensory dimension [scales not reported] of the Pain Perception Scale in one fair-quality trial) compared with waitlist or attention control in two trials (SOE: moderate). Intermediate-term and long-term outcomes were not reported.
    b. Cochrane review 2017 (Eccleston) https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010323.pub3/full
        i. N=3 studies. Two studies found a significant difference between groups at post-treatment and follow-up in opioid consumption. The remaining study found reduction in opioid consumption in both treatment and control groups, and between-group differences were not significant. We also found mixed findings for pain intensity and physical functioning.
        ii. Authors' conclusions No conclusions can be drawn from this small amount of information.

4) **Multidisciplinary rehabilitation programs**
    a. AHRQ 2018 https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/nonpharma-chronic-pain-cer-209.pdf
        i. More multidisciplinary treatment participants experienced a clinically meaningful improvement in FIQ total score (≥14% change) compared with usual care at short (odds ratio [OR] 3.1, 95% CI 1.6 to 6.2), intermediate (OR 3.1, 95% CI 1.5 to 6.4) and long term (OR 8.8, 95% CI 2.5 to 30.9) in one poor-quality trial. Multidisciplinary treatment was associated with a slight improvement in function (based on a 0-100 FIQ total score) versus usual care or waitlist in the short-term (3 trials, pooled MD −6.52, 95% CI −12.84 to −0.21, I2=67.3%), and versus usual care at intermediate term (3 trials, pooled MD −7.84, 95% CI −11.43 to −4.25, I2=18.2%) and long term (2 trials, pooled MD −8.42, 95% CI −13.76 to −3.08, I2=24.9%) (SOE: low for short, intermediate and long term).
        ii. Multidisciplinary treatment was associated with a slight improvement in pain compared with usual care or waitlist at intermediate term (3 trials, pooled MD −0.68, 95% CI −1.07 to −0.30, I2 = 0%); there were no clear differences compared with usual care or waitlist in the short term (2 trials [excluding an outlier trial], pooled MD on a 0-10 scale −0.24, 95% CI −0.63 to 0.15, I2 = 0%) or with usual care in the long term (2 trials, pooled MD −0.25, 95% CI −0.68 to 0.17, I2 = 0%) (SOE: low for short, intermediate and long-term).
            1. Note: MCID for VAS pain scale is 1.0-1.4
        iii. Data were insufficient for harms.
    b. MED 2014

i. Multidisciplinary chronic pain programs are likely to be more effective than usual care at reducing pain intensity, disability, and number of sick days, and increasing quality of life and return-to-work likelihood compared to usual care. The majority of studies evaluating multidisciplinary chronic pain programs focus on, or include a high proportion of, individuals with low back pain.
ii. A limited body of evidence suggests that multidisciplinary pain programs may be cost-effective at reducing sick absences and increasing return-to-work status for individuals with chronic non-cancer pain. There is insufficient evidence to determine the cost-effectiveness of multidisciplinary pain programs for other outcomes.

5) Massage

a. See AHRQ 2018 under Physical Therapy below
b. 2016 meta-analysis (Crawford 2016) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4925170/pdf/pnw099.pdf
    i. For pain
        1. N=5 studies of massage vs sham for musculoskeletal pain
            a. overall standardized mean difference (SMD) of -0.44 (95% CI, -0.84 to -0.05).
            b. Note: MCID for VAS pain scale is 1.0-1.4
        2. N=4 studies (245 patients) of massage vs no treatment
            a. The overall SMD across these studies (219 participants) was -1.14 (95% CI, -1.94 to -0.35)
        3. N=24 studies (1349 patients) of massage vs active therapy
            a. Overall SMD of -0.26 (95% CI, -0.53 to 0.003)
    ii. For activity
        1. N=3 studies (211 patients) of massage vs sham
            a. overall SMD of 0.36 (95% CI, -0.53 to 1.25);
            b. Note: unclear what scale was utilized
        2. N=7 studies (450 patients) of massage vs active therapy
            a. The overall SMD of -0.23 (95% CI, -0.50 to 0.05
    iii. Overall, low confidence in evidence that showed a small but statistically significant improvement in pain with massage for pain, activity and mood [note: not clinically meaningful]

6) Cognitive behavioral therapy

a. AHRQ 2018 https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/nonpharma-chronic-pain-cer-209.pdf
    i. CBT was associated with a slightly greater effect on function (FIQ Total Score) compared with usual care or waitlist in the short term (2 trials, pooled MD −10.67, 95% CI −17 to −4.30, I2=0%, 0-100 scale). The pooled estimate at intermediate term was not statistically significant (SOE: low for short term and intermediate term, insufficient for long term).
        1. Note: MCID for FIQ is a 14% change
    ii. CBT was associated with a slight improvement in pain (on a 0-10 scale) compared with usual care or waitlist in the short term (3 trials, pooled MD −0.78, 95% CI −1.30 to −0.17), but not in the intermediate term (2 trials, pooled MD −0.44, 95% CI −1.30 to 0.01); evidence from one poor-quality trial

was insufficient to determine effects on long-term pain (SOE: low for short term and intermediate term, insufficient for long term
    1. Note: MCID for VAS pain scale is 1.0-1.4
iii. Data on harms were insufficient.

b. Cochrane review 2017 (35 studies, 4788 patients) (Williams) https://www.ncbi.nlm.nih.gov/pubmed/23152245
    i. CBT vs active control (N=13 studies, 1258 patients)
        1. The overall effect of CBT on pain was not significant immediately post treatment (Z = 1.43, P > 0.05) or at follow up (Z = 1.12, P > 0.05)
        2. The effects of CBT on disability immediately after treatment was significant (Z = 2.66, P < 0.01) with a small effect size: standardised mean difference (SMD) -0.19 (95%confidence interval (CI) -0.33 to -0.05). The effect of CBT at follow-up was significant (Z = 2.28, P < 0.05) with a small effect size of SMD -0.15 (95% CI -0.28 to -0.02)
        3. The effect of CBT on mood; the overall effect was not significant (Z = 0.72, P > 0.05) immediately after treatment or at follow up (Z = 1.15, P > 0.05)
    ii. CBT vs usual care (N=16 studies with 1148 patient)
        1. The effect on pain was significant (Z = 2.59, P < 0.05) with an effect size of SMD -0.21 (95% CI -0.37 to -0.05) immediately after treatment; however, on follow up, the effect was non-significant (Z = 0.99, P > 0.05)
        2. The effect on disability was significant (Z = 2.35, P < 0.05) with an effect size of SMD - 0.26 (95% CI -0.47 to -0.04) immediately after treatment; however, on follow up, the effect was non-significant (Z = 0.66, P > 0.05)
    iii. The effect on mood was significant (Z = 3.84, P < 0.01) with an effect size of SMD -0.38 (95% CI -0.57 to -0.18) immediately after treatment; follow up showed with an overall effect of CBT was just significant (Z = 1.99, P = 0.05) with a small effect size of SMD -0.26 (95%CI -0.51 to 0.00)

7) Pain education

a. 2015 systematic review and meta-analysis (9 studies) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4591560/pdf/13643_2015_Article_120.pdf
    i. Pooled data from five studies, where the comparator group was usual care, showed no improvement in pain or disability.
    ii. Conclusions: The evidence base is limited by the small numbers of studies, their relatively small sample sizes, and the diversity in types of education studied.

8) Physical therapy (specifically myofascial release)

a. AHRQ 2018 https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/nonpharma-chronic-pain-cer-209.pdf
    i. Myofascial release therapy was associated with a slightly greater effect on intermediate-term function as measured by the FIQ (mean 58.6 ± 16.3 vs. 64.1 ± 18.1 on a 100 point scale, P=0.048 for group by repeated measures ANOVA), but not long-term function (mean 62.8 ± 20.1 vs. 65.0 ± 19.8 on the FIQ, 0-100

scale, P=0.329), compared with sham in one fair-quality trial (SOE: low). Short-term function was not reported.

1. Note: MCID for FIQ is a 14% change

ii. There was insufficient evidence to determine the effects of myofascial release therapy on short-term pain (1 poor-quality trial) and intermediate-term pain (1 fair-quality and 1 poor-quality trial) compared with sham; there were inconsistencies in effect estimates between the intermediate-term trials (SOE: insufficient).

iii. Data were insufficient for harms

HERC staff summary of evidence for non-pharmacologic interventions

1) **Tai chi**: small but clinically significant benefit in pain and function in the short term but not intermediate or long term (SOE: low)
2) **Yoga**: inconsistent evidence (SOE: low)
3) **Exercise**: short term non-clinically significant improvement in pain and function (SOE: low to moderate); intermediate term non-clinically significant improvement in function (SOE: moderate); no long term impact on pain (SOE: moderate)
4) **Acupuncture:** small, short to intermediate term, non-clinically significant improvement in function (SOE: moderate); no improvement in pain (SOE: low)
5) **Interdisciplinary rehabilitation**: clinically meaningful improvement in function in the short, intermediate, and long term based on one poor quality study (SOE: low). No clinically meaningful impact on pain (SOE: low)
6) **Mindfulness**: no clear improvement in function or pain (SOE: moderate)
7) **Massage/PT with myofascial release**: small, non-clinically significant impact on short term function (SOE: low); insufficient evidence of impact on pain
8) **Cognitive behavioral therapy**: small, non-clinically significant effects on pain, function and mood immediately post-treatment that is not sustained in the intermediate or long term (SOE: low)
9) **Pain education**: no improvement in pain or disability (SOE: low)

Summary of evidence for non-pharmacological treatments for fibromyalgia from AHRQ review article (2018) compared with usual care, placebo, sham, attention control, or waitlist:

	Function *Short-Term* *Effect Size SOE*	**Function** *Intermediate - Term* Effect Size SOE	**Function** *Long-Term* Effect Size SOE	**Pain** *Short-Term* Effect Size SOE	**Pain** *Intermediate-Term* Effect Size SOE	**Pain** *Long-Term* Effect Size SOE
Exercise	slight +	slight ++	none +	slight ++	none ++	none ++
Psychological Therapies: CBT	slight +	slight +	insufficient evidence	slight +	none +	insufficient evidence
Psychological Therapies: Biofeedback, Imagery	insufficient evidence	insufficient evidence	insufficient evidence	insufficient evidence	insufficient evidence	insufficient evidence
Physical Modalities: Magnetic Pads	insufficient evidence	none +	no evidence	insufficient evidence	none +	no evidence
Manual Therapies: Massage (Myofascial Release)	no evidence	slight +	none +	insufficient evidence	insufficient evidence	slight +
Mindfulness Practices: MBSR	none ++	no evidence	no evidence	none ++	no evidence	no evidence
Mind-Body Practices: Qigong, Tai Chi	slight +	no evidence	no evidence	moderate +	no evidence	no evidence
Acupuncture	slight ++	slight ++	no evidence	none +	none +	no evidence
Multidisciplinary Rehabilitation	slight +	slight +	slight +	none +	slight +	none +

Short-Term: 1 to <6 months; Intermediate-Term: ≥6 to <12 months; Long-Term: ≥12 months
Effect Size: none, slight/small, moderate, or large improvement
Strength of Evidence: + = low, ++ = moderate, +++ = high
CBT = cognitive-behavioral therapy; MBSR = mindfulness-based stress reduction; none = no effect/no statistically significant effect; SOE = strength of evidence

Summary of Evidence for Non-Pharmacologic Therapies for Back and Neck Pain

Treatment	Strength of Evidence	Magnitude of Benefit
Spinal manipulation	Good	Small to moderate short term benefit
Yoga (viniyoga)	Fair	Moderate benefit
Acupuncture	Fair	Moderate benefit
Cognitive behavioral therapy	Good	Moderate benefit
Exercise therapy	Good	Moderate benefit
Intensive interdisciplinary rehabilitation	Good	Moderate benefit
Massage therapy	Fair	Moderate benefit
Progressive relaxation	Fair	Moderate benefit

Note: This evidence table was previously reviewed by the HERC when considering coverage for back pain. The back pain interventions summarized above are abstracted from Chou 2007 and may not be directly comparable to the same treatment summarized by HERC staff above for chronic pain conditions

Evidence for Non-opioid Therapy

Pharmacy and Therapeutics (P&T) Committee review of non-opioid pharmacologic interventions for fibromyalgia

Note: Chronic pain was too undefined a condition for P&T to conduct a meaningful literature review

- There is no moderate or high strength evidence for any pharmacological treatment compared to placebo or other therapy. Like many other conditions for chronic pain, evidence supporting benefit of long-term pharmacological treatment for fibromyalgia is limited, efficacy of pharmacotherapy is relatively modest, and clinical trials often document a large placebo response upon evaluation of symptom improvement. Pharmacological interventions with the most evidence of benefit include duloxetine, milnacipran, and pregabalin, but applicability to a broader population is limited.
- There is low strength evidence that milnacipran or duloxetine may improve pain symptoms as evaluated by patient global impression of improvement or change (PGI-I or PGIC) of much or very much improved, 30% improvement in pain, pain intensity, and disability, but have no clinical improvement for pain relief of 50% or more, sleep, fatigue, depression, cognitive disturbances, anxiety or quality of life. The number needed to treat (NNT) for pain improvement ranged from 5-11 depending on the outcome evaluated.
- There is low strength evidence that, compared to placebo, pregabalin may improve outcomes of pain relief of more than 50%, pain relief of more than 30%, and pain improvement as evaluated by a PGIC score of much or very much improved. The estimated NNT varied depending on dose and outcome, but ranged from 7 to 22.
- Adverse effects more common with pregabalin compared to placebo included somnolence (number needed to harm [NNH] 7), dizziness (NNH 3), weight gain (NNH 18) and peripheral edema (NNH 19; low strength evidence). SNRIs (duloxetine, milnacipran and desvenlafaxine) were associated with an increased incidence of nausea (NNH 6) and somnolence (NNH 20).
- Evidence of benefit or harms for other pharmacological treatments was insufficient.

Update of Evidence for Opioid Therapy

1) **Busse 2018,** JAMA systematic review and meta-analysis of opioids for chronic non-cancer pain
    a. N=96 RCTs (26, 169 patients)
    http://www.partnershiphp.org/Providers/Quality/Documents/MPS%202019/jama_busse_2018_01_09_19.pdf
        i. 25 trials of neuropathic pain, 32 trials of nociceptive pain, 33 trials of central sensitization (pain present in the absence of tissue damage), and 6 trials of mixed types of pain.
        ii. Studies were a minimum of 4 weeks long
        iii. It was not stated what the maximum length of studies were
    b. The primary outcomes were pain intensity (score range, 0-10 cm on a visual analog scale for pain; lower is better and the minimally important difference [MID] is 1 cm), physical functioning (score range, 0-100 points on the 36-item Short Form physical component score [SF-36 PCS]; higher is better and the MID is 5 points)

c. Compared with placebo, opioid use was associated with reduced pain (weighted mean difference [WMD], −0.69 cm [95%CI, −0.82 to −0.56 cm] on a 10-cm visual analog scale for pain, although the difference did not reach the minimally important difference of 1 cm; modeled risk difference for achieving the MID, 11.9% [95%CI, 9.7%to 14.1%]). Studies with longer follow-up reported less pain relief.
d. High-quality evidence from 51RCTs (15 754patients) showed opioids were associated with a small improvement in physical functioning compared with placebo, but did not meet the criterion for the minimally important difference (weighted mean difference, 2.04 points [95% CI, 1.41-2.68 points] on the 100-point SF-36 physical component score, *P* < .001; minimally important difference, 5 points; modeled risk difference for achieving the minimally important difference, 8.5% [95% CI, 5.9%-11.2%]
e. Opioids were not significantly associated with emotional functioning compared with placebo (weighted mean difference, 0.14 points [95% CI, −0.58 to 0.86 points] on the 100-point SF-36 mental component score, *P* = .70)
f. Opioids were associated with increased vomiting (5.9% with opioids vs 2.3% with placebo for trials that excluded patients with adverse events during a run-in period).
g. Low- to moderate-quality evidence suggested similar associations of opioids with improvements in pain and physical functioning compared with nonsteroidal anti-inflammatory drugs (pain: WMD, −0.60 cm [95%CI, −1.54 to 0.34 cm]; physical functioning: WMD, −0.90 points [95%CI, −2.69 to 0.89 points]), tricyclic antidepressants (pain: WMD, −0.13 cm [95%CI, −0.99 to 0.74 cm]; physical functioning: WMD, −5.31 points [95%CI, −13.77 to 3.14 points]), and anticonvulsants (pain: WMD, −0.90 cm[95%CI, −1.65 to −0.14 cm]; physical functioning: WMD, 0.45 points [95%CI, −5.77 to 6.66 points]).
h. CONCLUSIONS Compared with placebo, opioids were associated with small improvements in pain, physical functioning, and sleep quality; unimportant improvements in social functioning; and no improvements in emotional functioning or role functioning. Compared with placebo, opioids were associated with increased vomiting, drowsiness, constipation, dizziness, nausea, dry mouth, and pruritus.

