

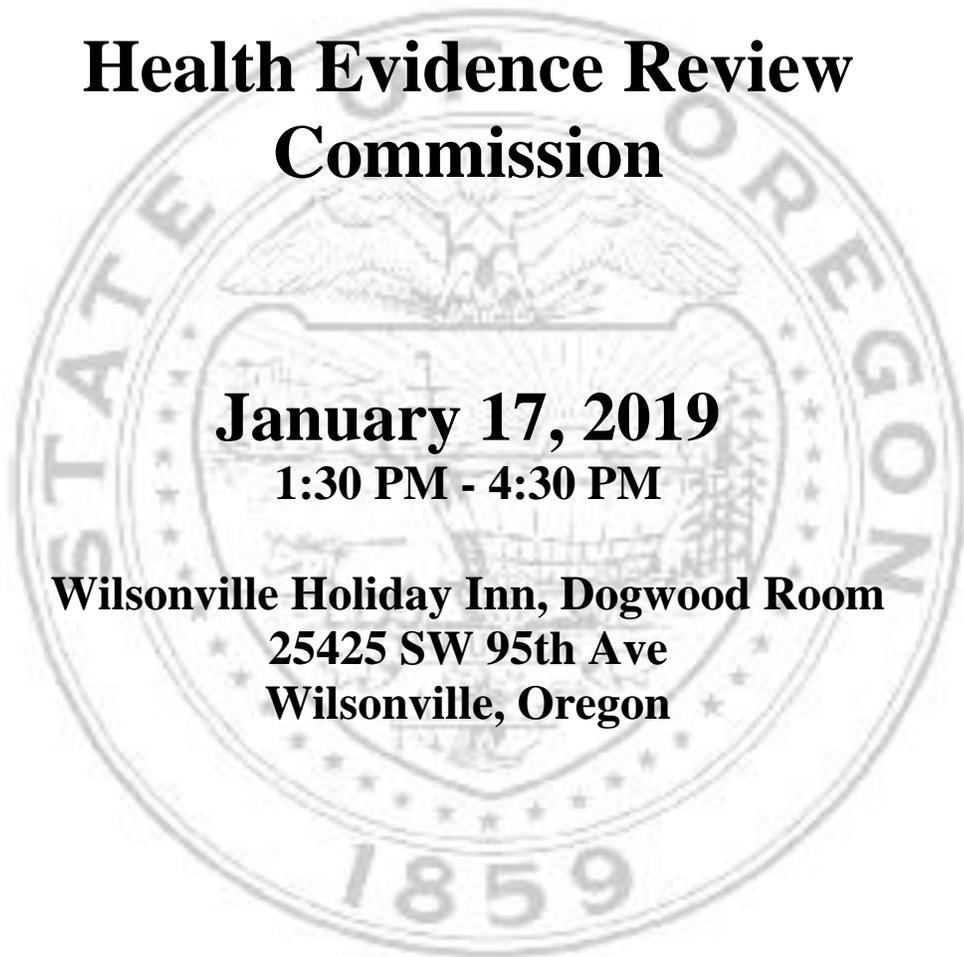


Health Evidence Review Commission

January 17, 2019

1:30 PM - 4:30 PM

**Wilsonville Holiday Inn, Dogwood Room
25425 SW 95th Ave
Wilsonville, Oregon**



Section 1.0

Call to Order

AGENDA

HEALTH EVIDENCE REVIEW COMMISSION

Wilsonville Holiday Inn, Dogwood Room

25425 SW 95th Ave, Wilsonville, Oregon

January 17, 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 (11/8/18)	Kevin Olson	X
3	1:40 PM	Director's report	Darren Coffman	
4	1:50 PM	Value-based Benefits Subcommittee report	Ariel Smits Cat Livingston	X
5	2:15 PM	Temporary Percutaneous Mechanical Circulatory Support with Impella Devices <ul style="list-style-type: none">• Coverage guidance• Prioritized List changes	Adam Obley Cat Livingston	X
6	3:30 PM	Newer Interventional Procedures for GERD <ul style="list-style-type: none">• Coverage guidance• Prioritized List changes	Adam Obley Wally Shaffer	X
8	4:20 PM	Next steps <ul style="list-style-type: none">• Schedule next meeting – March 14, 2019 Human Services Bldg, Rooms 137 A-D, Salem	Kevin Olson	
9	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
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
November 8, 2018

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, Vice-Chair (by phone until 3:30); Mark Gibson; Leda Garside, RN, MBA; Susan Williams, MD (by phone until 3:30 pm); Angela Senders, ND (by phone); Gary Allen, DMD; Leslie Sutton (by phone until 3:30 pm); Adriane Irwin, PharmD (by phone); Michael Adler, MD (by phone until 3:30 pm); Kevin Cuccaro, DO (by phone).

Members Absent: Lynnea Lindsey, PhD; Devan Kansagara, MD.

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

Also Attending: Renae Wentz, MD, MPH (Oregon Health Authority); Val King, MD, MPH (OHSU Center for Evidence-based Policy); Devki Saraiya and Karen Heller (Myriad); Duncan Neilson, MD (Legacy Health); Sharron Fuchs; Alice Austin (OR Assoc. of Behavior Analysis).

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 10/4/2018 meeting as presented. CARRIES 10-0. (Absent: Irwin)

Director's Report

Membership

Coffman offered his appreciation to Susan Williams as this marks her final meeting as a Commissioner. The Governor's office is taking more time recruiting a replacement with a possible appointment in February, 2019.

Coffman said a member of the Health Technology Assessment Subcommittee (HTAS), Mark Bradshaw, is relocating out of state. Coffman recommended Mary Engrav, CareOregon Medical Director and ED physician, as a replacement.

MOTION: To appoint Mary Engrav to HTAS. Carries 11-0.

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

[Meeting materials](#) pages 58-204

Ariel Smits reported the VbBS met earlier in the day, November 8, 2018. She summarized the subcommittee's recommendations.

RECOMMENDED CODE MOVEMENT (effective 1/1/2019)

- Add the diagnosis codes used for latent tuberculosis infection to a covered line
- Add the procedure code for Yttrium-90 therapy to the covered liver cancer line with a new guideline
- Add the procedure codes for amniotic membrane transplant for eye conditions to three covered lines and removed from 3 other covered lines
- Add the 2019 CPT codes to various covered and uncovered lines on the Prioritized List with guideline note changes as needed to accommodate these codes
- Add the 2019 HCPCS codes to various covered and uncovered lines on the Prioritized List with changes to guidelines as required by placements
- Add the 2019 CDT codes to various covered and uncovered lines on the Prioritized List
- Add the procedure code for the iStent glaucoma surgery to a covered line with a new guideline

RECOMMENDED GUIDELINE CHANGES (effective 1/1/2019)

- Modify the non-prenatal genetic testing guideline and remove the hereditary cancer testing section to make into its own guideline
- Modify the prenatal genetic testing guideline
- Modify the guideline on human donor breast milk for high-risk infants

Modified from the VbBS report:

Place 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 a corresponding entry on Guideline Note 173.