2) **Els 2018**, Cochrane review on intermediate and long term harms of opioid therapy for chronic non-cancer pain
https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD012509.pub2/epdf/full
   a. N=16 reviews
      i. The longest study was 13 months in duration, with most in the 6- to 16-week range.
      ii. The quality of the included reviews was high using AMSTAR criteria
      iii. The quality of the evidence for the generic adverse event outcomes according to GRADE ranged from very low to moderate. A GRADE assessment of the quality of the evidence for specific adverse events led to a downgrading to very low- to moderate-quality evidence due to risk of bias, indirectness, and imprecision.
   b. Based on the 14 selected Cochrane Reviews, there was a significantly increased risk of experiencing any adverse event with opioids compared to placebo (risk ratio (RR) 1.42, 95% confidence interval (CI) 1.22 to 1.66) as well as with opioids compared to a non-opioid active pharmacological comparator, with a similar risk ratio (RR 1.21, 95% CI 1.10 to 1.33).

c. There was also a significantly increased risk of experiencing a serious adverse event with opioids compared to placebo (RR 2.75, 95% CI 2.06 to 3.67).
d. Furthermore, we found significantly increased risk ratios with opioids compared to placebo for a number of specific adverse events: constipation, dizziness, drowsiness, fatigue, hot flushes, increased sweating, nausea, pruritus, and vomiting.
e. There was no data on any of the following prespecified adverse events of interest in any of the included reviews in this overview of Cochrane Reviews: addiction, cognitive dysfunction, depressive symptoms or mood disturbances, hypogonadism or other endocrine dysfunction, respiratory depression, sexual dysfunction, and sleep apnea or sleep-disordered breathing.
f. **Authors' conclusions** A number of adverse events, including serious adverse events, are associated with the medium- and long-term use of opioids for CNCP. The absolute event rate for any adverse event with opioids in trials using a placebo as comparison was 78%, with an absolute event rate of 7.5% for any serious adverse event. Based on the adverse events identified, clinically relevant benefit would need to be clearly demonstrated before long-term use could be considered in people with CNCP in clinical practice.

Evidence on Opioid Tapering

The following is a summary of the MED 2018 Evidence Review for opioid tapering as completed by Oregon Health & Science University's Center for Evidence-based Policy:

1) Overall quality of the evidence is very low
2) Findings suggested that pain, function, and quality of life might improve during and after opioid discontinuation or dose reduction
3) Scant evidence on harms associated with tapering strategies
    a. Adverse events—mortality, suicide or overdose
        i. 5 studies in the Frank review included adverse events
            1. 1 opioid-related overdose death in a patient in a buprenorphine treatment program (after discontinuation of buprenorphine) out of a total of 5 studies (no N given)
        ii. A retrospective cohort study conducted in a VA population whose opioid therapy was discontinued by their clinician (primarily for aberrant behaviors) reported that 12% of the cohort had documented suicidal ideation and nonfatal suicidal self-directed violence (SSV) in the 12 months after opioid discontinuation
            1. This study identified Hispanic ethnicity (adjusted odds ratio [OR] 7.25 (95% CI 1.96–27.18), PTSD diagnosis: 2.56 (1.23–5.32), and psychotic-spectrum disorder diagnoses (OR 3.19; 95% CI 1.14 to 8.89) were correlated with suicidal ideation and SSV in the 12 months following clinician-initiated opioid discontinuation.
        iii. Other new studies did not report information on serious adverse events such as mortality, suicide, or overdose events.
    b. Adverse events—opioid withdrawal symptoms

   i. In the systematic review by Frank et al., 18 studies (3 fair and 15 poor methodological quality) reported opioid withdrawal symptoms. Rates of withdrawal symptoms ranged widely across the studies (0% to 100%).

4) Taper length
   a. Not able to draw any conclusions regarding rapid versus slow tapering.
5) Patient-initiated vs nonpatient-initiated tapering
   a. Very little information found on this issue. In almost all of the studies included in the previous MED report and in this update, patients had some autonomy in the decision to taper their opioids.

HERC Staff Evidence Summary of overall evidence for pharmacologic and non-pharmacologic treatments for certain chronic pain conditions

Of the various non-pharmacologic interventions proposed for the new chronic pain line, only Tai Chi and interdisciplinary rehabilitation resulted in clinically meaningful but small improvements in short term function. This improvement only continued into the intermediate and long term for interdisciplinary rehabilitation. Tai Chi and possibly massage/PT with myofascial release had clinically meaningful improvement in short term pain, but this improvement did not continue to the intermediate or long term. The strength of evidence for all these findings is low. Topic experts making up the Chronic Pain Taskforce recommended inclusion of these therapies because, in their experience, these therapies can be helpful for certain patients and have low level of risk. Overall, there was a significantly higher level of evidence that non-pharmacological therapies had a clinically significant impact on back pain (which informed the HERC's Back Pain Guideline) as compared to the chronic pain conditions under current coverage consideration.

The pharmacologic interventions indicated for fibromyalgia included only 3 medications with low evidence of effectiveness (duloxetine [Cymbalta], milnacipran [Savella], and pregabalin [Lyrica]). All other medications reviewed had insufficient evidence of effectiveness. Non-opioid pharmacologic interventions had evidence of adverse effects, including weight gain, nausea and somnolence. Opioid therapy has no to minimal evidence of long term clinically significant benefit for chronic pain conditions for improvement of pain function, or role functioning; there is evidence of harms associated with long term opioid therapy including fatigue, constipation, and nausea, as well as reported risks of dependence, overdose, opioid-induced hyperalgesia, and death. There is limited evidence on the benefits or harms of opioid tapering, although early studies indicate that tapering long term opioid therapy may improve pain, function, and quality of life.

OPTIONS FOR HERC CONSIDERATION:

NO CHANGE

Do not reprioritize chronic pain syndrome, fibromyalgia and related conditions due to lack of evidence of effectiveness of available treatment modalities. Consider readdressing the prioritization of these conditions as part of the 2022 or 2024 Biennial Review.

Note: if this option is adopted, the HERC will still need to discuss any changes required to the chronic back line opioid guideline (see below)

Rationale: There is limited evidence that the proposed interventions have meaningful clinical impact on fibromyalgia and chronic pain syndrome; these interventions will have costs associated with them. The revised proposal may have the effect of increasing access to opioid medications. The decision regarding reprioritization of certain chronic pain conditions can be delayed until the 2022 or 2024 Biennial Review, to allow this decision to be informed by emerging evidence, including the impacts of the 2016 changes in coverage for back conditions. These studies will provide the most relevant evidence to date on the proposed policy, including a better understanding of the impact of the back pain policy on outcomes (positive and negative) in the OHP population.

Impact: Making no change in the prioritization of certain chronic pain conditions including fibromyalgia will continue the status quo. This does not allow access for patients with these conditions to non-pharmaceutical treatments such as physical therapy, acupuncture, or cognitive behavioral therapy, as well as not allowing access to certain medications which require a prior authorization, unless the patient has a covered comorbid condition (e.g. arthritis) or has gone through the exceptions process.

ADOPT MODIFIED PROPOSAL

Adopt the modified CPTF proposal from January with consideration of VbBS/HERC staff suggested edits

Rationale: Currently, patients with these five chronic pain conditions (and who do not have co-morbid covered conditions) do not have access to any therapies other than medications which are not currently subject to prior authorization controls by their CCO or FFS. Such medications may include opioids and gabapentin. In the face of the opioid epidemic, alternative nonpharmacologic therapies for these conditions would be offered to patients. The Chronic Pain Taskforce recommended these changes based on their expert opinion and experience.

Impact: New coverage will be created for non-pharmacologic and pharmacologic treatments for patients with these specific chronic pain conditions, including new coverage of long-term opioid therapy for these conditions if patients meet certain criteria. This will have cost implications that have initially been estimated by the Actuarial Services Unit to be between $10.8-$16.2 million/year starting in 2020. Patients with fibromyalgia will continue to not have opioids intended to be covered, although an opioid taper for patients with fibromyalgia would be newly covered.

The following are the recommended edits for adopting the modified proposal:

a. Create a new line for five chronic pain conditions including fibromyalgia for the 2020 Biennial Review Prioritized List as shown below
b. Adopt a new guideline for this line as shown below
    i. Discuss if all suggested treatments should be included on this line
c. Determine scoring for this new line
d. Modify line 528 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME AND RELATED CONDITIONS as shown below
    i. Remove all diagnoses other than chronic fatigue syndrome and modify line title
    ii. Rescore this line if necessary
e. Modify GUIDELINE NOTE 56, NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE as shown below
    i. Matches changes in the new chronic pain conditions guideline
    ii. Removes obsolete table
f. Modify GUIDELINE NOTE 92, ACUPUNCTURE as shown below
    i. Adds the new chronic pain line to the guideline
g. Delete GUIDELINE NOTE 135, FIBROMYALGIA
    i. Components are all incorporated into the new guideline

LINE: XXX
CONDITION: FIBROMYALGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS
TREATMENT: LIMITED PHYSICAL MODALITIES, COGNITIVE BEHAVIORAL THERAPY, MEDICAL THERAPY
ICD-10: G89.21 (Chronic pain due to trauma), G89.28 (Other chronic postprocedural pain), G89.29 (Other chronic pain), G89.4 (Chronic pain syndrome), M79.7 (fibromyalgia)
CPT: 90785, 90832-90840, 90853 (psychotherapy—for CBT and ACT), 96150-96155 (Health and behavior assessment and intervention), 97110-97124, 97140-97168, 97530, 97535 (PT/OT), 97810-97814 (acupuncture), 98966-98969, 99051, 99060,99070,99078,99201-99215,99281-99285,99304-99337,99340-99404,99408-99449,99487-99490,99495,99496,99605-99607 (medical office visits, including ER and SNF)
HCPCS: G0157-G0160 (PT/OT assistant), G0396-G0397 (alcohol and substance abuse screening), G0463-G0467,G0469,G0470 (FQHC care), G0490, G0511-G0513 (RFQHC care), G0514 (prolonged office visit)

GUIDELINE NOTE XXX, TREATMENT OF FIBROMYALGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS

Line XXX

Chronic pain syndrome (ICD-10 G89.4), chronic pain due to trauma (ICD-10 G89.21), other chronic postprocedural pain (ICD-10 G89.28), other chronic pain (ICD-10 G89.29), and fibromyalgia (ICD-10 M79.7) are included on line XXX when symptoms have been present for at least 3 months.

The following treatments are included on line XXX:

- Office evaluation, consultation and education.
    - Pain education, if done, should include but not be limited to sleep, nutrition, stress reduction/mood, exercise, and knowledge of pain as a biopsychosocial phenomenon. All providers with primary responsibility for managing fibromyalgia, chronic pain

syndrome and related conditions ~~patients~~ should be trained in pain science (e.g., a contemporary understanding of the central and peripheral nervous system in chronic pain), motivational interviewing, culturally sensitive care, and trauma informed care. Care should be multidisciplinary and focus on active therapies.

- Cognitive behavioral therapy (CBT). The necessity for CBT should be re-evaluated every 90 days and coverage will only be continued if there is documented evidence of decreasing depression or anxiety symptomatology, improved ability to work/function, increased self-efficacy, or other clinically significant, objective improvement.
- The following therapies, when available, may be provided: adaptive and restorative yoga, Tai Chi, mindfulness training, massage, supervised exercise therapy (land based and aquatic), intensive interdisciplinary rehabilitation. HCPCS S9451 is only included on Line XXX for the provision of yoga, Tai Chi, or supervised exercise therapy.
- A total of 30 visits per year of any combination of the following therapies when available and medically appropriate. These therapies are only included on these lines if provided by a provider licensed to provide the therapy and when there is documentation of measurable clinically significant progress toward the therapy plan of care goals and objectives using evidence-based objective tools. Once the pre-determined goals of care have been achieved, an additional two visits may be authorized for maintenance therapy to maintain these improvements. These 30 visits count toward the visit totals in GUIDELINE NOTE 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE if the patient has comorbid back or spine conditions.
    1) Rehabilitative therapy (physical and/or occupational therapy), if provided according to Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES. Rehabilitation services provided under this guideline also count towards visit totals in Guideline Note 6. CPT 97124 is included in this category.
    2) Acupuncture

Non-opioid medications are only included on line XXX if all of the following apply:

1) The patient is also being treated with active therapy (e.g., physical therapy, CBT) or is continuing maintenance of self-management strategies learned from such therapy.
2) The benefit of non-opioid medication is re-evaluated at least every 90 days and medications are only continued if there is documented evidence of initial improvement of function of at least fifteen percent as compared to baseline based on a validated tool (e.g., Pain average, interference with Enjoyment of life, and interference with General activity" (PEG) Assessment Scale, Oswestry, SF-MPQ, MSPQ), and function is maintained thereafter. Less frequent monitoring may be appropriate for certain medications after safety and efficacy are established.

Short term opioid therapy (<90 days) is included on these lines only for chronic pain syndrome (ICD-10 G89.4), chronic pain due to trauma (ICD-10 G89.21), other chronic postprocedural pain (ICD-10 G89.28), and other chronic pain (ICD-10 G89.29), and only when prescribed in alignment with the Oregon Opioid Prescribing Guideline (2017-2018 version) https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/taskforce/oregon-opioid-prescribing-guidelines.pdf

Long-term opioid therapy (>90 days) is included on these lines only for chronic pain syndrome (ICD-10 G89.4), chronic pain due to trauma (ICD-10 G89.21), other chronic postprocedural pain (ICD-10 G89.28), and other chronic pain (ICD-10 G89.29) when all of the following criteria are met:

- In alignment with the Oregon Opioid Prescribing Guideline (2017-2018 version) https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/taskforce/oregon-opioid-prescribing-guidelines.pdf
    - No illicit drug use or active substance use disorder (excluding tobacco)
    - The patient has been prescribed the patient pain education module through OPMC when it becomes available
    - Verification that the patient is not high risk for opioid misuse or abuse
        - Appropriate risk assessment has been performed (e.g., Opioid Risk Assessment Tool)
        - PDMP checked at least annually and shows no aberrant behavior
        - Urine drug testing is performed at least once per year and is appropriate
- Prescribing criteria
    - Initial functional improvement has been documented of at least 30%, and function is maintained throughout the prescribing period
    - When prescribed with nonpharmacologic treatment options for managing pain
    - Careful reassessment of the evidence of individual benefits and risks should be undertaken for dosages > 50 MED. Dosages >90 MED should be avoided or carefully justified. When dosages > 50 MED are prescribed, naloxone should also be prescribed to the patient.
    - Patient and provider have assessed the relative risks and benefits of therapy and agree benefits outweigh risks, and have completed a material risk notice https://www.oregon.gov/omb/OMBForms1/material-risk-notice.pdf
    - No additional opioids are prescribed for flares of the chronic pain condition, although opioids may be prescribed separately for other acute injuries or surgeries as clinically appropriate
    - Comorbid mental health disorders are appropriately addressed
    - ~~No concurrent prescribing of benzodiazepines without extenuating circumstances~~ [strike from previous CPTF recommendation as this is included in the Oregon Opioid Prescribing Guideline]
- ~~Prescriber criteria~~
    - ~~Prescriber has updated opioid prescribing CME and ideally has completed the Oregon Pain Management Commission (OPMC) pain module~~
    - ~~[strike this language from previous recommendation as it would not be implementable]~~

~~Opioid tapering for fibromyalgia and patients failing to meet the opioid prescribing criteria above:~~
Opioid therapy is not included on this line for the following conditions/situations due to the evidence for harm:

- When prescribed for fibromyalgia
- For patients who fail to meet the guideline requirements regarding opioids above who have chronic pain syndrome, chronic pain due to trauma, other chronic postprocedural pain, and other chronic pain conditions included on this line

If a patient is already receiving long-term opioid therapy for these conditions/situations, then tapering is indicated. Opioid tapering should be done on an individualized basis which includes a taper goal of zero. Tapering should be unidirectional with a shared goal set by the patient and provider, generally with a 5-10% decrease monthly, and can be paused or slowed if the prescriber believes this is medically appropriate 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 opioid use disorder, treatment is included on Line 4 SUBSTANCE USE DISORDER**.**

Line Scoring if Reprioritized

	Line 401	Line XXX	Line 528
Category (Non-Fatal Condition)	7	7	7
Healthy Life (0-10)	5	TBD	4
Suffering (0-5)	3	TBD	3
Population effects (0-5)	0	0	0
Vulnerable population (0-5)	0	0	0
Tertiary prevention (0-5)	2	TBD	0
Effectiveness (0-5)	3	TBD	1
Need for service (0-1)	0.8	TBD	0.8
Net cost	2	2	2
Score	432	TBD	112
Approximate line	401	TBD	528

Line 401 CONDITIONS OF THE BACK AND SPINE
Line XXX FIBROMYALGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS [proposed]
Line 528 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS [current]

Scoring comparators

Healthy Life (0-10)

- Score = 5
    - 356 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS AND ASEPTIC NECROSIS OF BONE/JOINT REPLACEMENT
    - 361 SCOLIOSIS
    - 395 ENDOMETRIOSIS AND ADENOMYOSIS
    - 401 CONDITIONS OF THE BACK AND SPINE/MEDICAL THERAPY
    - 526 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS
- Score = 4
    - 409 MIGRAINE HEADACHES
    - 421 LYMPHEDEMA
    - 431 PERSISTENT DEPRESSIVE DISORDER
    - 527 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS/SURGERY
    - 529 CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME, DYSPAREUNIA

Tertiary prevention (0-5)

- Score = 2
    - 368 STREPTOCOCCAL SORE THROAT AND SCARLET FEVER; VINCENT'S DISEASE; ULCER OF TONSIL; UNILATERAL HYPERTROPHY OF TONSIL
    - 387 ANOGENITAL VIRAL WARTS
    - 395 ENDOMETRIOSIS AND ADENOMYOSIS
    - 401 CONDITIONS OF THE BACK AND SPINE/MEDICAL THERAPY
    - 420 MENSTRUAL BLEEDING DISORDERS
    - 421 LYMPHEDEMA
- Score = 1
    - 376 DISRUPTIONS OF THE LIGAMENTS AND TENDONS OF THE ARMS AND LEGS, EXCLUDING THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT
    - 413 OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED
    - 431 PERSISTENT DEPRESSIVE DISORDER
    - 510 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM
    - 534 PERIPHERAL NERVE DISORDERS/SURGERY
- Score = 0
    - 356 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS AND ASEPTIC NECROSIS OF BONE/JOINT REPLACEMENT (surgical line)
    - 409 MIGRAINE HEADACHES
    - 461 OSTEOARTHRITIS AND ALLIED DISORDERS
    - 507 PERIPHERAL NERVE DISORDERS
    - 522 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER OR DIAPHRAGMATIC HERNIA)
    - 538 TENSION HEADACHES

Effectiveness (0-5)

- Score = 3
    - 395 ENDOMETRIOSIS AND ADENOMYOSIS
    - 401 CONDITIONS OF THE BACK AND SPINE/MEDICAL THERAPY
    - 413 OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED
    - 461 OSTEOARTHRITIS AND ALLIED DISORDERS
    - 494 RAYNAUD'S SYNDROME
    - 538 TENSION HEADACHES
    - 549 SOMATIC SYMPTOMS AND RELATED DISORDERS
- Score = 2
    - 431 PERSISTENT DEPRESSIVE DISORDER
    - 507 PERIPHERAL NERVE DISORDERS
    - 510 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM
    - 513 CHRONIC PROSTATITIS, OTHER DISORDERS OF PROSTATE
- Score = 1
    - 489 SPASTIC DIPLEGIA/RHIZOTOMY
    - 529 CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME, DYSPAREUNIA

- 534 PERIPHERAL NERVE DISORDERS/SURGERY
- 550 OTHER NONINFECTIOUS GASTROENTERITIS AND COLITIS

Rescoring remainder of line 528

Line: 528
Condition: ~~FIBROMYALGIA,~~ CHRONIC FATIGUE SYNDROME~~, AND RELATED DISORDERS~~ (See Guideline Notes 64,65~~,135~~)
Treatment: MEDICAL THERAPY
ICD-10: ~~G89.21,G89.28-G89.29,G89.4,M79.7,~~R53.82
CPT: 90785,90832-90840,90846-90853,93792,93793,98966-98969,99051,99060,99070,99078, 99201-99215,99281-99285,99341-99378,99381-99404,99408-99449,99487-99490,99495-99498,99605-99607
HCPCS: G0248-G0250,G0396,G0397,G0463-G0467,G0490,G0511,G0513,G0514

Maintain the 2014 prioritization for Chronic Fatigue Syndrome line as shown below

	Current Line 528	Chronic Fatigue Syndrome
Category (Non-Fatal Condition)	7	7
Healthy Life Years (0-10)	4	4
Suffering (0-5)	3	3
Population effects (0-5)	0	0
Vulnerable population (0-5)	0	0
Tertiary prevention (0-5)	0	0
Effectiveness (0-5)	1	1
Need for service (0-1)	0.8	0.8
Net cost	2	2
Score	112	112
Approximate line	528	528

Accompanying guideline note changes

GUIDELINE NOTE 56, NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE

Lines 361,401

Patients seeking care for back pain should be assessed for potentially serious conditions ("red flag" symptoms requiring immediate diagnostic testing), as defined in Diagnostic Guideline D4. Patients lacking red flag symptoms should be assessed using a validated assessment tool (e.g. STarT Back Assessment Tool) in order to determine their risk level for poor functional prognosis based on psychosocial indicators.
For patients who are determined to be low risk on the assessment tool, the following services are included on these lines:

- Office evaluation and education,
- Up to four total visits, consisting of the following treatments: OMT/CMT, acupuncture, and PT/OT. Massage, if available, may be provided as part of these four total visits.
- First line medications: NSAIDs, acetaminophen, and/or muscle relaxers. Opioids may be considered as a second line treatment, subject to the limitations on coverage of opioids in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE. ~~See evidence table.~~

For patients who are determined to be medium- or high risk on the validated assessment tool, as well as patients undergoing opioid tapers as in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE, the following treatments are included on these lines:

- Office evaluation, consultation and education
- Cognitive behavioral therapy (CBT). The necessity for CBT should be re-evaluated every 90 days and coverage will only be continued if there is documented evidence of decreasing depression or anxiety symptomatology, improved ability to work/function, increased self-efficacy, or other clinically significant, objective improvement.
- Prescription and over-the-counter medications; opioid medications subject to the limitations on coverage of opioids in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE. ~~See evidence table.~~
- The following evidence-based therapies, when available, may be provided: yoga, massage, supervised exercise therapy, intensive interdisciplinary rehabilitation. HCPCS S9451 is only included on Line 401 for the provision of yoga or supervised exercise therapy.
- A total of 30 visits per year of any combination of the following evidence-based therapies when available and medically appropriate. These therapies are only included on these lines if provided by a provider licensed to provide the therapy and when there is documentation of measurable clinically significant progress toward the therapy plan of care goals and objectives using evidence based objective tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ). <u>These 30 visits count toward the visit totals in GUIDELINE NOTE XXX TREATMENT OF FIBROMYALGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS if the patient has one or more of these comorbid chronic pain conditions.</u>
    3) Rehabilitative therapy (physical and/or occupational therapy), if provided according to Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES. Rehabilitation services provided under this guideline also count towards visit totals in Guideline Note 6. CPT 97124 is included in this category.
    4) Chiropractic or osteopathic manipulation
    5) Acupuncture

Mechanical traction (CPT 97012) is not included on these lines, due to evidence of lack of effectiveness for treatment of back and neck conditions.

The development of this guideline note was informed by HERC coverage guidances on Low Back Pain Non-Pharmacologic, Non-Invasive Intervention, Low Back Pain, Pharmacological and Herbal Therapies. See http://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx.

[delete the table below]

~~**Evidence Table of Effective Treatments for the Management of Low Back Pain**~~

Intervention Category*	Intervention	Acute < 4 Weeks	Subacute & Chronic > 4 Weeks
Self-care	Advice to remain active	•	•
	Books, handout	•	•
	Application of superficial heat	•	
Nonpharmacologic therapy	Spinal manipulation	•	•
	Exercise therapy		•
	Massage		•
	Acupuncture		•
	Yoga		•
	Cognitive-behavioral therapy		•
	Progressive relaxation		•
Pharmacologic therapy (Carefully consider risks/harms)	Acetaminophen	•	•
	NSAIDs	•(▲)	•(▲)
	Skeletal muscle relaxants	•	
	Antidepressants (TCA)		•
	*Benzodiazepines***	•(▲)	•(▲)
	*Tramadol, opioids***	•(▲)	•(▲)
Interdisciplinary therapy	Intensive interdisciplinary rehabilitation		•

- Interventions supported by grade B evidence (at least fair-quality evidence of moderate benefit, or small benefit but no significant harms, costs, or burdens). No intervention was supported by grade "A" evidence (good-quality evidence of substantial benefit).

▲ *Carries greater risk of harms than other agents in table.*

NSAIDs = nonsteroidal anti-inflammatory drugs; TCA = tricyclic antidepressants.

*These are general categories only. Individual care plans need to be developed on a case by case basis. For more detailed information please see: http://www.annals.org/content/147/7/478.full.pdf

**Associated with significant risks related to potential for abuse, addiction and tolerance. This evidence evaluates effectiveness of these agents with relatively short term use studies. Chronic use of these agents may result in significant harms.

Reprioritization of Certain Chronic Pain Conditions
March 2019

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

Lines 346,361,401,527

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. Pain average, interference with Enjoyment of life, and interference with General activity" (PEG) Assessment Scale, Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
   b) When prescribed in conjunction with therapies such as spinal manipulation, physical therapy, yoga, or acupuncture.
   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.

Transitional coverage for patients on long-term opioid therapy ~~as of July 1, 2016~~:
For patients ~~on covered chronic~~ receiving long-term opioid therapy (>90 days) for conditions of the back and spine ~~as of July 1, 2016, opioid medication is included on these lines only from July 1, 2016 to December 31, 2016. During the period from January 1, 2017 to December 31, 2017~~, continued coverage of opioid medications requires an individual treatment plan which includes a taper plan ~~developed by January 1, 2017 which includes a taper with an end to opioid therapy no later than January 1, 2018~~. Opioid tapering should be done on an individualized basis and include a taper goal to zero. Tapering should be unidirectional with a shared goal set by the patient and provider, generally with a 5-10% decrease monthly and can be paused or slowed if the prescriber believes this is medically appropriate based on the patient's overall status. Taper plans ~~must~~ should include nonpharmacological treatment

strategies for managing the patient's pain ~~based on Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE~~. 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 ~~dependence and/or addiction related to their opioids~~ opioid use disorder, treatment is ~~available~~ included on Line 4 SUBSTANCE USE DISORDER**.**

New language (without showing changes from previous version)

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 an individual treatment plan which includes a taper plan. Opioid tapering should be done on an individualized basis and include a taper goal to zero. Tapering should be unidirectional with a shared goal set by the patient and provider, generally with a 5-10% decrease monthly and can be paused or slowed if the prescriber believes this is medically appropriate 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 opioid use disorder, treatment is included on Line 4 SUBSTANCE USE DISORDER.

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,5,202,361,401,409,461,538

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

Line 1 PREGNANCY

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

Hyperemesis gravidarum

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

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

Breech presentation

ICD-10-CM: O32.1

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

Back and pelvic pain of pregnancy

ICD-10-CM: O99.89

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

Line 5 TOBACCO DEPENDENCE

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

Line 202 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS

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

Line 361 SCOLIOSIS

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

Line 401 CONDITIONS OF THE BACK AND SPINE

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

Line 409 MIGRAINE HEADACHES

Acupuncture pairs on Line 409 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), for up to 12 sessions per year.

Line XXX FIBROMYAGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS

Acupuncture is included on this line with visit limitations as in Guideline Note XXX TREATMENT OF FIBROMYAGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS

Line 461 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 461 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions per year.

*Line 538 TENSION HEADACHES

Acupuncture is included on Line 538 for treatment of tension headaches (ICD-10-CM G44.2), for up to 12 sessions per year.

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

*Below the current funding line

~~**GUIDELINE NOTE 135, FIBROMYALGIA**~~

~~*Line 528*~~

~~Fibromyalgia (ICD-10-CM M79.7) treatment should consist of a multi-modal approach, which should include two of more of the following:~~

~~A) medications other than opioids~~
~~B) exercise advice/programs~~
~~C) cognitive behavioral therapy.~~

~~Care should be provided in the primary care setting. Referrals to specialists are generally not required. Use of opioids should be avoided due to evidence of harm in this condition~~

Update on proposed changes to coverage of treatments for certain chronic pain conditions for the Oregon Health Plan

The Oregon Health Authority (OHA) is committed to transforming health care to improve the health of Oregonians. The Health Evidence Review Commission (HERC), a volunteer panel of health leaders and experts, plays a critical role in fulfilling this mission by prioritizing health services covered by the Oregon Health Plan. In recent months, OHA staff has been working in collaboration with the advisory Chronic Pain Task Force, to prepare a proposal for the HERC's consideration to expand treatment options for certain chronic pain conditions and protect against overprescribing of opioid painkillers.

The CPTF and OHA staff completed the development of a proposal in December 2018 to enhance coverage of treatments for fibromyalgia and four other diagnoses related to chronic pain. The goal of this proposal is to expand treatment options for patients with chronic pain conditions that are currently not covered in the Oregon Health Plan, with the goal of improving patient health and safety. At its March 14, 2019 meeting, the HERC and its Value-based Benefits Subcommittee (VbBS) must consider this proposal as it relates to the entire benefit package for the Oregon Health Plan.

This proposed benefit expansion includes a menu of pharmacologic and non-pharmacologic pain treatment services that are currently not covered for these conditions. If adopted, it would take effect January 1, 2020. Additional options will be considered by the HERC, including not adopting the proposal. HERC will use its prioritization methodology to weigh the potential options based on the evidence of benefit, cost impact and public input.

Questions and answers

I've just learned of this proposal. How did we get to this point? The Chronic Pain Task Force met seven times between September, 2017 and December, 2018. The task force's recommendations were initially presented to the VbBS in August, 2018. The VbBS began reviewing a revised proposal based on additional evidence, public testimony and implementation concerns on January 17, 2019. Meeting materials and minutes are available on our Meeting Archives page. All meetings were public, and members of the task force received extensive written and oral public input on the proposal, including testimony from national experts on pain management and opioid tapering.

What is the current proposal? The proposal to be considered March 14, 2019 will be similar to what was considered at VbBS and HERC on January 17, 2019. The HERC will also consider an option not to adopt the proposal.

The critical component of the modified CPTF proposal is to reprioritize five chronic pain diagnosis codes to their own line on the Prioritized List. In addition, there are proposed additions to related guidelines. The new line would include:

- Fibromyalgia and four broad chronic pain diagnoses (G89.21 Chronic pain due to trauma, G89.28 Other chronic postprocedural pain, G89.29 Other chronic pain, and G89.4 Chronic pain syndrome) moved to the funded region.

- Nonpharmacologic treatments including exercise therapy, acupuncture, tai chi, acupuncture, physical therapy and cognitive behavioral therapy.
- Non-opioid medications, with a requirement the patient also be treated with active therapy or continuing self-maintenance of strategies learned in active therapy.
- Opioid medications for all these conditions except fibromyalgia (which would continue to be excluded from coverage by the Prioritized List). For the other conditions, the proposal contains some requirements for safe and effective prescribing in alignment with the Oregon Opioid Prescribing Guidelines. For patients currently receiving opioids for fibromyalgia through an exception to the Prioritized List, and for other patients receiving prescriptions for opioids which do not align with the prescribing guidelines, the proposal includes coverage of opioids during an individualized taper plan. The plan must include a goal of achieving cessation of opioids, though the taper plan may be slowed or paused if appropriate. The plan does not include a duration or deadline for completion of the taper.

There is also an option to not make any changes to the current prioritization of fibromyalgia and certain other chronic pain conditions due to the low level of effectiveness for various therapies and due to the other consequences of reprioritizing these diagnoses in the funded region, such as an increase in coverage for opioid medications.

Would the proposal take away all opioids for all chronic pain patients? No. At no time has the proposal affected opioids being prescribed for other funded conditions under the Oregon Health Plan (e.g. arthritis, cancer, end-of-life care, etc).

The HERC has had a long-term guideline that opioids are not intended to be covered for fibromyalgia due to their lack of effectiveness and risk of harm. For patients who are currently receiving opioids for fibromyalgia despite this guideline, the new coverage proposal may result in them being required to begin an individualized taper plan.

Patients receiving opioids for the other four chronic pain conditions under consideration could be required to taper as part of Oregon Health Plan coverage, but only if their current prescriptions do not align (or cannot be adjusted to align) with safe and effective prescribing as outlined in the Oregon Opioid Prescribing Guidelines. Decisions about the pace of any taper plan would be made by prescribers, not health plans, and taper plans could be paused if needed. As has always been the case, providers may refuse to prescribe opioids, or decide to initiate a taper plan based on their clinical judgement.