MOTION: To accept the VbBS recommendations on *Prioritized List changes*, as modified. [See the VbBS minutes of 11/8/18](#) for a full description. Carries: 11-0.

Planned Out-of-hospital Birth Scoping Statement

[Meeting materials](#) pages 210-224

[Handout](#)

This item was moved up in the agenda to accommodate members who needed to leave early.

Livingston gave an overview of the current coverage guidance which was approved in November of 2015 after an 18-month process. Though the HERC does not do an automatic rescan of current coverage guidances, we have been asked to reconsider looking at this coverage guidance by multiple parties. The question before the Commission is should the coverage guidance be reopened.

Some providers hope to make the coverage guidance more restrictive while advocates hope it will be more flexible.

Adler asked for an overview of how the pre-authorization process works and Livingston and Smits gave a brief summary of the OHA process. Adler expressed concern about signs and symptoms of preeclampsia.

Livingston reviewed the rescan/scope statement document.

King gave a [presentation](#) focusing on the Snowden study from Oregon. She also spoke about the Grünebaum and the Tilden studies.

Invited commenter

The co-author of the Grünebaum study, Dr. Frank Chervenak, joined the meeting by phone. He spoke about patient safety in planned home birth. He said in 2017 a scientific paper identified two additional evidence-based contraindications for planned home birth: nulliparity (or first delivery) and gestational age of 41 weeks or more (1 in 400 deaths and 1 in 600 deaths, respectively).

Staff assessment

The evidence reviewed in the rescan generally supports the current understanding of the literature: that planned out-of-hospital birth significantly decreases women's risk of interventions such as cesarean section and assisted vaginal delivery, but that there are increased risks of serious but rare neonatal harms including death. The additional evidence available on VBAC (vaginal delivery after caesarian) would be informative but not change the coverage guidance, which already considers VBAC a high-risk coverage exclusion criteria. There are several potential new indications that could arise out of a review of the literature (gestational age over 41 weeks, over 35 years old, and nulliparity or a combination of those). However, there are significant limitations to the Grünebaum study that might suggest these criteria be examined, and it is not clear given those limitations how much this would change the coverage guidance if re-reviewed.

Public comment from the out-of-hospital birth community received during the posting of the draft scope statement proposed modifying the consultation criteria (to delete some required consultation criteria such as obesity). It also included the submission of studies related to out-of-hospital birth, some of which did not meet the search criteria.

It seems unlikely, based on the rescan, that there would be significant new information to lead to modifying those consultation criteria, although there are some updates to guidelines used in the 2015 review that may result in minor modifications.

Public comment also proposed modifications to add additional exclusion criteria such as additional neonatal transfer criteria.

Altogether reopening the coverage guidance may result in limited changes to the current coverage language.

Discussion

Olson asked if the Commission can apply a different rule to the Prioritized List than what is stipulated in the current coverage guidance. Coffman explained in the past when something like that occurred, a coverage guidance has been retired.

Gibson said he is reluctant to create a conflict with the recommendations that come out of the Commission. He feels they should be consistent. He said before we decide, we should think though the implications and that he is okay with opening up this coverage guidance for review.

Garside asked if we have all the risks in the current guideline from the 2015 review. Livingston said there is a possibility of adding more or removing some, depending on the conclusions drawn from an updated literature review. Garside said she is in favor of a new review in case it is determined that changes need to be made.

Olson said we tend to favor data that indicates there may be harms, even if the data is imperfect. We want to be able to say we gave this topic its due attention.

Cuccaro said if there is evidence of harm we should open it back up.

Irwin questioned whether we should open the topic based on a single low-quality study.

MOTION: Return the Planned Out-of-hospital Birth Coverage Guidance to EbGS for review. Carries: 7-0. (Absent: Hodges, Williams, Sutton, Adler)

Public comment

Sharon Fuchs commented that she is on one of the out-of-hospital workgroup committees. She delivered her first child outside the hospital in 1979 and filed her first concern with the state about that in 1980. She said there is no other committee doing the work that HERC is doing. She wanted to express appreciation for Dr. Chervenak and for the work of the HERC.

Duncan Neilson, MD, of Legacy Health, said we have heard an impassioned plea based on a large study to add another risk factor. He would like to make sure we keep the topic in proper perspective: home births are going to happen. We should do the best we can to ensure patient safety. He expressed a desire to be involved in continued discussions.

Multisector Intervention Topics

[Meeting materials](#) pages 206-208

Livingston reviewed the scoping statement of the following proposed two topics:

Community Health Worker (CHW): Engagement with a CHW for adults or children with at least one of the following: asthma, diabetes, hypertension, heart failure, HIV, serious mental illness, high utilizers

Multisector Interventions to Reduce the Frequency of Asthma Exacerbations: Case management programs, school-based interventions, home-based interventions, provider- or pharmacist- directed programs

MOTION: To approve Community Health Worker & Interventions to Reduce the Frequency of Asthma Exacerbations as new multisector intervention topics. Carries: 7-0. (Absent: Hodges, Williams, Sutton, Adler)

Priorities for Evidence-based Reports

[Meeting materials](#) pages 226-227

King said CEBP prefers not to start out-of-hospital birth in February, but to wait until a late date in 2019.

The other priorities were left to EbGS's discretion.

Public Comment

There was no further public comment at this time.

Adjournment

Meeting adjourned at 4:15 pm. Next meeting will be from 1:30-4:30 pm on Thursday January 17, 2019 at a location yet to be determined.

**Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on November 8, 2018**

For specific coding recommendations and guideline wording, please see the text of the 11/8/2018 VbBS minutes.

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

- Add the diagnosis codes used for latent tuberculosis infection to a covered line
- Add the procedure code for Yttrium-90 therapy to the covered liver cancer line with a new guideline
- Add the procedure codes for amniotic membrane transplant for eye conditions to three covered lines and removed from 3 other covered lines
- Add the 2019 CPT codes to various covered and uncovered lines on the Prioritized List with guideline note changes as needed to accommodate these codes
- Add the 2019 HCPCS codes to various covered and uncovered lines on the Prioritized List with changes to guidelines as required by placements
- Add the 2019 CDT codes to various covered and uncovered lines on the Prioritized List
- Add the procedure code for the iStent glaucoma surgery to a covered line with a new guideline

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- No change was made to the non-coverage of pancreas only transplant
- No change was made to the non-coverage of non-invasive prenatal screening for average risk women

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

- Modify the non-prenatal genetic testing guideline, and remove the hereditary cancer testing section to make into its own guideline
- Modify the prenatal genetic testing guideline
- Modify the guideline on human donor breast milk for high-risk infants

VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
November 8, 2018
8:30 AM – 1:30 PM

Members Present: Kevin Olson, MD, Chair; Susan Williams, MD (via phone); Mark Gibson; Holly Jo Hodges, MD; Vern Saboe, DC (via phone, left at 12:30); Gary Allen, DMD; Adriane Irwin, PharmD (via phone at 10:15, left at 1:30).