If the HERC chooses not to change the prioritization of fibromyalgia and certain other chronic pain conditions, then these conditions will continue to be “below the line” and will continue to not be eligible for opioid prescriptions if the patient’s CCO has prescription controls on opioids.

How many people could this proposal impact? During calendar year 2017, OHA’s Actuarial Services Unit (ASU) found approximately 90,000 OHP recipients had a claim including one of the diagnoses affected by the proposal. Of these, approximately 63,000 also had a diagnosis of back or spine pain, meaning they would already be eligible for a package of services similar to those proposed under the CPTF proposal. This leaves about 27,000 recipients who might be eligible for the new nonpharmacologic benefits, though some of these might already have access to certain benefits such as physical therapy because of other orthopedic conditions. Of the 90,000 recipients, about 40,000 had at least one opioid prescription during the time period and 13,000 had at least 120 days supply of opioids during that year.

What will it cost? OHA's Actuarial Service Unit (ASU) estimates the cost of the nonpharmacologic therapies to be $10.8 to $16.8 million for all of the Oregon Health Plan in 2020. These cost adjustments assume no significant impact on pharmaceutical costs, as most of the patients receiving opioids would already be eligible to receive them due to a comorbid funded diagnosis. They assume no significant cost from increased access to pregabalin as it will be available in generic form in 2019.

What factors will the Commission consider as it prioritizes these treatments? The Commission's legislative mandate is to rank services "by priority, from the most important to the least important, representing the comparative benefits of each service to the population to be served." The Commission will use its Prioritization Methodology, which includes consideration of several factors including the effectiveness of the treatments, the proportion of affected patients who need the services, pain and suffering caused by the condition, the overall effect of the condition on a person's healthy life and the ability of the treatment to prevent acute exacerbations of the chronically painful condition. These are used to determine a score which ranks the line under consideration relative to other lines on the Prioritized List.

What options does the Commission have in addressing the proposal? The Commission could choose to accept the proposal as presented or to adopt a modified version. Alternately, it could decide not to create a new line for the reprioritization of these services at all.

Whether or not the Commission creates the new line, the Commission will consider modifying Guideline Note 60, Opioids for Conditions of the Back and Spine, to remove the existing reference to an end date for tapering that has already passed (January 1, 2018) and to update language related to tapering in light of the work of the Chronic Pain Task Force.

Why are back and spine pain guidelines being addressed as part of this work?

HERC reviewed the evidence for a variety of nonpharmacologic and pharmacologic interventions for back pain starting in 2013. They decided to reprioritize back pain to the funded region of the Prioritized List which allowed access to evidence-based treatments, but also restricted opioid coverage because of a lack of evidence of benefit, and concerns given the opioid epidemic. This back pain policy went into effect July 1, 2016 and is not a new HERC policy. The new suggested changes to the back and spine guidelines are to remove references to dates that have passed and to consider adding language allowing for a more individualized taper plan.

How can I participate or get updates on HERC's activities?
You can subscribe at the HERC website at https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/ to receive notifications of future meetings and look at materials being discussed. Materials for the March 14th meetings will be posted on Thursday, March 7th at https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Meetings-Public.aspx. You can attend the meetings, which are open to the public, and speak during time set aside for public comment. You can listen to the meetings by dialing 1-888-204-5984, participant code 801373 and also register for the meeting webinar at https://attendee.gotowebinar.com/rt/4563145172385374211. You can also send written comment of up to 1,000 words to HERC.Info@state.or.us by 12:00 PM PDT, Tuesday, March 12th. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Policy-Comment-Current-Topics.aspx for further details on HERC's policies for providing verbal or written comments.

Everyone has a right to know about and use Oregon Health Authority (OHA) programs and services. OHA provides free help. Some examples of the free help OHA can provide are:

- Sign language and spoken language interpreters
- Written materials in other languages
- Braille
- Large print
- Audio and other formats

If you need help or have questions, please contact Daphne Peck at 503-373-1985, 711 TTY or herc.info@state.or.us at least 48 hours before the meeting.

Section 3.0

Travel Reimbursement Policy Changes

Section 4.0

Coverage Guidances

Newer Interventions for Osteoarthritis of the Knee

Draft Coverage Guidance for VbBS/HERC Consideration

March 14, 2019

Oregon Health Authority

Oregon Health & Science University

Center For Evidence-based Policy

Background

- Osteoarthritis treatments aim to reduce symptoms and improve function; most treatments do not modify the natural history or progression of the disease
- Knee osteoarthritis is often treated with multiple therapies:
  - Physical activity
  - Recommendation to lose weight
  - Medications, prescription drugs, and over-the-counter pain relievers
  - Physical therapy
  - Alternative therapies (e.g., massage, acupuncture)
  - Corticosteroid injections
  - Surgery

Background

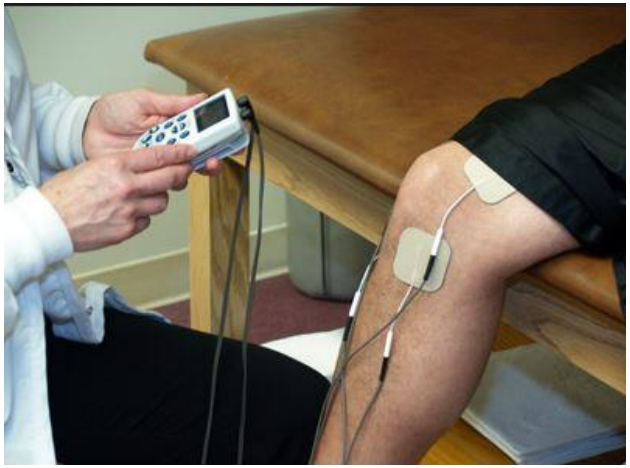
- Common pain scales
  - Visual analog scale (VAS)
    - A straight line with the endpoints defining extreme limits such as “no pain at all” and “pain as bad as it could be”
    - Patients indicate pain intensity on the line between the 2 endpoints
    - Can be a 10-point or 100-point scale
  - Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)
    - Often used to evaluate patients with lower limb osteoarthritis
    - Composite measure that includes pain, stiffness, and functional limitations
    - Scores range from zero to 68

Background

- Whole body vibration
  Placing a person on a vibrating platform to perform exercises

Source: Amazon.com

- Transcutaneous electrical nerve stimulation (TENS)
  Application of electrical current through electrodes placed on the skin for pain control, applied with varying frequencies from low (< 10 Hz) to high (> 50 Hz)


Source: Bethlehem Rehabilitation Specialists

Background

- Glucosamine and chondroitin
  - Glucosamine and chondroitin are produced naturally in the body and are structural components of cartilage
  - Glucosamine and chondroitin are available as dietary supplements
- Intra-articular injections of platelet-rich plasma
  - To prepare platelet-rich plasma, autologous blood is put through a centrifuge, yielding a higher concentration of platelets

Scope Statement

- Populations
  - Adults with osteoarthritis of the knee
- Interventions
  - Whole-body vibration, TENS, glucosamine-chondroitin, platelet-rich plasma
- Comparators
  - Effective nonsurgical care (e.g., oral analgesics, exercise therapy)

Scope Statement

- Critical Outcomes
  - Long-term pain
  - Long-term function
- Important Outcomes
  - Intermediate-term function
  - Intermediate-term pain
  - Harms

Scope Statement

Key Questions

1. What is the comparative effectiveness of newer interventions for the treatment of osteoarthritis of the knees?
2. Does the comparative effectiveness of newer interventions for the treatment of osteoarthritis of the knees vary by:
    a. Patient characteristics (age, gender, socioeconomic status, baseline weight)
    b. Baseline severity
    c. Disease subtype
    d. Comorbidities
    e. Prior treatments
3. What are the harms of newer interventions for the treatment of osteoarthritis of the knees?

Evidence Sources

- Main evidence source:
  AHRQ systematic review – Treatment of Osteoarthritis of the Knee: An Update Review (Newberry et al., 2017)
  - Good-quality systematic review and health technology assessment of selected nonsurgical treatments of knee osteoarthritis
  - For efficacy outcomes, only RCTs were eligible for inclusion
  - For outcomes related to adverse events, prospective observational studies and case reports were included
  - Outcomes: pain, function, and quality of life in the short term (4-12 weeks)

GRADE Table: Whole Body Vibration

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Long-term pain (Critical outcome)	Insufficient evidence
Long-term function (Critical outcome)	Insufficient evidence
Intermediate-term pain (Important outcome)	No significant difference between exercise programs with whole body vibration and exercise and strength training programs alone SMD -0.20 (95% CI -1.12 to 0.71) ●●○○ (Low confidence, based on 4 RCTs, n = 180)

GRADE Table: Whole Body Vibration

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Intermediate-term function (Important outcome)	Improved in exercise programs with whole body vibration compared to exercise and strength-training programs alone SMD -0.26 (95% CI -0.45 to -0.06) ●●○○ (Low confidence, based on 4 RCTs, n = 180)
Harms (Important outcome)	Adverse events were rare and did not differ significantly between active and control groups ●●○○ (Low confidence, based on 4 studies, n = 180)

Payer Policies: Whole Body Vibration

- Washington State Medicaid Program:
  - No Washington Medicaid policy was identified for whole body vibration
- Medicare:
  - No Medicare National Coverage Determination (NCD) or Local Coverage Determination (LCD) was identified for whole body vibration
- Private Payers:
  - Aetna does not provide coverage for whole body vibration
  - Coverage policies for whole body vibration were not identified for Cigna, Moda, or Regence

Guidelines

- None of the 5 identified guidelines included recommendations on whole body vibration
  - U.S. Department of Veterans Affairs and Department of Defense guideline on nonsurgical management of hip and knee osteoarthritis (VA/DoD, 2014)
  - American Academy of Orthopaedic Surgeons (AAOS) guideline on knee osteoarthritis (Jevsevar, 2013)
  - American College of Rheumatology (ACR) recommendations for osteoarthritis of the hand, hip, and knee (Hochberg et al., 2012). Note: publication of an update to these guidelines is anticipated in 2018 (ACR, 2018)
  - European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ESCEO) guidelines for knee osteoarthritis (Bruyere et al., 2014)
  - Osteoarthritis Research Society International (OARSI) guidelines on nonsurgical management of knee osteoarthritis (McAlindon et al., 2014)

Discussion: Whole Body Vibration

Values and Preferences

Patients would likely prefer noninvasive interventions. Whole body vibration appears to be popular based on its widespread availability for home purchase, but the physical experience of doing this intervention might not be universally appealing (e.g., for older adults who are unsteady on their feet). We would expect moderate variability in values and preferences.

Resource Allocation

The machines for home use range from $100 to $250 to thousands of dollars. Clinic-based treatments would be low to moderate expense depending on what is charged and the frequency of treatments.

Discussion: Whole Body Vibration

Other Considerations

The improvement in intermediate-term function did not meet the threshold of minimal clinically important difference.

Balance of Benefits and Harms

We have low confidence that whole body vibration improves intermediate-term function but not to a clinically significant degree, and it is similar to exercise and strength-training programs in terms of pain. There appear to be few adverse events.

Discussion: Whole Body Vibration

Rationale

We recommend against coverage because of the low evidence for a lack of clinically significant improvement in outcomes, moderate cost, and moderate variability in values and preferences. It is a strong recommendation because there is no evidence of clinically significant improvement, and there are alternative treatments for this condition. Because of the prevalence of this condition and the ease of studying this intervention, we would require at least moderate-quality evidence of benefit in order to recommend coverage.

Whole body vibration is not recommended for coverage *(strong recommendation)*.

GRADE Table: TENS

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Long-term pain (Critical outcome)	Insufficient evidence
Long-term function (Critical outcome)	Insufficient evidence
Intermediate-term pain (Important outcome)	No significant difference between TENS and sham control Pooled estimates not provided ●●○○ (Low confidence, based on 2 RCTs, n = 650)
Intermediate-term function (Important outcome)	No significant difference between TENS and sham control Pooled estimates not provided ●●○○ (Low confidence, based on 2 RCTs, n = 650)
Harms (Important outcome)	Adverse events were rare and did not differ significantly between active and sham control groups ●●○○ (Low confidence, based on 2 studies, n = 650)

Payer Policies: TENS

- Washington State Medicaid Program:
  - TENS is not covered
- Medicare:
  - 2006 NCD: TENS is to be used on a trial basis (1 month) while its effectiveness in modulating pain is monitored
  - 2017 LCD: does not provide coverage for TENS
- Private Payers:
  - Aetna and Moda provide coverage for TENS under certain conditions
  - Cigna covers TENS only for conventional postoperative pain management within 30 days of surgery
  - Regence does not cover TENS

Guidelines: TENS

- ACR and ESCEO include TENS as a treatment option
- AAOS is unable to recommend for or against TENS
- OARSI considers TENS a treatment of uncertain appropriateness
- VA/DoD guidelines do not mention TENS

Discussion: TENS

Values and Preferences

Patients would prefer simple, inexpensive, noninvasive treatments for knee osteoarthritis that improve pain and function. Some patients have preferences for or against nonallopathic treatments, which leads to moderate variability in values and preferences.

Resource Allocation

TENS is generally an inexpensive intervention (although very expensive models are available). If it were effective, its low price would make it very appealing.

Discussion: TENS

Balance of Benefits and Harms

We have low confidence that TENS appears to have no benefits in terms of intermediate-term pain and function, has no harms, and has insufficient evidence for long-term outcomes.

Discussion: TENS

Rationale

Given that there is evidence that TENS is ineffective, even though it is inexpensive and patients may be willing to try it, coverage is not recommended. It is a strong recommendation because available evidence supports inefficacy rather than clinical benefit. Because of the prevalence of this condition and the ease of studying this intervention, we would require at least moderate quality evidence of benefit in order to recommend coverage

TENS is not recommended for coverage *(strong recommendation)*.

GRADE Table: Glucosamine Alone

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Long-term pain (Critical outcome)	No significant difference between glucosamine and placebo control SMD -0.05 (95% CI -0.22 to 0.12) ●●●○ (Moderate confidence, based on 3 RCTs, n = 1,007)
Long-term function (Critical outcome)	No significant difference between glucosamine and placebo control Pooled estimates not provided ●●○○ (Low confidence, based on 3 RCTs, n = 1,007)

GRADE Table: Glucosamine Alone

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Intermediate-term pain (Important outcome)	Insufficient evidence
Intermediate-term function (Important outcome)	Insufficient evidence
Harms (Important outcome)	Adverse effects were rare and did not differ significantly between active and placebo control groups ●●●◌ (Moderate confidence, based on 6 studies, n = 4,195)

GRADE Table: Chondroitin Alone

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Long-term pain (Critical outcome)	No significant difference between chondroitin and control Pooled estimates not provided ●●●○ (Moderate confidence, based on 3 RCTs, n = 1,889)
Long-term function (Critical outcome)	No significant difference between chondroitin and control Pooled estimates not provided ●●○○ (Low confidence, based on 2 RCTs, n = 1,267)

GRADE Table: Chondroitin Alone

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Intermediate-term pain (Important outcome)	Improved with chondroitin compared to control Pooled estimates not provided ●●○○ (Low confidence, based on 2 RCTs, n = 974)
Intermediate-term function (Important outcome)	Insufficient evidence
Harms (Important outcome)	Adverse effects were rare and did not differ significantly between active and control groups ●●●○ (Moderate confidence, based on 6 studies, n = 4,195)

GRADE Table: Glucosamine-Chondroitin

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Long-term pain (Critical outcome)	No significant difference between glucosamine-chondroitin and placebo control SMD -0.73 (95% CI -4.03 to 2.57) ●●●◌ (Moderate confidence, based on 3 RCTs, n = 466)
Long-term function (Critical outcome)	No significant difference between glucosamine-chondroitin and placebo control SMD -0.45 (95% CI -2.75 to 1.84) ●●●◌ (Moderate confidence, based on 3 RCTs, n = 466)

GRADE Table: Glucosamine-Chondroitin

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Intermediate-term pain (Important outcome)	Improved with glucosamine-chondroitin compared to placebo control Pooled estimates not provided ●●○○ (Low confidence, based on 3 RCTs, n = 881)
Intermediate-term function (Important outcome)	Improved with glucosamine-chondroitin compared to placebo control Pooled estimates not provided ●●○○ (Low confidence, based on 3 RCTs, n = 881)
Harms (Important outcome)	Adverse effects were rare and did not differ significantly between active and control groups ●●●○ (Moderate confidence, based on 6 studies, n = 4,195)

Payer Policies

- Washington State Medicaid Program:
  - No policy identified for glucosamine or chondroitin
- Medicare:
  - No national or local coverage determinations were identified for glucosamine or chondroitin
- Private Payers:
  - Glucosamine: Aetna and Cigna do not provide coverage; no policy was found for Moda or Regence
  - Chondroitin: no policy found for Aetna, Cigna, Moda, or Regence

Guidelines

- Glucosamine and chondroitin sulfate are not recommended in the VA/DoD and AAOS guidelines
- ACR conditionally recommends that patients should not use glucosamine and chondroitin sulfate
- OARSI considers glucosamine and chondroitin sulfate as treatments of uncertain appropriateness
- ESCEO recommends the use of glucosamine and chondroitin
  - ESCEO advocates the use of prescription patented crystalline glucosamine sulfate as a first-line slow-acting drug for medium- to long-term control of knee osteoarthritis symptoms

Discussion: Glucosamine, Chondroitin, and in Combination

Values and Preferences

Patients would prefer simple, inexpensive, noninvasive treatments for knee osteoarthritis that improve pain and function. A daily supplement would likely be acceptable to many patients, so we would expect low variability of values and preferences.