Members Absent: none

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

Also Attending: K. Renae Wentz, MD (Oregon Health Authority); Kevin Sasadeusz, MD (Providence interventional radiology); Ken Kolbech, MD (OHSU interventional radiology); Pippa Newell, MD (Providence hepatobiliary surgery, via phone); Devki Saraiya and Karen Heller (Myriad); Alice Austin (OR Assoc. of Behavior Analysis); Katy McDowell (Tonkin Torp).

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

The meeting was called to order at 8:30 am and roll was called. Minutes from the October 2018 VbBS meeting were reviewed and approved with the addition of a guideline note entry for CardioMEMS to guideline note 173 in the appendix of the minutes. **Approved 6-0, Irwin absent.**

Smits reviewed the two errata items. There was no discussion. Smits noted that the fusion for sacroiliac joint dysfunction discussion was tabled until January to allow the Washington HTA group to complete their evidence review.

Coffman noted that this was Williams last meeting, and she was thanked for her excellent service to the VbBS and HERC.

➤ **Topic: Straightforward/Consent Agenda**

Discussion: There was no discussion about the consent agenda item. The diabetes prevention program topic was discussed with the HCPCS code discussion later in the meeting (see topic below).

Recommended Actions:

- 1) Add ICD10 R76.11 (Nonspecific reaction to tuberculin skin test without active tuberculosis) and R76.12 (Nonspecific reaction to cell mediated immunity measurement of gamma interferon antigen response without active tuberculosis) to line 50 PULMONARY TUBERCULOSIS

MOTION: To approve the recommendation stated in the consent agenda. **CARRIES 6-0** (*Absent: Irwin*)

➤ **Topic: Yttrium 90 therapy for limited circumstances in hepatocellular carcinoma (HCC)**

Discussion: Smits reviewed the summary document and the staff proposed changes.

Expert testimony was heard from Kevin Sasadeusz, MD (Providence interventional radiology); Ken Kolbech, MD (OHSU interventional radiology); and Pippa Newell, MD (Providence hepatobiliary surgery, via phone).

Sasadeusz critiqued the SARAH trial. He noted that that trial used a different form of Y90 than what is used in the US. Another critique of the SARAH study was that the patient selection not what the OHSU and Providence oncology groups consider appropriate (for example, some had main portal vein thrombosis, which is a contraindication). Additionally, many patients had already had locoregional therapy and so this selected patients who were radiation resistant. Physicians in SARAH trial may also not have been experienced in use of Y90. Newell noted that a large percent of patients in SARAH did not receive the treatment they were randomized to receive. Kolbech noted that this trial, like many other Y90 trials, was industry driven.

Sasadeusz stated that in using Y90 at Providence, patients are reviewed by a multidisciplinary group to see if they are appropriate for Y90. The Providence group does the best to try to keep cost down for Y90. Kolbech showed the OHSU HCC treatment algorithm, which is very similar to the algorithm from Providence in the meeting materials.

There was a question about whether main portal vein thrombosis was different than unilateral portal vein thrombosis. It was explained that unilateral portal vein thrombosis involves only one branch of the portal vein and is not a contraindication to Y90, while main portal vein thrombosis is a contraindication. The VbBS group decided to add wording to the proposed guideline to clarify this distinction.

It was noted that liver transplant for liver cancer is on line 560 CANCER OF LIVER AND INTRAHEPATIC BILE DUCTS. Based on this, the VbBS group discussed taking out #1 as criteria in the proposed guideline (use of Y90 to keep a patient on the transplant list). It was further noted that cirrhosis is covered on line 307 for liver transplant, so most patients with HCC would be eligible for liver transplant as they also have cirrhosis. Newell requested consideration for reprioritization of line 560, which will be done as a possible future biennial review topic. She noted that such a review should wait until January 2019, as new guidelines are coming out for liver transplant recommendations in HCC.

Discussion then turned to the second proposed criteria (downsizing of patients who would be eligible for definitive treatment including liver transplant). Newell stated that the more common curative treatment offered to patients is ablation. Patients need to have their tumor downsized to less than 3 cm to be eligible for ablation or resection. Kolbech noted that OHSU is the only liver transplant provider in Oregon. It is a long, complex process to get on the liver transplant list. He did not advise keeping proposed criteria #1 (see above); but he felt proposed criteria #2 should be kept.

There was discussion that >90% of patients in Oregon are treated with Y90 by OHSU or Providence. Gibson asked if there was a registry of these patients to follow outcomes. Newell noted that a large,

multicenter registry trial was currently underway. Kolbech noted that OHSU has a database for all their Y90 patients and uses the data for internal quality review. There was discussion about whether low volume providers should be allowed to use Y90. The experts felt that it was appropriate if done on the recommendation of a multidisciplinary team. VbBS members decided to add wording requiring that patients need an evaluation by a multidisciplinary team or tumor board prior to coverage of Y90 therapy. Kolbech noted that non-OHSU/Providence providers can submit patients to the OHSU tumor board for reviewed if desired.

Recommended Actions:

- 1) Remove CPT 79440 (Radiopharmaceutical therapy, by intra-articular administration) from all current lines except
 - a. 201 CANCER OF BONES
 - b. 400 BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS
 - c. 556 BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE INCLUDING OSTEOID OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE
- 2) Add Yttrium 90 therapy to line 315 CANCER OF LIVER
 - a. CPT 79445 (Radiopharmaceutical therapy, by intra-arterial particulate administration for use in treating primary hepatocellular carcinoma or colorectal cancer metastatic to the liver)
 - b. HCPCS C2616 (Brachytherapy source, non-stranded, yttrium-90, per source, for use in treating primary liver cancer or metastatic cancer to the liver)
 - c. HCPCS S2095 (Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres, for use in treating primary liver cancer or metastatic cancer to the liver)
- 3) Remove the entry regarding Yttrium 90 from line 500/GN172 as shown in Appendix A
- 4) Add a new guideline to line 315 CANCER OF LIVER as shown in Appendix B

MOTION: To recommend the code and guideline note changes as modified. CARRIES 6-0. (Absent: Irwin)

➤ **Topic: Pancreas only transplant**

Discussion: Livingston reviewed the summary document. Coffman highlighted that the question was about transplanting the pancreas earlier rather than waiting until renal failure had occurred. Members discussed that pancreas transplant is a major surgery and the study showing increased risk of renal failure associated with pancreas transplant alone is concerning. Members discussed that there was insufficient evidence to support benefit and there are significant harms. Olson said if pancreas transplant was a home run then it may be worth it, but the evidence does not show pancreas transplant alone is effective. Allen asked about Medicare coverage for pancreas transplant alone. Livingston said it was covered but clarified that there was insufficient evidence supporting improved outcomes for the patients identified in those coverage guidelines.