Resource Allocation

Glucosamine and chondroitin are inexpensive daily supplements. Their low cost would increase favorability.

Discussion: Glucosamine, Chondroitin, and in Combination

Other Considerations

A separate systematic review with serious limitations raised questions about whether the individual components were more effective than the combination. Individual patient data meta-analysis showed that glucosamine alone has no effect. Because these are over-the-counter supplements, product quality may vary significantly.

Balance of Benefits and Harms

We have low to moderate confidence that glucosamine, chondroitin, or the combination has no effect on long-term pain or function. We have low confidence that chondroitin or the combination with glucosamine may improve intermediate-term pain and function. There appear to be no significant adverse effects.

Discussion: Glucosamine, Chondroitin, and in Combination

Rationale

These are low-cost, apparently safe, and acceptable interventions, although none have a long-term effect. We make a weak recommendation against coverage for chondroitin and glucosamine-chondroitin because evidence supports intermediate-term improvements in pain and function. Evidence suggests glucosamine alone is an ineffective intervention, so we make a strong recommendation against coverage.

Because of the prevalence of this condition and the ease of studying this intervention, we would require at least moderate-quality evidence of benefit in order to recommend coverage.

Discussion: Glucosamine, Chondroitin, and in Combination

Glucosamine alone is not recommended for coverage *(strong recommendation)*.

Chondroitin alone is not recommended for coverage *(weak recommendation)*.

Glucosamine-chondroitin is not recommended for coverage *(weak recommendation)*.

GRADE Table: Platelet-Rich Plasma

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Long-term pain (Critical outcome)	Improved with platelet-rich plasma compared to control MD 6.0 on WOMAC pain score (95% CI not provided, $p < 0.05$) ●●○○ (Low confidence, based on 1 RCT, n = 30)
Long-term function (Critical outcome)	Improved with platelet-rich plasma compared to control MD 24.0 on WOMAC function score (95% CI not provided, $p < 0.05$) ●●○○ (Low confidence, based on 1 RCT, n = 30)

GRADE Table: Platelet-Rich Plasma

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Intermediate-term pain (Important outcome)	Improved with platelet-rich plasma compared to controls Pooled estimates not provided ●●○○ (Low confidence, based on 5 RCTs, n = 439)
Intermediate-term function (Important outcome)	Insufficient evidence
Harms (Important outcome)	Adverse events were rare and did not differ significantly between active and control groups ●●○○ (Low confidence, based on 3 studies, n = 215)

Payer Policies: Platelet-Rich Plasma

- Washington State Medicaid Program:
  - 2016 coverage decision: autologous blood/platelet-rich plasma injections are not covered
- Medicare:
  - No NCD or LCD identified for platelet-rich plasma for knee osteoarthritis
- Private Payers:
  - Platelet-rich plasma is not covered by Aetna, Cigna, Moda, or Regence

Guidelines: Platelet-Rich Plasma

- AAOS guidelines are unable to recommend for or against platelet-rich plasma
- No recommendation on platelet-rich plasma in the other 4 guidelines

Discussion: Platelet-Rich Plasma

Values and Preferences

Patients would generally prefer noninvasive interventions. However, a single minimally invasive intervention would likely be appealing if it offered long-term relief and had few risks. We would expect low variability in patient preferences.

Resource Allocation

Platelet-rich plasma injections are relatively expensive, ranging from hundreds to thousands of dollars.

Discussion: Platelet-Rich Plasma

Other Considerations

The one study evaluating long-term pain and function was industry-funded but well designed.

Balance of Benefits and Harms

There is low confidence that platelet-rich plasma injections yield improvements in intermediate-term pain and long-term pain and function with no increased risk of adverse effects.

Discussion: Platelet-Rich Plasma

Rationale

We do not recommend coverage for platelet-rich plasma for osteoarthritis of the knee because the data supporting long-term efficacy are based on a single, small, industry-funded trial, and there is low confidence in intermediate-term improvements in pain (however, this assessment appears to be based on studies with mixed results), and moderate resource allocation. For such a common condition, which is relatively straightforward to research, further research is necessary to support use of platelet-rich plasma prior to covering it. The recommendation is weak because there would likely be low variability in patient values and preferences and further evidence could change the recommendation. Because of the prevalence of this condition and the ease of studying this intervention, we would require at least moderate-quality evidence of benefit in order to recommend coverage.

Platelet-rich plasma is not recommended for coverage *(weak recommendation)*

Discussion

Whole body vibration is not recommended for coverage (*strong recommendation*).

TENS is not recommended for coverage (*strong recommendation*).

Glucosamine/chondroitin is not recommended for coverage (*weak recommendation*).
Glucosamine alone is not recommended for coverage (*strong recommendation*).
Chondroitin alone is not recommended for coverage (*weak recommendation*).

Platelet-rich plasma is not recommended for coverage (*weak recommendation*)

Health Evidence Review Commission (HERC)

Coverage Guidance: Newer Interventions for Osteoarthritis of the Knee

DRAFT for VbBS/HERC meeting materials 3/14/2019

HERC Coverage Guidance

Whole body vibration

Whole body vibration is not recommended for coverage (*strong recommendation*).

TENS

TENS is not recommended for coverage (*strong recommendation*).

Glucosamine-chondroitin

Glucosamine-chondroitin is not recommended for coverage (*weak recommendation*).

Glucosamine alone is not recommended for coverage (*strong recommendation*).

Chondroitin alone is not recommended for coverage (*weak recommendation*).

Platelet-rich plasma

Platelet-rich plasma is not recommended for coverage (*weak recommendation*)

Note: Definitions for strength of recommendation are in Appendix A. *GRADE Table Element Descriptions*.

Rationales for each recommendation appear below in the GRADE table.

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Rationale for development of coverage guidances and multisector intervention reports

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as plan administrators seek to improve patients' experience of care, population health, and the cost-effectiveness of health care. In the era of public and private sector health system transformation, reaching these goals requires a focus on maximizing the benefits and minimizing the harms and costs of health interventions.

HERC uses the following principles in selecting topics for its reports to guide public and private payers:

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

HERC bases its reports on a review of the best available research applicable to the intervention(s) in question. For coverage guidances, which focus on diagnostic and clinical interventions, evidence is evaluated using an adaptation of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat, or manage disease at a population level. In some cases, HERC has reviewed evidence and identified effective interventions, but has not made formal coverage recommendations when these policies are implemented in settings other than traditional health care delivery systems because effectiveness could depend on the environment in which the intervention is implemented.

GRADE Table

HERC develops recommendations by using the concepts of the GRADE system. GRADE is a transparent and structured process for developing and presenting evidence and for performing the steps involved in developing recommendations. The table below lists the elements that determine the strength of a recommendation. HERC reviews the evidence and assesses each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Estimates of effect are derived from the evidence presented in this document. Assessments of confidence are from the published systematic reviews and meta-analyses, where available and judged to be reliable.

In some cases, no systematic reviews or meta-analyses encompass the most current literature. In those cases, HERC may describe the additional evidence or alter the assessments of confidence in light of all available information. Such assessments are informed by clinical epidemiologists from the Center for Evidence-based Policy. Unless otherwise noted, statements regarding resource allocation, values and preferences and other considerations are the assessments of HERC, as informed by the evidence reviewed, public testimony, and subcommittee discussion.

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Recommendations for coverage are based on the balance of benefit and harms, resource allocation, values and preferences, and other considerations. See Appendix A for more details about the factors that constitute the GRADE table.

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GRADE Table

Should whole body vibration be recommended for coverage for osteoarthritis of the knee?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Long-term pain *(Critical outcome)*	Insufficient evidence	The machines for home use range from $100 to $250 to thousands of dollars. Clinic-based treatments would be low to moderate expense depending on what is charged and the frequency of treatments.	Patients would likely prefer noninvasive interventions. Whole body vibration appears to be popular based on its widespread availability for home purchase, but the physical experience of doing this intervention might not be universally appealing (e.g., for older adults who are unsteady on their feet). We would expect moderate variability in values and preferences.	The improvement in intermediate-term function did not meet the threshold of minimal clinically important difference.
Long-term function *(Critical outcome)*	Insufficient evidence			
Intermediate-term pain *(Important outcome)*	No significant difference between exercise programs with whole body vibration and exercise and strength-training programs alone SMD -0.20 (95% CI -1.12 to 0.71) ●●○○ *(Low confidence, based on 4 RCTs, n = 180)*			
Intermediate-term function *(Important outcome)*	Improved in exercise programs with whole body vibration compared to exercise and strength-training programs alone SMD -0.26 (95% CI -0.45 to -0.06) ●●○○ *(Low confidence, based on 4 RCTs, n = 180)*			
Harms *(Important outcome)*	Adverse events were rare and did not differ significantly between active and control groups ●●○○ *(Low confidence, based on 4 studies, n = 180)*			

Balance of benefits and harms: We have low confidence that whole body vibration improves intermediate-term function but not to a clinically significant degree, and it is similar to exercise and strength-training programs in terms of pain. There appear to be few adverse events.
Rationale: We recommend against coverage because of the low evidence for a lack of clinically significant improvement in outcomes, moderate cost, and moderate variability in values and preferences. It is a strong recommendation because there is no evidence of clinically significant improvement, and there are alternative treatments for this condition. Because of the prevalence of this condition and the ease of studying this intervention, we would require at least moderate-quality evidence of benefit in order to recommend coverage.

Recommendation: Whole body vibration is not recommended for coverage (*strong recommendation*).

Should transcutaneous electrical nerve stimulation (TENS) be recommended for coverage for osteoarthritis of the knee?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Long-term pain *(Critical outcome)*	Insufficient evidence	TENS is generally an inexpensive intervention (although very expensive models are available). If it were effective, its low price would make it very appealing.	Patients would prefer simple, inexpensive, noninvasive treatments for knee osteoarthritis that improve pain and function. Some patients have preferences for or against nonallopathic treatments, which leads to moderate variability in values and preferences.	
Long-term function *(Critical outcome)*	Insufficient evidence			
Intermediate-term pain *(Important outcome)*	No significant difference between TENS and sham control Pooled estimates not provided ●●○○ *(Low confidence, based on 2 RCTs, n = 650)*			
Intermediate-term function *(Important outcome)*	No significant difference between TENS and sham control Pooled estimates not provided ●●○○ *(Low confidence, based on 2 RCTs, n = 650)*			
Harms *(Important outcome)*	Adverse events were rare and did not differ significantly between active and sham control groups ●●○○ *(Low confidence, based on 2 studies, n = 650*			

Balance of benefits and harms: We have low confidence that TENS appears to have no benefits in terms of intermediate-term pain and function, has no harms, and insufficient evidence for long-term outcomes.

Rationale: Given that there is evidence that TENS is ineffective, even though it is inexpensive and patients may be willing to try it, coverage is not recommended. It is a strong recommendation because available evidence supports inefficacy rather than clinical benefit. Because of the prevalence of this condition and the ease of studying this intervention, we would require at least moderate-quality evidence of benefit in order to recommend coverage.

Recommendation: TENS is not recommended for coverage for osteoarthritis of the knee (*strong recommendation*).

Should glucosamine-chondroitin be recommended for coverage for osteoarthritis of the knee?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Long-term pain *(Critical outcome)*	No significant difference between glucosamine-chondroitin and placebo control SMD -0.73 (95% CI -4.03 to 2.57) ●●●○ *(Moderate confidence, based on 3 RCTs, n = 466)*	Glucosamine-chondroitin is an inexpensive daily supplement. Its low cost would increase its favorability.	Patients would prefer simple, inexpensive, noninvasive treatments for knee osteoarthritis that improve pain and function. A daily supplement would likely be acceptable to many patients, so we would expect low variability of values and preferences.	A separate systematic review with serious limitations raised questions about whether the individual components were more effective than the combination. Individual patient data meta-analysis showed that glucosamine alone has no effect. Because this is an over-the-counter supplement, product quality may vary significantly.
Long-term function *(Critical outcome)*	No significant difference between glucosamine-chondroitin and placebo control SMD -0.45 (95% CI -2.75 to 1.84) ●●●○ *(Moderate confidence, based on 3 RCTs, n = 466)*			
Intermediate-term pain *(Important outcome)*	Improved with glucosamine-chondroitin compared to placebo control Pooled estimates not provided ●●○○ *(Low confidence, based on 3 RCTs, n = 881)*			
Intermediate-term function *(Important outcome)*	Improved with glucosamine-chondroitin compared to placebo control Pooled estimates not provided ●●○○ *(Low confidence, based on 3 RCTs, n = 881)*			
Harms *(Important outcome)*	Adverse effects were rare and did not differ significantly between active and control groups ●●●○ *(Moderate confidence, based on 6 studies, n = 4,195)*			

Balance of benefits and harms: We have moderate confidence that glucosamine-chondroitin has no effect on long-term pain or function, but have low confidence that it improves intermediate-term pain and function (although the estimates include mixed effect sizes with regards to clinical significance). There appear to be no harms.

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Rationale: We recommend against coverage because of moderate-quality evidence of no benefit in long-term pain and function, and it is unclear that the intermediate-term benefit is clinically significant given the mixed effect sizes. The low cost and low variability in patient preferences temper the recommendation against, and the combination of these factors and the possible clinically significant intermediate effect lead to a weak recommendation against coverage. Because of the prevalence of this condition and the ease of studying this intervention, we would require at least moderate-quality evidence of benefit in order to recommend coverage.
Recommendation: Glucosamine-chondroitin is not recommended for coverage (*weak recommendation*).

Should glucosamine alone be recommended for coverage for osteoarthritis of the knee?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Long-term pain *(Critical outcome)*	No significant difference between glucosamine and placebo control SMD -0.05 (95% CI -0.22 to 0.12) ●●●○ *(Moderate confidence, based on 3 RCTs, n = 1,007)*	Glucosamine alone is a very inexpensive daily supplement. Its low cost would increase its favorability.	Patients would prefer simple, inexpensive, noninvasive treatments for knee osteoarthritis that improve pain and function. A daily supplement would likely be acceptable to many patients, so we would expect low variability of values and preferences.	Because this is an over-the-counter supplement, product quality may vary significantly.
Long-term function *(Critical outcome)*	No significant difference between glucosamine and placebo control Pooled estimates not provided ●●○○ *(Low confidence, based on 3 RCTs, n = 1,007)*			
Intermediate-term pain *(Important outcome)*	Insufficient evidence			
Intermediate-term function *(Important outcome)*	Insufficient evidence			
Harms *(Important outcome)*	Adverse effects were rare and did not differ significantly between active and placebo control groups ●●●○ *(Moderate confidence, based on 6 studies, n = 4,195)*			

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Balance of benefits and harms: We have low to moderate confidence that glucosamine alone is ineffective for long-term pain and function; there is insufficient evidence for other outcomes. There appear to be no significant adverse effects.
Rationale: Despite patients' willingness to take a supplement and the supplement being low cost and not harmful, the available evidence suggests glucosamine alone is an ineffective intervention. Therefore, we make a strong recommendation against coverage. Because of the prevalence of this condition and the ease of studying this intervention, we would require at least moderate-quality evidence of benefit in order to recommend coverage.
Recommendation: Glucosamine alone is not recommended for coverage (*strong recommendation*).