Recommended Actions:

- 1) Make no change to the noncoverage of pancreas transplant alone

➤ **Topic: Amniotic membrane transplant for ocular conditions**

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

Recommended Actions:

- 1) Remove ocular amniotic membrane transplant CPT codes [65778 (Placement of amniotic membrane on the ocular surface; without sutures), 65779 (Placement of amniotic membrane on the ocular surface; single layer, sutured), 65780 (Ocular surface reconstruction; amniotic membrane transplantation, multiple layers)] from the following lines:
 - a. 56 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE
 - b. 159 TOXIC EPIDERMAL NECROLYSIS AND STAPHYLOCOCCAL SCALDED SKIN SYNDROME; STEVENS-JOHNSON SYNDROME; ERYTHEMA MULTIFORME MAJOR; ECZEMA HERPETICUM
 - c. 213 BULLOUS DERMATOSES OF THE SKIN
- 2) Add ocular amniotic membrane transplant CPT codes (same as above) to the following lines:
 - a. 113 CANCER OF EYE AND ORBIT
 - b. 470 KERATOCONJUNCTIVITIS
 - c. 493 ECTROPION AND BENIGN NEOPLASM OF EYE

MOTION: To recommend the code changes as presented. **CARRIES 6-0.** (*Absent: Irwin*)

➤ **Topic: 2019 CPT code review**

Discussion: Smits reviewed the multiple summary documents and spreadsheets comprising the 2019 CPT code review. There was no discussion regarding the proposed placements of the straightforward, applied behavior analysis (ABA), or psychology testing codes.

There was specific discussion about the following CPT codes:

- 1) 76391 (Magnetic resonance (eg, vibration) elastography)
 - a. Wentz suggested adding this code to line 500 with exception criteria rather than to line 199 CHRONIC HEPATITIS; VIRAL HEPATITIS as it is less cost effective than non-MR elastography. Hodges felt that it was better to follow the staff recommendation and place on line 199 and allow the CCOs to PA the test. Gingerich noted that MR elastography was added to the hepatitis C guideline for obese patients and other patients for whom the more cost-effective tests to not work, a decision that was based on expert testimony. The decision was to add to line 199. It was noted that the hepatitis C guideline would need revisions if the MR elastography code was added to line 500.

Alice Austin, Public Policy Chair of the Oregon Association of Behavior Analysis, testified in favor of the ABA code placements.

There was a question about whether the coverage guidance on molecular biomarkers should be updated based on the decisions regarding the new oncology CPT codes. Olson felt that things were moving to panels of genes for oncology. There is also the question about covering the genetic test or

the medications for treatment of a cancer found to have a genetic mutation not initially studied for that cancer. Gingerich noted that next generation sequencing has been tabled by HTAS as a topic.

Recommended Actions:

- 1) The 2019 CPT codes were placed as shown in Appendix C
- 2) Various guidelines were modified as shown in Appendix A

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

➤ **Topic: 2019 HCPCS code review**

Discussion: Smits reviewed the summary documents. There was no substantial discussion of any of the HCPCS code placement at the VBBS meeting.

Note: The 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) was changed at the subsequent HERC meeting on November 8, 2018. The revised placement is shown in Appendix D with the revision required to Guideline Note 173 shown in Appendix A. The VBBS decision was to recommend placement on lines 9,124,223,313,531,550,559, 566. The revised decision was to place on line 660 due to a recent MED report showing that evidence did not support home administration of immunotherapy because of concerns for anaphylaxis. HERC staff was directed to obtain the MED report and bring to the January meeting if the staff recommendation would be placement other than on line 660. See the HERC minutes for details.

Recommended Actions:

- 1) 2019 HCPCS code placement as shown in Appendix D
- 2) Guideline 173 entries as shown in Appendix A

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

➤ **Topic: Oral Health Advisory Panel report**

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

Recommended Actions:

- 1) The 2019 CDT codes were placed as shown in Appendix E

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

➤ **Topic: Genetic Advisory Panel (GAP) report – 2019 CPT code placement**

Discussion: Smits reviewed the various summary documents comprising the GAP report. There was no discussion regarding the recommended placement of the 2019 genetic CPT codes other than CPT 81443.

CPT 81443 (expanded carrier screening) was discussed in detail. Hodges was concerned about coverage for partners. The partner only needs to be tested for the few genes mom is positive for. Smits noted that a few gene tests may be more expensive than the panel, so just testing the few genes found in mom's test might be more expensive.

There was general concern about how to interpret the results. The VBBS members felt that the interpretation would be difficult for most maternity care providers, and that patients should have genetic counseling with this test, which is a limited resource. There was discussion about unintended harm of too much genetic information being given to patients with an unclear idea of how to deal with this information. There was concern over interventions that might be done that might not be needed, or additional testing done that might not be needed. Medicaid is a vulnerable population and needs protections in place.

There was also concern about how to control the quality of what genes are in the panel, to ensure that all include genes recommended by ACOG guidelines.

There was discussion that if VBBS/HERC chose not to cover panel testing, then CCOs could still cover it if they chose to do so. There was also discussion that if VBBS/HERC adopted coverage, that providers would not have to order the test if they did not feel comfortable interpreting the results.

Public testimony:

Devki Saraiya, Myriad Labs, testified that current OHP coverage for carrier screening is by ethnicity-based screening. Ethnicity-based screening finds only 53% of patients at risk for having a child with a condition vs expanded carrier screening approaches. ACOG has guidelines on when tests are included, and labs offering this type of test are following ACOG guidelines. Ethnicity screening is difficult to determine when appropriate for a patient. Labs offer genetic counseling to help to determine when a partner needs to be tested. Variants of uncertain significance are not reported by Myriad in the carrier screening testing. CPT is specific for carrier screening, so if mom is not affected but is a carrier, then the partner then needs to be tested; if he is a carrier, then pregnancy has a 25% chance of being affected. This is about pregnancy/preconception decision making. This type of testing might lead to need for prenatal diagnostic testing. Myriad tries to make genetic counseling available to patients and/or providers to help with interpretation. Wentz: "How does the provider know what information was given to the patient by Myriad?" Surai: "We try to send documentation to the provider when the patient allows us to do so."

Olson noted that providers included in the current guideline know how to counsel folks and so are more comfortable with these tests. Hodges noted that this type of testing involved a long sequence: test mom, then need to test dad, then possibly test pregnancy. This sequence takes time, requires follow up. She expressed concern for timing of such testing during pregnancy (late gestation testing has few options for treatment). Hodges was also concerned about adequate shared decision making without genetic counseling. Smits asked whether this concern could be addressed with an entry in the prenatal genetic testing guideline about requiring genetic counseling.

Saraiya noted that OHP is already doing cystic fibrosis and spinal muscular atrophy testing for everyone. This expanded carrier testing adds more autosomal recessive genes that typically don't have a family history. She reported that there is a study on clinical utility showing that 37% of couples who tested positive for both being carriers went on to have prenatal diagnostic testing such as amniocentesis. Therefore, this information is being used for pregnancy decisions.

Hodges noted that her CCO initially had a large demand from providers for expanded carrier screening, but that she found no push back from providers once she explained the lack of coverage for such a test by her CCO. She noted the initial push back came from providers that are being told that this is standard of care.

Gibson noted that ACOG is not evidence-based much of the time. There was discussion that expanded carrier screening was not appropriate to be ordered for every pregnancy. The group struggled with how to put reasonable guidance on who should get this test. There was discussion of not covering expanded carrier screening until the OB community brings this to HERC with a request for coverage and explains who really needs the testing and what to do with the data. Irwin wanted to hear from providers who order this test. It was noted that Dr. Adler, an OB/Gyn, would be at the later HERC meeting and could give input.

The decision on expanded carrier screening was to put the CPT code on line 660 with a GN173 entry and leave prenatal guideline entries expressly stating this test is not covered. The HERC should revisit expanded carrier screening in the future to see if this testing should be covered with GN changes if brought forward by OB/maternity care community.

Recommended Actions:

- 1) The 2019 genetics CPT codes were placed as shown in Appendix C
- 2) GN173 was modified as shown in Appendix A

MOTION: To recommend the code and guideline note changes as modified. CARRIES 6-0. (Absent: Saboe)

➤ **Topic: Genetic Advisory Panel (GAP) report – Changes to the non-prenatal genetic testing guideline**

Discussion: Smits reviewed the various summary documents comprising the GAP report. There was minimal discussion about the changes to the non-prenatal genetic testing guideline, apart from clarification that the hereditary cancer testing section was being removed in order to create a separate guideline note.

The proposed new hereditary cancer guideline note focused on the suggested removal of the definition of “suitably trained” providers doing genetic counseling. Hodges noted that the CCO medical directors were opposed to this change. The medical directors felt that there was a need to define who was adequately trained. A provider who does not have the outlined qualifications but convinces a medical director that they are indeed adequately trained can be allowed to do genetic counseling at a CCO's discretion.

Public testimony was heard from Karen Haller from Myriad Genetics. She discussed that the issue of access to genetic counseling is real and is discussed at GAP every year. There is a lack of providers in Oregon and in the US in general. NCCN delineates criteria for testing in these hereditary cases. NCCN and USPSTF do not state that genetic counselors need to see every patient, and list other types of providers equipped to give this type of counseling. This information is being used more and more frequently in care—screening changes, treatment changes, etc. Providers cannot adequately manage patients without this information. Multiple specialty societies have stated that this type of counseling is within the scope of their specialty.

Hodges noted that this section of the new hereditary cancer guideline is about elective testing of asymptomatic patients. Such testing is not time sensitive and can wait for genetic counseling. Olson also expressed concern that variants of uncertain significance is important factor in this situation.

The decision was made to not delete the definition of “suitably trained.”

The next discussion centered on the proposed change regarding wording for panel testing for hereditary cancers. The group wanted only NCCN guidelines mentioned (not “or other expert” guidelines).

Recommended Actions:

- 1) Modifications to the non-prenatal genetic testing guideline as shown in Appendix A
- 2) Creation of a new hereditary cancer testing guideline as shown in Appendix B
 - a. *Note: strikethrough and underlined language in the new guideline note reflects modifications from the wording as it originally appeared in the non-prenatal genetic testing guideline.*

MOTION: To recommend the guideline note changes as modified. CARRIES 6-0. (Absent: Saboe)

➤ **Topic: Genetic Advisory Panel (GAP) report – Changes to the prenatal genetic testing guideline**

Discussion: Smits reviewed the various summary documents comprising the GAP report. There was minimal discussion of the proposed changes to the prenatal genetic testing guideline other than non-invasive prenatal screening.

Non-invasive prenatal screening (NIPS) discussion:

Devki Sariaya, Myriad, testified that all guidelines say that using NIPS in the general population is appropriate, including ACOG. BCBS TEC report was redone in 2018 and found sufficient evidence that NIPS used in a general risk population improved health outcomes. She noted that any screening test performs less well in low-risk population because prevalence of the conditions being screened for are lower in this population. NIPS provides a 100-fold lower false positive rate, reduces rates of amniocentesis or CVS and avoids the cost and complications of these procedures. Evidence supports that it is a superior test to serum tests. Requested that coverage be extended to average risk population.

The VBBS members felt that NIPS should be reserved for high-risk women. If ACOG comes out with a guideline expressly recommending this test for all-risk women, then this coverage can be revisited.

Recommended Actions:

- 1) Modify the prenatal genetic testing guideline as shown in Appendix A
- 2) Make no changes to the lack of coverage for low-risk women for non-invasive prenatal screening

MOTION: To recommend the guideline note changes as modified. CARRIES 5-0. (Absent: Saboe, Irwin)

➤ **Topic: iStent and cataract removal**

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

Recommended Actions:

- 3) Add CPT 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork) to line 139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE
- 4) Add a new guideline note to line 139 as shown in Appendix B

MOTION: To recommend the code and guideline note changes as presented. CARRIES 5-0. (Absent: Saboe, Irwin)

➤ **Topic: Human donor breast milk indications**

Discussion: Livingston reviewed the summary document and highlighted limitations of the evidence. Wentz discussed that recurrent necrotizing enterocolitis can occur and so ongoing donor breast milk is important, although this may be primarily in hospitalized infants. Livingston clarified that this guideline only applies to infants who have been discharged from the hospital and spoke about the rationale for the modified language which would require ongoing medical need for human donor breast milk.

Recommended Actions:

- 1) Revise the Guideline Note on Human Donor Breast Milk for High Risk Infants as shown in Appendix A.
- 2) Delay implementation until October 1, 2019 because a State Plan Amendment (SPA) is necessary. *[Note: After further review, staff found a SPA is not necessary and implementation can occur 1/1/19.]*

MOTION: To recommend the code and guideline note changes as presented. CARRIES 5-0. (Absent: Saboe, Irwin)

➤ **Public Comment:**

No additional public comment was received.

- **Issues for next meeting:**
 - HERC staff will obtain the MED report on home immunotherapy administration for the VBBS/HERC information

- **Next meeting:**

January 17, 2019, at a location TBD.

- **Adjournment:**

The meeting adjourned at 1:50 PM.