Should chondroitin alone be recommended for coverage for osteoarthritis of the knee?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Long-term pain *(Critical outcome)*	No significant difference between chondroitin and control Pooled estimates not provided ●●●○ *(Moderate confidence, based on 3 RCTs, n = 1,889)*	Chondroitin alone is a very inexpensive daily supplement. Its low cost would increase its favorability.	Patients would prefer simple, inexpensive, noninvasive treatments for knee osteoarthritis that improve pain and function. A daily supplement would likely be acceptable to many patients, so we would expect low variability of values and preferences.	Because this is an over-the-counter supplement, product quality may vary significantly.
Long-term function *(Critical outcome)*	No significant difference between chondroitin and control Pooled estimates not provided ●●○○ *(Low confidence, based on 2 RCTs, n = 1,267)*			
Intermediate-term pain *(Important outcome)*	Improved with chondroitin compared to control Pooled estimates not provided ●●○○ *(Low confidence, based on 2 RCTs, n = 974)*			
Intermediate-term function *(Important outcome)*	Insufficient evidence			
Harms *(Important outcome)*	Adverse effects were rare and did not differ significantly between active and control groups ●●●○ *(Moderate confidence, based on 6 studies, n = 4,195)*			

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Balance of benefits and harms: Chondroitin alone has no benefit for long-term pain or function, but we have low confidence that it improves intermediate-term pain. There do not appear to be significant adverse effects.
Rationale: This is a low-cost, apparently safe, and acceptable intervention that improves intermediate-term pain but has no long-term impact. There is less evidence to support it than glucosamine and chondroitin in combination. Therefore, we make a recommendation against coverage; it is a weak recommendation because further evidence could support intermediate-term improvements in pain and function. Because of the prevalence of this condition and the ease of studying this intervention, we would require at least moderate-quality evidence of benefit in order to recommend coverage.
Recommendation: Chondroitin alone is not recommended for coverage (*weak recommendation*).

Should platelet-rich plasma be recommended for coverage for osteoarthritis of the knee?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Long-term pain *(Critical outcome)*	Improved with platelet-rich plasma compared to control MD 6.0 on WOMAC pain score (95% CI not provided, p < 0.05) ●●○○ *(Low confidence, based on 1 RCT, n = 30)*	Platelet-rich plasma injections are relatively expensive, ranging from hundreds to thousands of dollars.	Patients would generally prefer noninvasive interventions. However, a single minimally invasive intervention would likely be appealing if it offered long-term relief and had few risks. We would expect low variability in patient preferences.	The one study evaluating long-term pain and function was industry-funded but well designed.
Long-term function *(Critical outcome)*	Improved with platelet-rich plasma compared to control MD 24.0 on WOMAC function score (95% CI not provided, p < 0.05) ●●○○ *(Low confidence, based on 1 RCT, n = 30)*			
Intermediate-term pain *(Important outcome)*	Improved with platelet-rich plasma compared to controls Pooled estimates not provided ●●○○ *(Low confidence, based on 5 RCTs, n = 439)*			
Intermediate-term function *(Important outcome)*	Insufficient evidence			

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Should platelet-rich plasma be recommended for coverage for osteoarthritis of the knee?

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Harms *(Important outcome)*	Adverse events were rare and did not differ significantly between active and control groups ●●○○ *(Low confidence, based on 3 studies, n = 215)*			

Balance of benefits and harms: There is low confidence that platelet-rich plasma injections yield improvements in intermediate-term pain and long-term pain and function with no increased risk of adverse effects.
Rationale: We do not recommend coverage for platelet-rich plasma for osteoarthritis of the knee because the data supporting long-term efficacy are based on a single, small, industry-funded trial and there is low confidence in intermediate-term improvements on pain (however, this assessment appears to be based on studies with mixed results), and also moderate resource allocation. For such a common condition, which is relatively straightforward to research, further research is necessary to support use of platelet-rich plasma prior to covering it. The recommendation is weak because there would likely be low variability in patient values and preferences and further evidence could change the recommendation. Because of the prevalence of this condition and the ease of studying this intervention, we would require at least moderate-quality evidence of benefit in order to recommend coverage.
Recommendation: Platelet-rich plasma is not recommended for coverage (*weak recommendation*)

Note: GRADE table elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.

DRAFT

Background

Osteoarthritis is a common cause of pain in the limbs, and it frequently occurs in the knees; the risk of osteoarthritis increases with age (Centers for Disease Control and Prevention, 2017). Knee osteoarthritis is the progressive destruction of the cartilage that lines the knee joints, the subchondral bone surfaces, and synovium, which can cause pain, immobility, muscle weakness, and reduction in function (Newberry et al., 2017). Osteoarthritis is usually the result of progressive joint cartilage destruction over time, but can also be caused by trauma, inactivity, excess weight, or disease processes such as rheumatoid arthritis (Newberry et al., 2017). The aging of the population and the increasing prevalence of obesity have led to an increase in the incidence of knee osteoarthritis (Newberry et al., 2017).

Osteoarthritis is usually treated with a combination of therapies, including physical activity, weight loss, medications (prescription drugs and over-the-counter pain relievers), physical therapy, alternative therapies (e.g., massage, acupuncture), corticosteroid injections, and surgery (National Institute of Arthritis and Musculoskeletal and Skin Disease, 2014). Treatments for osteoarthritis aim to reduce symptoms and improve function, and most treatments do not modify the natural history or progression of the disease (Newberry et al., 2017).

The visual analog scale (VAS) is a common way to measure pain, consisting of a straight line with the endpoints defining extreme limits such as “no pain at all” and “pain as bad as it could be.” The patient is asked to indicate the pain intensity on the line between the two endpoints. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is one of the most commonly used measures to evaluate patients with lower limb osteoarthritis (Walker et al, 2018). WOMAC is a composite measure that includes pain, stiffness, and functional limitations, with scores ranging from zero to 68. Appendix E shows the minimal clinically important difference (MCID) for these scales as defined by a representative sample of studies in a review by Newberry et al. (2017) for the Agency for Healthcare Research and Quality (AHRQ).

Indications

The clinical diagnosis of knee osteoarthritis is usually based on presentation, including gradual onset of weight-bearing knee pain that is exacerbated by use of the joint and tends to worsen over the course of the day (Newberry et al., 2017). Radiographs may be used to diagnose osteoarthritis, but radiographic osteoarthritis scales do not correlate well with symptoms (Newberry et al., 2017).

Technology Description

This coverage guidance reviews four treatments for knee osteoarthritis: whole body vibration, TENS, glucosamine and/or chondroitin, and platelet-rich plasma. Whole body vibration involves placing a person on a vibrating platform (Wang et al., 2016). TENS is the application of electrical current through electrodes placed on the skin for pain control, applied with varying frequencies, from low (< 10 Hz) to high (> 50 Hz) (DeSantana et al., 2008).

Glucosamine is one of the most abundant monosaccharides in the human body and is an amino sugar precursor in the synthesis of glycosylated proteins and lipids. The proposed mechanism of action for glucosamine is based on its supposed anti-inflammatory activity, stimulation of proteoglycan synthesis, and inhibition of proteolytic enzyme synthesis (Simental-Mendia et al., 2018).

In the past decade, there has been growing interest in the use of autologous growth factors for the treatment of knee osteoarthritis, such as intra-articular injections of platelet-rich plasma. To prepare platelet-rich plasma, autologous blood is put through a centrifuge, yielding a higher concentration of platelets than baseline values. The regenerative effect and anti-inflammatory potential of platelet-rich plasma in the tissue healing process have led to investigation of platelet-rich plasma as a treatment for musculoskeletal indications, including osteoarthritis (Shen et al., 2018).

Evidence Review

Whole Body Vibration

Newberry et al., 2017

This is a good-quality systematic review and health technology assessment of selected nonsurgical treatments of osteoarthritis of the knee conducted for the AHRQ. The interventions included in this report are glucosamine and chondroitin, cell-based therapies, exercise therapies, balneotherapy, electrical stimulation, whole body vibration, heat, ultrasound, orthoses, weight loss diets, and home-based or self-management programs. The report updates earlier systematic reviews of the included interventions that had previously been conducted for AHRQ. The authors used standard AHRQ methods for conducting this updated review, and the final searches were conducted in September 2016. For efficacy outcomes, only randomized controlled trials (RCTs) were eligible for inclusion, with the exception that prospective cohort studies of weight loss could also be included. Because of the large amount of data available for glucosamine-chondroitin, small trials (those with fewer than 50 participants per arm) were excluded. For outcomes related to adverse events, prospective observational studies and case reports were included. The report analyzed outcomes of pain, function, and quality of life in the short term (4-12 weeks), medium term (12-26 weeks), and long term (> 26 weeks). Studies with less than four weeks of follow-up were excluded. The authors applied an adapted GRADE methodology to rate the strength of evidence.

The authors identified four RCTs (n = 180) assessing the effects of whole body vibration on medium-term pain and function. Treatment was provided three to five times per week in a 30-minute session. A random effects meta-analysis of these studies found no statistically significant difference in medium-term WOMAC pain scores between whole body vibration and controls (exercise and strength-training programs) (SMD -0.20, 95% CI -1.12 to 0.71, I^2 = 74.2%), and a small but statistically significant improvement in medium-term WOMAC function with whole body vibration (SMD -0.26, 95% CI -0.45 to -0.06, I^2 = 0%). This improvement did not meet the threshold for a minimal clinically important difference (defined as a SMD of -0.37). With regard to adverse effects, the authors observed that there were no significant differences in adverse events between whole body vibration and control groups, although one patient who received whole body vibration reported minor back pain. Overall, the authors concluded that there was low strength of evidence of no effect of whole body vibration on medium-term pain, but low strength of evidence that whole body vibration resulted in small but statistically significant improvements in medium-term function.

Transcutaneous Electrical Nerve Stimulation

Newberry et al., 2017

This review is described above. The authors identified two RCTs (n = 650) that reported on medium-term pain and function. One of the studies compared TENS to sham TENS, and the second study compared TENS plus exercise to sham TENS plus exercise or exercise alone. With respect to medium-term pain and function, neither study showed significant between-group differences for TENS and sham TENS at six months. The latter study showed no statistically significant difference for any outcome between the TENS plus exercise and exercise-alone groups. With regard to adverse events, there was no significant difference between TENS and control groups in adverse events. Overall, the authors concluded that although there was moderate strength of evidence that TENS produced small improvements in short-term pain, there was low-strength evidence of no effect of TENS on short-term function, medium-term pain, and medium-term function.

Glucosamine and Chondroitin

Newberry et al., 2017

This review is described above. For the combination of glucosamine and chondroitin, the authors identified three RCTs (n = 881) that addressed medium-term pain and function. One study comparing glucosamine-chondroitin to celecoxib showed similar clinically significant reductions in pain. The WOMAC function score showed similar clinically significant declines in function in both groups in a six-month period (45.5% for glucosamine chondroitin and 46.4% for celecoxib, RR 1.02, 95% CI 0.86 to 1.21). The second RCT, an open-label study that compared glucosamine-chondroitin plus a low-calorie weight loss diet to diet alone found that the glucosamine-chondroitin group had greater improvement in WOMAC pain scores (MD -1.59, 95% CI -2.31 to -0.87) and VAS pain scores (MD -2.08, 95% CI -2.40 to -1.76). The glucosamine-chondroitin group also had significant improvements in WOMAC function compared to diet alone (MD -3.86, 95% CI -6.16 to -1.56). A third trial comparing glucosamine-chondroitin to a placebo found greater improvement in pain scores in the placebo arm, and no difference in WOMAC function between the two arms.

For the combination of glucosamine and chondroitin, the authors identified three RCTs (n = 466) that addressed long-term pain and function. A random effects meta-analysis of these studies found no statistically significant difference in long-term WOMAC pain scores between glucosamine-chondroitin and controls (SMD -0.73, 95% CI -4.03 to 2.57, I^2 = 96.8%). Similarly, a random effects meta-analysis of these studies found no statistically significant difference in long-term WOMAC function scores between glucosamine-chondroitin and controls (SMD -0.45, 95% CI -2.75 to 1.84, I^2 = 94.5%).

Overall, the authors concluded that there was low strength of evidence that glucosamine-chondroitin improved medium-term pain and function, and moderate strength of evidence that glucosamine-chondroitin had no effect on long-term pain and function.

For glucosamine alone, the authors identified three studies (two RCTs and one post-hoc analysis of two additional RCTs) (n = 1,007) assessing long-term pain. A random effects meta-analysis of these studies found no statistically significant difference in long-term WOMAC pain scores between glucosamine and controls (SMD -0.05, 95% CI -0.22 to 0.12, I^2 = 0%). In two of the three trials, there were no significant differences between glucosamine and placebos in long-term WOMAC function, whereas the third study

found that glucosamine improved function compared to a placebo in a three-year period as measured by the Lequesne index. A pooled analysis of long-term functional outcomes was not performed.

Overall, the authors concluded that there was moderate strength of evidence that glucosamine alone had no effect on long-term pain and low strength of evidence of no effect on long-term function.

For chondroitin alone, two RCTs (n = 974) assessed medium-term pain and function. In the first RCT, both chondroitin dosing regimens (1,200 mg once daily or 400 mg thrice daily), performed better than a placebo with respect to VAS pain scores (MD -7.70, 95% CI -14.43 to -0.97 for once daily dosing and MD -8.30, 95% CI -15.20 to -1.40 for thrice daily dosing). This trial also found improved medium-term function in the chondroitin arm compared to a placebo as measured by the Lequesne index (MD -2.2, 95% CI -3.37 to -1.03 for once daily dosing and MD -1.90, 95% CI -3.11 to -0.69 for thrice daily dosing). The second RCT compared chondroitin to a placebo and reported three categorical pain response outcomes: 40 mm and 60 mm decreases in VAS were achieved more often in the chondroitin group (RR 0.68, 95% CI 0.51 to 0.91 and RR 0.44, 95% CI 0.23 to 0.85, respectively), but there was no statistically significant difference in the achievement of a 40% reduction in WOMAC pain score (RR 0.83, 95% CI 0.68 to 1.02). In this study, there was no difference between chondroitin and a placebo in WOMAC function scores at six months.

For chondroitin alone, three RCTs (n = 1,889) assessed long-term pain and two RCTs (n = 1,267) assessed long-term function. Among the three RCTs assessing WOMAC pain scores at one to two years, none found statistically significant differences between chondroitin and a placebo. Similarly, the two RCTs reporting on WOMAC function scores at one to two years found no statistically significant differences between chondroitin and placebo.

Overall, the authors concluded that there was low strength of evidence that chondroitin alone improved medium-term pain, but insufficient evidence on medium-term function. There was moderate strength evidence of no effect on long-term pain and low strength of evidence of no effect on long-term function.

With regard to adverse effects, the authors observed that serious adverse events were rare in all studies. In particular, glucosamine and chondroitin did not appear to result in greater rates of gastrointestinal side effects or hyperglycemia compared to placebos. However, in one study comparing chondroitin to a placebo, there was a higher rate of withdrawal due to adverse effects in the chondroitin group, but the specific effects were not described.

Simental-Mendia et al., 2018

This is a fair-quality systematic review and meta-analysis of randomized placebo-controlled trials of glucosamine, chondroitin, or their combination for treatment of osteoarthritis of the knee. Studies were eligible for inclusion if they were designed as parallel arm or crossover placebo-controlled randomized trials with a treatment duration of at least one month and that reported on VAS or WOMAC pain scores. Overall, the authors identified 29 trials with a total of 6,120 participants. Compared to the AHRQ review, many of the trials included in this review were older, reported only short-term outcomes, and had fewer than 50 participants in each arm. Additionally, many of the studies had methodological limitations: six failed to report random sequence generation, 13 trials failed to report adequate methods of allocation concealment, and 16 trials had insufficient information about blinding. The meta-analytic results were not stratified by follow-up period and sensitivity analyses were not performed. A random-effects model was used for meta-analysis.

On the basis of six studies with 1,168 patients, glucosamine alone resulted in a small but statistically significant reduction in VAS pain score compared to a placebo (weighted mean difference [WMD] -7.41, 95% CI -14.31 to -0.51, I^2 = 78%). Based on 10 studies with 1,967 patients, glucosamine alone did not result in statistically significant improvement in the WOMAC pain score (WMD -0.76, 95% CI -1.93 to 0.40, I^2 = 91%), or in the WOMAC function score (WMD -1.57, 95% CI -3.81 to 0.68, I^2 = 78%).

On the basis of 16 studies with 3,462 patients, chondroitin alone resulted in a small but statistically significant reduction in VAS pain score compared to a placebo (WMD -8.35, 95% CI -11.84 to -4.85, I^2 = 80%). Based on two studies with 933 patients, chondroitin alone did not result in statistically significant improvement in the WOMAC pain score (WMD -0.13, 95% CI -0.65 to 0.40, I^2 = 0%). Based on one study with 631 patients, chondroitin alone did not result in statistically significant improvement in the WOMAC function score (WMD 0.30, 95% CI -0.02 to 0.62).