DRAFT

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DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE

- A) Genetic tests are covered as diagnostic, unless they are listed below in section FE1 as excluded or have other restrictions listed in this guideline. To be covered, initial screening (e.g. physical exam, medical history, family history, laboratory studies, imaging studies) must indicate that the chance of genetic abnormality is > 10% and results would do at least one of the following:
- 1) Change treatment,
 - 2) Change health monitoring,
 - 3) Provide prognosis, or
 - 4) Provide information needed for genetic counseling for patient; or patient's parents, siblings, or children
- B) Pretest and posttest genetic counseling is required for presymptomatic and predisposition genetic testing. Pretest and posttest genetic evaluation (which includes genetic counseling) is covered when provided by a suitable trained health professional with expertise and experience in genetics.
- 1) "Suitably trained" is defined as board certified or active candidate status from the American Board of Medical Genetics, American Board of Genetic Counseling, or Genetic Nursing Credentialing Commission.
- C) A more expensive genetic test (generally one with a wider scope or more detailed testing) is not covered if a cheaper (smaller scope) test is available and has, in this clinical context, a substantially similar sensitivity. For example, do not cover CFTR gene sequencing as the first test in a person of Northern European Caucasian ancestry because the gene panels are less expensive and provide substantially similar sensitivity in that context.
- ~~D) Related to genetic testing for patients with breast/ovarian and colon/endometrial cancer or other related cancers suspected to be hereditary, or patients at increased risk to due to family history.~~
- ~~1) Services are provided according to the Comprehensive Cancer Network Guidelines.~~
 - ~~a) Lynch syndrome (hereditary colorectal, endometrial and other cancers associated with Lynch syndrome) services (CPT 81288, 81292-81300, 81317-81319, 81435, 81436) and familial adenomatous polyposis (FAP) services (CPT 81201-81203) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Colorectal V1.2018 (7/12/18) V3.2017 (10/10/17). www.nccn.org.~~
 - ~~b) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81211-81217, 81212, 81215-81217) for women without a personal history of breast, ovarian and other associated cancers should be provided to high risk women as defined by the US Preventive Services Task Force or according to the NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast and ovarian. V2.2019 (7/30/18) V1.2018 (10/3/17). www.nccn.org.~~
 - ~~c) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81211-81217, 81212, 81215-81217) for women with a personal history of breast, ovarian, and other associated cancers and for men with breast cancer should be provided according to the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovarian. V2.2019 (7/30/18) V1.2018 (10/3/17). www.nccn.org.~~
 - ~~d) PTEN (Cowden syndrome) services (CPT 81321-81323) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Colorectal Screening. V1.2018 (7/12/18) V3.2017 (10/10/17). www.nccn.org.~~

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- ~~2) Genetic counseling should precede genetic testing for hereditary cancer whenever possible.~~
 - ~~a) Pre and post test genetic counseling should be covered when provided by a suitable trained health professional with expertise and experience in cancer genetics. Genetic counseling is recommended for cancer survivors when test results would affect cancer screening.~~
 - ~~i) "Suitably trained" is defined as board certified or active candidate status from the American Board of Medical Genetics, American Board of Genetic Counseling, or Genetic Nursing Credentialing Commission.~~
 - ~~b) If timely pre-test genetic counseling is not possible for time-sensitive cases, appropriate genetic testing accompanied by pre- and post-test informed consent and post-test disclosure performed by a board-certified physician with experience in cancer genetics should be covered.~~
 - ~~i) Post-test genetic counseling should be performed as soon as is practical.~~
 - ~~3) If the mutation in the family is known, only the test for that mutation is covered. For example, if a mutation for BRCA 1 has been identified in a family, a single site mutation analysis for that mutation is covered (CPT 81215), while a full sequence BRCA 1 and 2 (CPT 81211 ~~81163~~) analyses is not. There is one exception, for individuals of Ashkenazi Jewish ancestry with a known mutation in the family, the panel for Ashkenazi Jewish BRCA mutations is covered (CPT 81212).~~
 - ~~4) Costs for rush genetic testing for hereditary breast/ovarian and colon/endometrial cancer is not covered.~~
 - ~~5) Hereditary breast cancer related disorders genomic sequence analysis panels (CPT 81432, 81433, 81479) are only included if the panel test~~
 - ~~a) Includes at least 5 genes that the NCCN Clinical Practice Guidelines in Oncology—Genetic/Familial High-Risk Assessment: Colorectal V1.2018 (7/12/18) V3.2017 (10/10/17). and/or NCCN Clinical Practice Guidelines in Oncology—Genetic/Familial High-Risk Assessment: Breast and Ovarian V2.2019 (7/30/18) V1.2018 (10/3/17) include(s) with specific guidance on clinical management; and,~~
 - ~~b) Includes no more than a reasonable number of genes (e.g. 40 genes total).~~

D) Related to diagnostic evaluation of individuals with intellectual disability (defined as a full scale or verbal IQ < 70 in an individual > age 5), developmental delay (defined as a cognitive index < 70 on a standardized test appropriate for children < 5 years of age), Autism Spectrum Disorder, or multiple congenital anomalies:

 - 1) CPT 81228, Cytogenomic constitutional microarray analysis for copy number variants for chromosomal abnormalities: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder.
 - 2) CPT 81229, Cytogenomic constitutional microarray analysis for copy number variants for chromosomal abnormalities; plus cytogenetic constitutional microarray analysis for single nucleotide polymorphism (SNP) variants for chromosomal abnormalities: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to

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- diagnose Autism Spectrum Disorder; only if (a) consanguinity and recessive disease is suspected, or (b) uniparental disomy is suspected, or (c) another mechanism is suspected that is not detected by the copy number variant test alone.
- 3) CPT 81243, 81244, [81171](#), [81172](#), Fragile X genetic testing is covered for individuals with intellectual disability/developmental delay. Although the yield of Fragile X is 3.5-10%, this is included because of additional reproductive implications.
 - 4) A visit with the appropriate specialist (often genetics, developmental pediatrics, or child neurology), including physical exam, medical history, and family history is covered. Physical exam, medical history, and family history by the appropriate specialist, prior to any genetic testing is often the most cost-effective strategy and is encouraged.
- E) Related to other tests with specific CPT codes:
- 1) Certain genetic tests have not been found to have proven clinical benefit. These tests are listed in Guideline Note 173, INTERVENTIONS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS; UNPROVEN INTERVENTIONS
 - 2) The following tests are covered only if they meet the criteria in section A above AND the specified situations:
 - a) CPT 81205, BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, Maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X): Cover only when the newborn screening test is abnormal and serum amino acids are normal
 - b) Diagnostic testing for cystic fibrosis (CF)
 - i) CFTR, cystic fibrosis transmembrane conductance regulator tests. CPT 81220, 81222, 81223: For infants with a positive newborn screen for cystic fibrosis or who are symptomatic for cystic fibrosis, or for clients that have previously been diagnosed with cystic fibrosis but have not had genetic testing, CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered. If two mutations are not identified, CFTR full gene sequencing (CPT 81223) is covered. If two mutations are still not identified, duplication/deletion testing (CPT 81222) is covered. These tests may be ordered as reflex testing on the same specimen.
 - c) Carrier testing for cystic fibrosis
 - i) CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered once in a lifetime.
 - d) CPT 81224, CFTR (cystic fibrosis transmembrane conductance regulator) (eg. cystic fibrosis) gene analysis; intron 8 poly-T analysis (eg. male infertility): Covered only after genetic counseling.
 - e) CPT 81240. F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant: Factor 2 20210G>A testing should not be covered for adults with idiopathic venous thromboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.

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- f) CPT 81241. F5 (coagulation Factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant: Factor V Leiden testing should not be covered for: adults with idiopathic venous thromboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.
- g) CPT 81247. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; common variant(s) (eg, A, A-) should only be covered
 - i) After G6PD enzyme activity testing is done and found to be normal; AND either
 - (a) There is an urgent clinical reason to know if a deficiency is present, e.g. in a case of acute hemolysis; OR
 - (b) In situations where the enzyme activity could be unreliable, e.g. female carrier with extreme Lyonization.
- h) CPT 81248. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; known familial variant(s) is only covered when the information is required for genetic counseling.
- i) CPT 81249. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; full gene sequence is only covered
 - i) after G6PD enzyme activity has been tested, and
 - ii) the requirements under CPT 81247 above have been met, and
 - iii) common variants (CPT 81247) have been tested for and not found.
- j) CPT 81256, HFE (hemochromatosis) (eg, hereditary hemochromatosis) gene analysis, common variants (eg, C282Y, H63D): Covered for diagnostic testing of patients with elevated transferrin saturation or ferritin levels. Covered for predictive testing ONLY when a first degree family member has treatable iron overload from HFE.
- k) CPT 81221, SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (eg, alpha-1-antitrypsin deficiency), gene analysis, common variants (eg, *S and *Z): The alpha-1-antitrypsin protein level should be the first line test for a suspected diagnosis of AAT deficiency in symptomatic individuals with unexplained liver disease or obstructive lung disease that is not asthma or in a middle age individual with unexplained dyspnea. Genetic testing of the alpha-1 phenotype test is appropriate if the protein test is abnormal or borderline. The genetic test is appropriate for siblings of people with AAT deficiency regardless of the AAT protein test results.
- l) [CPT 81329, Screening for spinal muscular atrophy: is covered once in a lifetime for preconception testing or testing of the male partner of a pregnant female carrier](#)
- m) CPT 81415-81416, exome testing: A genetic counseling/geneticist consultation is required prior to ordering test
- n) CPT 81430-81431, Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel: Testing for mutations in GJB2 and GJB6 need to be done first and be negative in non-syndromic patients prior to panel testing.
- o) CPT 81440, 81460, 81465, mitochondrial genome testing: A genetic counseling/geneticist or metabolic consultation is required prior to ordering test.
- p) CPT 81412 Ashkenazi Jewish carrier testing panel: panel testing is only covered when the panel would replace and would be similar or lower cost than individual gene testing including CF carrier testing.

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* American College of Medical Genetics Standards and Guidelines for Clinical Genetics Laboratories. 2008 Edition, Revised ~~3/2011~~ 7/2018 and found at <https://www.acmg.net/StaticContent/SGs/CFTR%20Mutation%20Testing.pdf>.
<http://www.acmg.net/PDFLibrary/Cystic-Fibrosis-Population-Based-Carrier-Screening-Standards.pdf>

DIAGNOSTIC GUIDELINE D2, IMPLANTABLE CARDIAC LOOP RECORDERS/SUBCUTANEOUS CARDIAC RHYTHM MONITORS

Use of an implantable cardiac loop recorder (ICLR)/subcutaneous cardiac rhythm monitor is a covered service only when the patient meets all of the following criteria:

- 1) The evaluation is for recurrent transient loss of consciousness (TLoC); and
- 2) A comprehensive evaluation including 30 days of noninvasive ambulatory cardiac monitoring did not demonstrate a cause of the TLoC; and
- 3) A cardiac arrhythmia is suspected to be the cause of the TLoC; and
- 4) There is a likely recurrence of the TLoC within the battery longevity of the device.

ICLRs and subcutaneous cardiac rhythm monitors are not a covered service for evaluation of cryptogenic stroke or any other indication.

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

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, 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.

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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DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

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

- A) Genetic counseling (CPT 96040, HPCPS S0265) for high risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect.
- B) Genetic counseling (CPT 96040, HPCPS S0265) prior to consideration of chorionic villus sampling (CVS), amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening
- C) Validated questionnaire to assess genetic risk in all pregnant women
- D) Screening high risk ethnic groups for hemoglobinopathies (CPT 83020, 83021)
- E) Screening for aneuploidy with any of five screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, and contingency] (CPT 76813, 76814, 81508-81511, [81512](#), [82105](#), [82677](#))
- F) Cell free fetal DNA testing (CPT 81420, 81507) for evaluation of aneuploidy in women who have an elevated risk of a fetus with aneuploidy (maternal age >34, family history or elevated risk based on screening).
- G) Ultrasound for structural anomalies between 18 and 20 weeks gestation (CPT 76811, 76812)
- H) CVS or amniocentesis (CPT 59000, 59015, [76945](#), [76946](#), 82106, 88235, [88261-88264](#), 88267, 88269, 88280, [88283](#), 88285, [88289](#), [88291](#)) for a positive aneuploidy screen, maternal age >34, fetal structural anomalies, family history of inheritable chromosomal disorder or elevated risk of neural tube defect.
- I) Array CGH (CPT 81228, 81229) when major fetal congenital anomalies are apparent on imaging, or with normal imaging when array CGH would replace karyotyping performed with CVS or amniocentesis in #8 above.
- J) FISH testing (CPT 88271, [88272](#), [88274](#), 88275) only if karyotyping is not possible due a need for rapid turnaround for reasons of reproductive decision-making (i.e. at 22w4d gestation or beyond)
- K) Screening for Tay-Sachs carrier status (CPT 81255) in high risk populations. First step is hex A, and then additional DNA analysis in individuals with ambiguous Hex A test results, suspected variant form of TSD or suspected pseudodeficiency of Hex A
- L) Screening for cystic fibrosis carrier status once in a lifetime (CPT 81220-81224)
- M) Screening for fragile X status (CPT 81243, 81244, [81171](#), [81172](#)) in patients with a personal or family history of
 - a. fragile X tremor/ataxia syndrome
 - b. premature ovarian failure
 - c. unexplained early onset intellectual disability
 - d. fragile X intellectual disability
 - e. unexplained autism through the pregnant woman's maternal line
- N) Screening for spinal muscular atrophy (CPT ~~81401~~ [81329](#)) once in a lifetime
- O) Screening those with Ashkenazi Jewish heritage for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255). Ashkenazi Jewish carrier panel testing (CPT 81412) is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing.
- P) Expanded carrier screening only for those genetic conditions identified above

The following genetic screening tests are not covered:

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- A) Serum triple screen
- B) Screening for thrombophilia in the general population or for recurrent pregnancy loss
- C) Expanded carrier screening which includes results for conditions not explicitly recommended for coverage

The development of this guideline note was informed by a HERC [coverage guidance](https://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx). See <https://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx>.

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 $\geq F2$ 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 $\geq F3$ 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 $\geq F2$ or $\geq F3$ only when at least one imaging test (FibroScan, ARFI, and SWE) has resulted in indeterminate results, a second one is similarly indeterminate, 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](https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx). See <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx>.