On the basis of three studies with 1,051 patients, glucosamine-chondroitin did not result in a statistically significant reduction in VAS pain score compared to a placebo (WMD -0.28, 95% CI -8.87 to 8.32, I^2 = 94%). Based on five studies with 1,236 patients, glucosamine-chondroitin did not result in statistically significant improvement in the WOMAC pain score (WMD 0.84, 95% CI -2.51 to 4.18, I^2 = 99%), or in the WOMAC function score (WMD -0.98, 95% CI -3.61 to 1.65, I^2 = 89%).

Overall, the authors concluded that glucosamine alone or chondroitin alone improved knee pain on the VAS, but did not result in statistically significant improvements in the WOMAC pain or function score. The combination of glucosamine and chondroitin did not result in statistically significant improvements in VAS pain score or the WOMAC pain or function scores. There was a moderate-to-high degree of heterogeneity in most of the analyses.

Runhaar et al., 2017

This is a good-quality individual patient data meta-analysis and subgroup analysis of the effectiveness of glucosamine alone for knee and hip osteoarthritis. The authors identified 21 eligible randomized placebo-controlled studies, but only six shared their data with the authors of this review. None of the six studies that shared data were industry funded. There were 1,625 patients in the included studies, which represented 55% of the total number of participants in the eligible placebo-controlled trials. Overall, two trials contributed to the estimate of short-term effects for knee osteoarthritis, two trials contributed to the estimates of long-term effects for knee osteoarthritis, and one trial contributed estimates of short- and long-term effects for hip osteoarthritis. In the overall meta-analysis, there were no differences in short-term WOMAC pain (SMD -0.03, 95% CI -0.15 to 0.09, I^2 = 0%), or long-term WOMAC pain (SMD -0.04, 95% CI -0.18 to 0.10, I^2 = 14%).

The use of individual patient data meta-analysis allows for subgroup analyses that are not generally possible with a traditional meta-analysis. For this review, the authors examined subgroups defined by baseline pain, body mass index, sex, radiographic arthritis grade, and evidence of inflammation. When considering only the four studies of knee osteoarthritis, there were no statistically significant treatment-subgroup interactions for any reported outcome (short- and long-term pain or function).

Overall, the body of evidence synthesis on the topic of glucosamine-chondroitin has found mixed results with generally high levels of heterogeneity. However, in the analyses that focus on summarizing large placebo-controlled trials and that report outcomes stratified by follow-up period, there may be a small benefit in medium-term pain and function, but no difference in long-term outcomes.

Platelet-Rich Plasma

Newberry et al., 2017

This review is described above. The authors identified five RCTs (n = 439) that assessed the effects of platelet-rich plasma on medium-term pain and two RCTs that assessed medium-term function.

In the first trial, participants were randomized to receive one platelet-rich plasma injection, two platelet-rich plasma injections, or a saline placebo injection. Both platelet-rich plasma groups showed significant reductions in VAS pain score at six months compared to the placebo (MD -2.45, 95% CI -2.92 to -1.98 for single injection and MD -2.07, 95% CI -2.59 to -1.55 for two injections). Similarly, at six months, WOMAC function scores were significantly better in the platelet-rich plasma groups than the placebo group (MD -19.38, 95% CI not reported for single injection and MD -17.06, 95% CI not reported for two injections).

In the second trial, participants were randomized to two injections of platelet-rich plasma separated by four weeks or to no treatment. At six months, there were no statistically significant differences in WOMAC pain scores between the groups (MD -0.96, 95% CI -2.88 to 0.96). Similarly, there was no significant difference between the groups with respect to WOMAC function score at six months.

In the third trial, participants were randomized to one platelet-rich plasma injection, three platelet-rich plasma injections, or saline placebo injection. Both platelet-rich plasma arms showed significant improvement over a placebo in EuroQol VAS pain scores at six months (MD -14.0, 95% CI -16.44 to -11.56 for one injection and MD -23.40, 95% CI -27.14 to -19.66 for three injections).

In the fourth trial, participants were randomized to two injections of platelet-rich plasma or to paracetamol (acetaminophen). At six months, the KOOS pain score was significantly lower in the platelet-rich plasma group than the paracetamol group (MD -6.90, 95% CI -18.29 to -4.49).

In the fifth trial, participants were randomized to three injections of platelet-rich plasma over six weeks or to acetaminophen. At six months, there were no significant differences between the groups with respect to VAS pain scores.

With regard to adverse events, the authors noted that one trial reported no serious adverse events, and the second trial reported that one participant had increased pain and stiffness after the platelet-rich plasma injection.

Overall, the authors concluded that there was low strength of evidence that platelet-rich plasma improved medium-term pain, and insufficient evidence to assess the effects of platelet-rich plasma on medium-term function.

Shen et al., 2017

This is a systematic review and meta-analysis of platelet-rich plasma injections. With the exception of one saline placebo-controlled study discussed separately below, the studies included in this review either used a variety of questionably effective active controls like hyaluronic acid or ozone injections, or were already included in the AHRQ review. In their meta-analysis, the authors did not separately consider studies using active and placebo controls. It is thus regarded as out of scope for this coverage guidance.

Smith, 2016

This is a small, single-center, but good-quality double-blind randomized placebo-controlled trial of autologous platelet-rich plasma injection for knee osteoarthritis. This study was not included in the Newberry review. In this study, 30 patients were randomized (1:1) to undergo three weekly injections with autologous platelet-rich plasma or with an equivalent amount of saline placebo control. Adequate allocation concealment and blinding measures are described. Participants were followed for 12 months with full retention of all study participants. However, the study likely did not enroll enough participants to attain optimal information size when assessing a continuous variable. The study author disclosed that he is a consultant for Arthrex Inc., which also funded the study (Arthrex Inc. makes a device to prepare autologous platelet-rich plasma for injection).

Eligible patients were between ages 30 and 80, had a documented diagnosis of osteoarthritis for at least six weeks, had Kellgren-Lawrence radiographic grade 2-3 knee osteoarthritis, and a WOMAC pain scale score of at least eight. There were multiple exclusions including clinically significant effusions, valgus or varus deformities, viscosupplementation or surgery on the target knee in the prior six months, anticoagulation, and the presence of osteoarthritis in the hips or contralateral knee. The groups were similar at baseline with respect to sex, BMI, and radiographic grade; the platelet-rich plasma group had a slightly older mean age than the saline control group.

At 12 months, the mean WOMAC pain score had improved from 10 to 2 (76% improvement) in the platelet-rich plasma group compared to 11 to 9 (19% improvement) in the saline control group. The mean WOMAC function score had improved from 32 to 7 (78% improvement) in the platelet-rich plasma group compared to 31 to 30 (3% improvement) in the control group. These between-group differences were statistically significant ($p < 0.05$). There were no serious adverse events in either group, although one patient in the placebo group reported increased pain in the target leg.

Evidence Summary

On the basis of a recently updated AHRQ review on selected nonsurgical interventions for osteoarthritis of the knee, there is low strength of evidence that glucosamine-chondroitin and platelet-rich plasma result in small improvements in medium-term pain and function. There was low strength of evidence that TENS has no significant effects on medium-term pain or function. Evidence for the long-term effectiveness of these interventions is generally lacking, although there is moderate strength of evidence that glucosamine-chondroitin has no significant long-term effects on pain or function. A small RCT of platelet-rich plasma that was not included in the AHRQ review concluded that there were statistically significant benefits for pain and function at 12 months; the AHRQ review itself only found low strength of evidence for improvement in medium-term pain. For all interventions, serious adverse events were rare and did not significantly differ between intervention and control groups.

Policy Landscape

Payer Coverage Policies

Medicaid

No Washington Medicaid policy was identified for whole body vibration, glucosamine, or chondroitin. A 2009 coverage decision for Washington Medicaid states that electrical neural stimulation, including

TENS, is a non-covered benefit. A 2016 coverage decision for Washington Medicaid states that autologous blood/platelet-rich plasma injections are not a covered benefit.

Medicare

No Medicare National Coverage Determination (NCD) or Local Coverage Determination (LCD) was identified for whole body vibration, glucosamine, chondroitin, or platelet-rich plasma for knee osteoarthritis.

An NCD for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (effective: 6/19/2006) provides coverage for electrical nerve stimulation for assessing a patient's suitability for ongoing treatment with a transcutaneous or an implanted nerve stimulator. TENS is to be used on a trial basis while its effectiveness in modulating pain is monitored by a physician or physical therapist. In most cases, a determination of whether the patient is likely to derive a significant therapeutic benefit from continuous use of TENS can be made within a trial period of one month. LCD L34821 on Transcutaneous Electrical Joint Stimulation Devices (effective: 1/1/2017) does not provide coverage for TENS.

Private Payers

The Aetna policy on complementary and alternative medicine (last review 6/15/2018) does not provide coverage for whole body vibration. Coverage policies for whole body vibration were not identified for Cigna, Moda, or Regence.

Aetna and Moda provide coverage for the use of TENS for knee osteoarthritis under certain conditions. The Cigna policy on electrical stimulation therapy (effective 7/15/2017) covers TENS only for conventional postoperative pain management within 30 days of surgery. The Regence policy on electrical stimulation therapy (effective 8/1/2018) does not provide coverage for electrical stimulation or electromagnetic therapy for the treatment of osteoarthritis or rheumatoid arthritis.

The Aetna policy on electrical stimulation for pain (last review: 3/12/2018) does not provide coverage for acute pain (less than 3 months duration) except for postoperative pain. Aetna considers TENS medically necessary durable medical equipment for certain types of chronic, intractable pain not adequately responsive to other methods of treatment including physical therapy and pharmacotherapy. Aetna considers use of TENS medically necessary initially for a trial period of one to two months. After this trial period, coverage depends on the treatment significantly alleviating pain.

The Moda policy on electrical stimulation therapy (last review: 10/25/2017) covers TENS for chronic pain other than low back pain when all of the following criteria are met:

- Pain must have been present for at least three months
- Other appropriate treatment modalities must have been tried and failed (e.g., physical therapy, pharmacotherapy)
- Patients must have an in-person examination with their provider for the condition prescribed

The Aetna policy on complementary and alternative medicine (last review 6/15/2018) and the Cigna policy on complementary and alternative medicine (effective: 8/15/2018) do not provide coverage for glucosamine, and no policy on glucosamine was found for Moda or Regence. No policy on chondroitin was identified for any of the four private payers: Aetna, Cigna, Moda, or Regence.

Platelet-rich plasma is not covered in policies identified for Aetna (last review 4/3/2018), Cigna (effective: 10/15/2017), Moda (effective 12/6/2017), and Regence (effective: 11/1/2017).

Recommendations from Others

Five guidelines were identified that encompassed knee osteoarthritis or osteoarthritis more broadly:

- U.S. Department of Veterans Affairs (VA) and Department of Defense (DoD) guideline on nonsurgical management of hip and knee osteoarthritis (VA/DoD, 2014)
- American Academy of Orthopaedic Surgeons (AAOS) guideline on knee osteoarthritis (Jevsevar, 2013)
- American College of Rheumatology (ACR) recommendations for osteoarthritis of the hand, hip, and knee (Hochberg et al., 2012). Note: publication of an update to these guidelines is anticipated in 2018 (ACR, 2018)
- European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ESCEO) guidelines for knee osteoarthritis (Bruyere et al., 2014)
- Osteoarthritis Research Society International (OARSI) guidelines on nonsurgical management of knee osteoarthritis (McAlindon et al., 2014)

None of the identified guidelines included recommendations on whole body vibration.

ACR and ESCEO include TENS as a treatment option. ACR conditionally recommends TENS only when the patient has chronic moderate to severe pain and is a candidate for total knee arthroplasty, but is unwilling to undergo the procedure, has comorbid medical conditions, or is taking concomitant medications that lead to a relative or absolute contraindication to surgery or a decision by the surgeon not to recommend the procedure. AAOS is unable to recommend for or against TENS, and OARSI considers TENS a treatment of uncertain appropriateness. TENS is not mentioned in the VA/DoD guidelines.

Glucosamine and chondroitin sulfate are not recommended in the VA/DoD and AAOS guidelines. ACR conditionally recommends that patients should not use glucosamine and chondroitin sulfate, and OARSI considers glucosamine and chondroitin sulfate as treatments of uncertain appropriateness. ESCEO recommends the use of glucosamine and chondroitin and provides updated recommendations on their use in a 2016 consensus statement (Bruyere et al., 2016). ESCEO advocates the use of prescription patented crystalline glucosamine sulfate as a first-line symptomatic slow-acting drug for medium-to long-term control of knee osteoarthritis symptoms.

Of the five identified guidelines, only AAOS includes a recommendation on platelet-rich plasma, and these guidelines are unable to recommend for or against platelet-rich plasma for knee osteoarthritis. The National Institute for Health and Care Excellence (NICE) published an interventional procedures guidance, which states that the evidence on efficacy is inadequate in quality and that there is no evidence of major safety concerns. Therefore, the guidance concludes that platelet-rich plasma should only be used with special arrangements for clinical governance, consent, and audit or research (NICE, 2014).

Quality Measures

No quality measures were identified when searching the National Quality Measures Clearinghouse for whole body vibration, transcutaneous electrical nerve stimulation, glucosamine, chondroitin, or platelet-rich plasma for osteoarthritis.

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Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

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Appendix A. GRADE Table Element Descriptions

Element	Description
Balance of benefits and harms	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. An estimate that is not statistically significant or has a confidence interval crossing a predetermined clinical decision threshold will be downgraded.
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed in the absence of likely cost offsets—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted
Other considerations	Other considerations include issues about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.

Strong recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors., but further research or additional information could lead to a different conclusion.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the balance of benefits and harms, cost and resource allocation, and values and preferences, but further research or additional information could lead to a different conclusion.

Confidence in estimate rating across studies for the intervention/outcome

Assessment of confidence in estimate includes factors such as risk of bias, precision, directness, consistency and publication bias.

High: The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

Moderate: The subcommittee is moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

Low: The subcommittee's confidence in the estimate of effect is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

Very low: The subcommittee has very little confidence in the estimate of effect: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

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Appendix B. GRADE Evidence Profile

Quality Assessment (Confidence in Estimate of Effect) for Whole Body Vibration							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Long-term pain							
0							Insufficient
Long-term function							
0							Insufficient
Intermediate-term pain							
4	RCTs	2 Low 1 moderate 1 unclear	Serious	Not serious	Not serious		Low ●●○○
Intermediate-term function							
4	RCTs	2 Low 1 moderate 1 unclear	Serious	Not serious	Not serious		Low ●●○○
Harms							
4	RCTs	N/A	N/A	N/A	N/A		Low ●●○○

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Quality Assessment (Confidence in Estimate of Effect) for Transcutaneous Electrical Nerve Stimulation							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Long-term pain							
0							Insufficient
Long-term function							
0							Insufficient
Intermediate-term pain							
2	RCTs	2 Low	Not serious	Not serious	Not serious		Low ●●○○
Intermediate-term function							
2	RCTs	2 Low	Not serious	Not serious	Not serious		Low ●●○○
Harms							
2	RCTs	N/A	N/A	N/A	N/A		Low ●●○○

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Quality Assessment (Confidence in Estimate of Effect) for Glucosamine alone							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Long-term pain							
3	RCTs	2 low 1 high	Serious	Not serious	Not serious		Low ●●○○
Long-term function							
3	RCTs	2 low 1 high	Serious	Not serious	Not serious		Low ●●○○
Intermediate-term pain							
0							Insufficient
Intermediate-term function							
0							Insufficient
Harms							
6	Mixed	N/A	N/A	N/A	N/A		Moderate ●●●○

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Quality Assessment (Confidence in Estimate of Effect) for Glucosamine-Chondroitin							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Long-term pain							
3	RCTs	2 low 1 high	Serious	Not serious	Not serious		Moderate ●●●○
Long-term function							
3	RCTs	2 low 1 high	Serious	Not serious	Not serious		Moderate ●●●○
Intermediate-term pain							
3	RCTs	2 low 1 high	Serious	Not serious	Not serious		Low ●●○○
Intermediate-term function							
3	RCTs	2 low 1 moderate	Serious	Not serious	Not serious		Low ●●○○
Harms							
6	Mixed	N/A	N/A	N/A	N/A		Moderate ●●●○

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Quality Assessment (Confidence in Estimate of Effect) for Chondroitin alone							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Long-term pain							
3	RCTs	3 low	Not serious	Not serious	Not serious		Moderate ●●●○
Long-term function							
2	RCTs	2 low	Not serious	Not serious	Not serious		Low ●●○○
Intermediate-term pain							
2	RCTs	2 Low	Not serious	Not serious	Not serious		Low ●●○○
Intermediate-term function							
2	RCTs	2 Low	Serious	Not serious	Not serious		Insufficient
Harms							
6	Mixed	N/A	N/A	N/A	N/A		Moderate ●●●○

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Quality Assessment (Confidence in Estimate of Effect) for Platelet-Rich Plasma							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Long-term pain							
1	RCT	Low	Not serious	Not serious	Serious	Sparse data Industry involvement	Very Low ●○○○
Long-term function							
1	RCT	Low	Not serious	Not serious	Serious	Sparse data Industry involvement	Very Low ●○○○
Intermediate-term pain							
5	RCTs	2 Low 1 moderate 2 high	Not serious	Not serious	Not serious		Low ●●○○
Intermediate-term function							
2	RCTs	2 moderate	N/A	Not serious	Not reported		Insufficient
Harms							
3	RCTs	N/A	N/A	N/A	N/A		Low ●●○○

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Quality Assessment (Confidence in Estimate of Effect) for Transcutaneous Electrical Nerve Stimulation							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Long-term pain							
0							Insufficient
Long-term function							
0							Insufficient
Intermediate-term pain							
2	RCTs	2 Low	Not serious	Not serious	Not serious		Low ●●○○
Intermediate-term function							
2	RCTs	2 Low	Not serious	Not serious	Not serious		Low ●●○○
Harms							
2	RCTs	N/A	N/A	N/A	N/A		Low ●●○○

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Appendix C. Methods

Scope Statement

Populations

Adults with osteoarthritis of the knee(s)

Population scoping notes: None

Interventions

Whole body vibration, transcutaneous electrical nerve stimulation, glucosamine-chondroitin, platelet-rich plasma

Intervention exclusions: None

Comparators

Effective nonsurgical care (e.g., oral analgesics, exercise therapy)

Outcomes

Critical: Long-term pain, long-term function

Important: Intermediate-term function, intermediate-term pain, harms

Considered but not selected for the GRADE table: None

Key Questions

KQ1: What is the comparative effectiveness of newer interventions for the treatment of osteoarthritis of the knees?

KQ2: Does the comparative effectiveness of newer interventions for the treatment of osteoarthritis of the knees vary by:

a. Patient characteristics (age, gender, socioeconomic status, baseline weight)
b. Baseline severity
c. Disease subtype
d. Comorbidities
e. Prior treatments

KQ3: What are the harms of newer interventions for the treatment of osteoarthritis of the knees?

Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, and technology assessments that meet the criteria for the scope described above. Searches of core sources were limited to citations published after 2013.

The following core sources were searched:

Agency for Healthcare Research and Quality (AHRQ)

Canadian Agency for Drugs and Technologies in Health (CADTH)

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Cochrane Library (Wiley Online Library)
Institute for Clinical and Economic Review (ICER)
Medicaid Evidence-based Decisions Project (MED)
National Institute for Health and Care Excellence (NICE)
Tufts Cost-effectiveness Analysis Registry
Veterans Administration Evidence-based Synthesis Program (ESP)
Washington State Health Technology Assessment Program

A MEDLINE® search was also conducted to identify systematic reviews, meta-analyses, and technology assessments, using the search terms knee osteoarthritis and (whole body vibration or transcutaneous electrical nerve stimulation or glucosamine or chondroitin or platelet-rich plasma). The search was limited to publications in English published since 2013. In addition, a MEDLINE® search was conducted for randomized controlled trials published after the search dates of the most recent systematic review selected for each indication.

Searches for clinical practice guidelines were limited to those published since 2013. A search for relevant clinical practice guidelines was also conducted using MEDLINE® and the following sources:

Australian Government National Health and Medical Research Council (NHMRC)
Canadian Agency for Drugs and Technologies in Health (CADTH)
Centers for Disease Control and Prevention (CDC), Community Preventive Services
National Guidelines Clearinghouse
National Institute for Health and Care Excellence (NICE)
Scottish Intercollegiate Guidelines Network (SIGN)
United States Preventive Services Task Force (USPSTF)
Veterans Administration/Department of Defense (VA/DoD) Clinical Practice Guidelines

Inclusion/Exclusion Criteria

Studies were excluded if they were not published in English; did not address the scope statement; or were study designs other than systematic reviews, meta-analyses, technology assessments, randomized controlled trials, or clinical practice guidelines.

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Appendix D. Applicable Codes

CODES	DESCRIPTION	
CPT Codes		**Intervention**
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed	Platelet rich plasma
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility	Whole body vibration (as physical therapy service)
97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities	Whole body vibration (as physical therapy service)
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes	Whole body vibration (as physical therapy service)
64550	Application of surface (transcutaneous) neurostimulator (eg, TENS unit)	TENS
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)	TENS
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes	TENS
HCPCS Level II Codes		
A9270	Non-covered item or service	Whole body vibration therapy machine
E0720	Transcutaneous electrical nerve stimulation (tens) device, two lead, localized stimulation	TENS
E0730	Transcutaneous electrical nerve stimulation (tens) device, four or more leads, for multiple nerve stimulation	TENS
E0731	Form fitting conductive garment for delivery of tens or nmes (with conductive fibers separated from the patient's skin by layers of fabric)	TENS

Note: Inclusion on this list does not guarantee coverage.

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Appendix E. MCID cutoffs developed or used in a representative sample of articles from the AHRQ review (Newberry et al., 2017)

Author, Year	Condition/Intervention/ Follow-up	Cutoffs	Notes
Eberle, 1999 PMID: 10489324	Knee OA hyaluronic acid injection, 6 month follow-up	VAS pain: 8.4mm on a 0-100 mm scale; 0.7 points on Lequesne 24-point scale	Anchor question: complaints reduced
Angst, 2001 PMID:11501727	Knee or hip OA Rehabilitation, 3 month follow-up	WOMAC pain: 0.75 (0-10 scale) WOMAC function and total: 0.67 SF-36 physical function: 3.3 (0-100 scale)	Anchor question: current subjective health much better, slightly better, no change, slightly worse. Converted all 5 WOMAC pain item scores to a 0-10 scale and took the average) Separate values for worsening and improvement
Salaffi, 2004 PMID: 15207508	Chronic musculoskeletal pain (OA knee, OA hip, AS, rheumatoid arthritis, OA hand) Not described	Numeric rating scale: 15% or 1 point decrease for minimum improvement, 33% or 2 points for much better (which they regarded as clinical improvement)	Anchor: Patient global impression of change
Tubach, 2005 PMID:15208174	Knee or hip OA nonsteroidal anti-inflammatory drugs, 4 weeks	Knee: VAS pain: −19.9mm (−40.8%) WOMAC function: −9.1 (−26%)	WOMAC 17 items, 5-point Likert scale, total score normalized to 0-100 scale MCII Initial severity affected MCII but age, disease duration, and sex did not
Wandel, 2010 PMID: 20847017	Knee or hip OA Glucosamine-chondroitin vs. placebo network meta-analysis	MCID 0.37 SD units, corresponding to 0.9cm (0-10cm VAS scale)	Median pooled SD of 2.5cm used to back transform effect sizes to 10cm VAS scale

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OMERACT-OARSI responder criteria Pham 2003 PMID: 12858473	Knee or hip OA	Clinical response was defined as either 1. improvement of at least 50% in pain or function and an absolute change of at least 20 points on a scale of 0-100 in the WOMAC pain or function subscores, or 2. at least 2 of the following criteria: improvement of at least 20% and an absolute change greater than 10 points on a scale of 0-100 in the WOMAC pain score, improvement of at least 20% and an absolute change greater than 10 points (on a 0-100 scale) in the WOMAC function score, or improvement of at least 20% in the patient Global Assessment score and an absolute change >10 points on a scale of 0-100	WOMAC pain and function scales converted to single 0-100 scores.

Abbreviations: OA: osteoarthritis; VAS: visual analog scale; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index

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CG - Newer Interventions for Osteoarthritis of the Knee

Question: How should the Coverage Guidance *Newer Interventions For Osteoarthritis Of The Knee* be applied to the Prioritized List?

Question source: Evidence-based Guideline Subcommittee

Issue: EbGS approved a draft Coverage Guidance on newer interventions for osteoarthritis of the knee. They recommended noncoverage of all interventions reviewed. There was no public comment received.

Coverage guidance box language:

Whole body vibration

Whole body vibration is not recommended for coverage (*strong recommendation*).

TENS

TENS is not recommended for coverage (*strong recommendation*).

Glucosamine/chondroitin

Glucosamine/chondroitin is not recommended for coverage (*weak recommendation*).

Glucosamine alone is not recommended for coverage (*strong recommendation*).

Chondroitin alone is not recommended for coverage (*weak recommendation*).

Platelet-rich plasma

Platelet-rich plasma is not recommended for coverage (*weak recommendation*)

Current Prioritized List Status

CODES	DESCRIPTION		
CPT Codes		**Intervention**	**Placement**
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed	Platelet rich plasma	Not on Prioritized List, temporary code
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility	Whole body vibration (as physical therapy service)	On 64 lines

97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities	Whole body vibration (as physical therapy service)	On 59 lines
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes	Whole body vibration (as physical therapy service)	On 60 lines
64550	Application of surface (transcutaneous) neurostimulator (eg, TENS unit)	TENS	Code deleted in 2019 from CPT
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)	TENS	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes	TENS	660
HCPCS Level II Codes			
A9270	Non-covered item or service	Whole body vibration therapy machine	Ancillary
E0720	Transcutaneous electrical nerve stimulation (TENS) device, two lead, localized stimulation	TENS	660
E0730	Transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation	TENS	660

E0731	Form fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)	TENS	Excluded File

Line: 356

Condition: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE (See Coding Specification Below) (See Guideline Notes 6,15,64,65,71,83,114,158)

Treatment: ARTHROPLASTY/RECONSTRUCTION

ICD-10: L40.50-L40.59,M02.10,M02.111-M02.19,M02.30,M02.311-M02.89,M05.611-M05.9, M06.00,M06.011-M06.29,M06.311-M06.39,M06.80,M06.811-M06.9,M08.00,M08.011-M08.48,M08.811-M08.99,M12.50,M12.511-M12.59,M13.871-M13.879,M16.0,M16.10-M16.9,M17.0,M17.10-M17.9,M18.0,M18.10-M18.9,M19.011-M19.93,M20.20-M20.22, M24.151-M24.176,M24.871-M24.872,M24.874-M24.875,M25.00,M25.011-M25.076, M25.151-M25.159,M25.851-M25.859,M25.871-M25.879,M76.20-M76.22,M87.00, M87.011-M87.9,M90.50,M90.511-M90.59,M93.20,M93.211-M93.29

CPT: 20610,20611,20690-20694,23120,23470-23474,23800,23802,24000,24006,24101,24102, 24130,24160,24164,24360-24371,24800,24802,25000,25101-25109,25115-25119,25210-25240,25270,25320,25337,25390-25393,25441-25492,25800,25810-25830,26320,26516-26536,26820-26863,26990-26992,27036,27090,27091,27122-27132,27187,27284,27286, 27358,27437-27454,27457,27580,27620-27626,27641,27700-27704,27870,27871,28090, 28104,28114,28116,28122,28289-28292,28446,28715,28725,28740,28750,29819-29826, 29834-29838,29843-29848,29861-29863,29871-29876,29884-29887,29891,29892,29894-29899,29904-29916,77014,77261-77290,77295,77300,77306,77307,77331-77336,77385-77387,77401-77423,77427,77470,93792,93793,97012,97018,97110-97124,97140,97150, 97161-97168,97530,97535,97542,97760-97763,98966-98969,99051,99060,99070,99078, 99184,99201-99239,99281-99285,99291-99404,99408-99449,99451,99452,99468-99480, 99487-99491,99495-99498,99605-99607

HCPCS: G0068,G0071,G0157-G0161,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427, G0463-G0467,G0490,G0508-G0511,G0513,G0514,G2010-G6017,S2118,S2325

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

Line: 430

Condition: INTERNAL DERANGEMENT OF KNEE AND LIGAMENTOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT (See Guideline Notes 6,64,65,98,104)

Treatment: REPAIR, MEDICAL THERAPY

ICD-10: M22.2X1-M22.3X9,M22.8X1-M22.8X9,M23.011-M23.205,M23.211-M23.305,M23.311-M23.8X9,M24.661-M24.669,M66.261-M66.269,S83.200A-S83.200D,S83.201A-S83.201D, S83.202A-S83.202D,S83.203A-S83.203D,S83.204A-S83.204D,S83.205A-S83.205D, S83.206A-S83.206D,S83.207A-S83.207D,S83.209A-S83.209D,S83.211A-S83.211D, S83.212A-S83.212D,S83.219A-S83.219D,S83.221A-S83.221D,S83.222A-S83.222D, S83.229A-S83.229D,S83.231A-S83.231D,S83.232A-S83.232D,S83.239A-S83.239D, S83.241A-S83.241D,S83.242A-S83.242D,S83.249A-S83.249D,S83.251A-S83.251D, S83.252A-S83.252D,S83.259A-S83.259D,S83.261A-S83.261D,S83.262A-S83.262D, S83.269A-S83.269D,S83.271A-S83.271D,S83.272A-S83.272D,S83.279A-S83.279D, S83.281A-S83.281D,S83.282A-S83.282D,S83.289A-S83.289D,S83.30XA-S83.30XD, S83.31XA-S83.31XD,S83.32XA-S83.32XD,S83.401A-S83.401D,S83.402A-S83.402D, S83.409A-S83.409D,S83.411A-S83.411D,S83.412A-S83.412D,S83.419A-S83.419D,

S83.421A-S83.421D,S83.422A-S83.422D,S83.429A-S83.429D,S83.501A-S83.501D, S83.502A-S83.502D,S83.509A-S83.509D,S83.511A-S83.511D,S83.512A-S83.512D, S83.519A-S83.519D,S83.521A-S83.521D,S83.522A-S83.522D,S83.529A-S83.529D, S83.60XA-S83.60XD,S83.61XA-S83.61XD,S83.62XA-S83.62XD,S83.8X1A-S83.8X1D, S83.8X2A-S83.8X2D,S83.8X9A-S83.8X9D,S83.90XA-S83.90XD,S83.91XA-S83.91XD, S83.92XA-S83.92XD

CPT: 20610,20611,27332-27335,27340,27350,27380,27381,27403-27416,27420-27430,27570, 29345-29445,29505,29530,29705,29871-29889,93792,93793,97012,97110-97124,97140, 97150,97161-97168,97530,97535,97542,97760-97763,98966-98969,99051,99060,99070, 99078,99184,99201-99239,99281-99285,99291-99404,99408-99449,99451,99452,99468-99480,99487-99491,99495-99498,99605-99607

HCPCS: G0068,G0071,G0157-G0161,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427, G0463-G0467,G0490,G0508-G0511,G0513,G0514,G2010-G2012

Line: 461

Condition: OSTEOARTHRITIS AND ALLIED DISORDERS (See Guideline Notes 6,64,65,92,104)

Treatment: MEDICAL THERAPY, INJECTIONS

ICD-10: M12.10,M12.111-M12.19,M12.40,M12.411-M12.59,M13.80,M13.811-M13.89,M15.0-M15.9,M16.0,M16.10-M16.9,M17.0,M17.10-M17.9,M18.0,M18.10-M18.9,M19.011-M19.93,M20.20-M20.22,M24.171-M24.176,M24.671-M24.673,M24.871-M24.872, M24.874-M24.875,M25.871-M25.879

CPT: 11042,11045,20600-20611,25000,29075,93792,93793,96150-96155,97012,97018,97110-97124,97140,97150,97161-97168,97530,97535,97542,97760-97763,97810-98942,98966-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99449,99451,99452,99468-99480,99487-99491,99495-99498,99605-99607

HCPCS: G0068,G0071,G0157-G0161,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427, G0463-G0467,G0490,G0508-G0511,G0513,G0514,G2010-G2012

GUIDELINE NOTE 104, VISCOSUPPLEMENTATION OF THE KNEE

Lines 430,461

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

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

HERC Staff Summary

All the interventions reviewed were recommended for noncoverage. There are not specific usable CPT/HCPCS codes to indicate noncoverage for whole body vibration, glucosamine/chondroitin, or platelet rich plasma (temporary code only). Therefore, a guideline is necessary to clarify intent.

HERC Staff Recommendations:

1) **Modify guideline note 104 as follows**

GUIDELINE NOTE 104, ~~VISCOSUPPLEMENTATION~~ NEWER INTERVENTIONS FOR OSTEOARTHRITIS OF THE KNEE

Lines 430,461

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

- Whole body vibration
- Glucosamine/chondroitin (alone, or in combination)
- Platelet rich plasma
- Viscosupplementation

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

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

2) **Advise HSD to move A9270 Non-covered item or service from Ancillary File to Excluded File**

HERC Coverage Guidance: Newer Interventions for Osteoarthritis of the Knee
Disposition of Public Comments

Table of Contents

Commenters

Identification	Stakeholder
	No comments submitted

DRAFT