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GUIDELINE NOTE 148, BIOMARKER TESTS OF CANCER TISSUE

Lines 157,184,191,230,263,271,329

The use of tissue of origin testing (e.g. CPT 81504) is included on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

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

- Oncotype DX Breast Recurrence Score (CPT 81519) for breast tumors that are estrogen receptor positive, HER2 negative, and either lymph node negative, or lymph node positive with 1-3 involved nodes.
- EndoPredict (using CPT 81599) and Prosigna (CPT 81520 or PLA 0008M) for breast tumors that are estrogen receptor positive, HER2 negative, and lymph node negative.
- MammaPrint (using CPT 81521 or HCPCS S3854) for breast tumors that are estrogen receptor or progesterone receptor positive, HER2 negative, lymph node negative, and only in those cases categorized as high clinical risk.

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

Oncotype DX Breast DCIS Score (CPT 81479) and Breast Cancer Index ([CPT 81518](#) ~~may use CPT 81479, 81599, 84999, S3854~~) are included on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

For melanoma, BRAF gene mutation testing (CPT 81210) is included on Line 230.

For lung cancer, epidermal growth factor receptor (EGFR) gene mutation testing (CPT 81235) is included on Line 263 only for non-small cell lung cancer. KRAS gene mutation testing (CPT 81275) is not included on this line.

For colorectal cancer, KRAS gene mutation testing (CPT 81275) is included on Line 157. BRAF (CPT 81210) and Oncotype DX are not included on this line. Microsatellite instability (MSI) is included on the Line 660.

For bladder cancer, Urovysion testing is included on Line 660.

For prostate cancer, Oncotype DX Genomic Prostate Score, Prolaris Score Assay, and Decipher Prostate RP are included on Line 660.

The development of this guideline note was informed by a HERC coverage guidance on [Biomarkers Tests of Cancer Tissue for Prognosis and Potential Response to Treatment](#); the prostate-related portion of that

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coverage guidance was superseded by a [Coverage Guidance on Gene Expression Profiling for Prostate Cancer](https://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx). See <https://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx>.

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:

79445	Radiopharmaceutical therapy, by intra-arterial particulate administration for use in treating primary hepatocellular carcinoma or colorectal cancer metastatic to the liver	Low-cost-effectiveness compared to equally effective but less-expensive standard chemotherapies; concern for possible harms compared to standard chemotherapy	<u>May, 2018</u>
C2616	Brachytherapy source, non-stranded, yttrium-90, per source, for use in treating primary liver cancer or metastatic cancer to the liver		
S2095	Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres, for use in treating primary liver cancer or metastatic cancer to the liver		

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
C8937	Computer aided detection of breast MRI	Insufficient evidence of effectiveness	November, 2018

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C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy	Insufficient evidence of effectiveness	November, 2018
C9754 C9755	Percutaneous arteriovenous fistula formation	Insufficient evidence of benefit	November, 2018
G0069	Subcutaneous immunotherapy in the home	Insufficient evidence of effectiveness; evidence of harm	November, 2018
33274 33275	Leadless cardiac pacemakers	Insufficient evidence of effectiveness; evidence of harm	November, 2018
33289, 93264 C2624, C9741	CardioMEMS™ – Implantable wireless pulmonary artery pressure monitor for heart failure monitoring	Insufficient evidence of effectiveness	October, 2018 Coverage guidance
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor	Insufficient evidence of effectiveness	November, 2018
64635-64636 C9752 C9753	Radiofrequency ablation of the lumbar and sacral spine	Insufficient evidence of benefit	November, 2014 Coverage Guidance Blog
76978 76979	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac)	Insufficient evidence of effectiveness	November, 2018
81237	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, diffuse large B-cell lymphoma) gene analysis, common variant(s) (eg, codon 646)	Insufficient evidence of effectiveness	November, 2018
81306	NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis	Insufficient evidence of effectiveness	November, 2018
81320	PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)	Insufficient evidence of effectiveness	November, 2018
81345	TERT (telomerase reverse transcriptase) (eg, thyroid	Insufficient evidence of effectiveness	November, 2018

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	carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)		
81443	Expanded carrier screening	Insufficient evidence of effectiveness	November, 2018
81518	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy	Insufficient evidence of effectiveness	November, 2018 Coverage Guidance May, 2018
Breast Cancer Gene Expression tests billed with nonspecific codes (e.g. 81479, 81599, 84999, S3854)	<ul style="list-style-type: none"> • Mammostrat • Oncotype DX Breast DCIS Score • Breast Cancer Index • IHC4 	Unproven intervention	May 2018 Coverage Guidance Blog
83722	Lipoprotein, direct measurement; small dense LDL cholesterol	Insufficient evidence of effectiveness	November, 2018
96116 96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities)		November, 2018

GUIDELINE NOTE XXX [HUMAN](#) DONOR BREAST MILK FOR HIGH RISK INFANTS

Line ~~2~~, 16, ~~18~~, 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](#)

Appendix A Revised Guideline Notes

- [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.

DRAFT

Appendix B New Guideline Notes

GUIDELINE NOTE 184 ANTERIOR SEGMENT AQUEOUS DRAINAGE DEVICE INSERTION

Line 139

Anterior segment aqueous drainage device (e.g. iStent©) insertion is only included on this line when done at the same time as cataract removal and when the two procedures are billed together as a bundled service.

GUIDELINE NOTE 185, YTTRIUM 90 THERAPY

Line 315

Yttrium 90 therapy is only included on this line for treatment of hepatocellular carcinoma (HCC) and only when recommended by a multidisciplinary tumor board or team in the following circumstances:

- 1) Downsizing tumors in patients who could become eligible for curative treatment (transplant, ablation, or resection), OR
- 2) Palliative treatment of incurable patients with unresectable or inoperable tumors that are not amenable to ablation therapy and
 - a. who have good liver function (Child-Pugh class A or B) and
 - b. good performance status (ECOG performance status 0-2), and
 - c. who have intermediate stage disease with tumors > 5 cm OR advanced stage HCC with unilateral (not main) portal vein tumor thrombus.

Note: strikethrough and underlined language for new diagnostic guideline D25 reflects modifications from the wording as it originally appeared in the non-prenatal genetic testing guideline

DIAGNOSTIC GUIDELINE D25, HEREDITARY CANCER GENETIC TESTING

- A) Related to genetic testing for patients with breast/ovarian and colon/endometrial cancer or other related cancers suspected to be hereditary, or patients at increased risk to due to family history.
 - 1) Services are provided according to the Comprehensive Cancer Network Guidelines.
 - a) Lynch syndrome (hereditary colorectal, endometrial and other cancers associated with Lynch syndrome) services (CPT 81288, 81292-81300, 81317-81319, 81435, 81436) and familial adenomatous polyposis (FAP) services (CPT 81201-81203) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Colorectal V1.2018 (7/12/18) ~~V3.2017 (10/10/17)~~. www.nccn.org.
 - b) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-~~81167~~, ~~81211-81217~~ ~~81212~~, ~~81215-81217~~) for women patients without a personal history of breast, ovarian and other associated cancers should be provided to high risk women patients as defined by the US Preventive Services Task Force or according to the NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast and ovarian. V2.2019 (7/30/18) ~~V1.2018 (10/3/17)~~. www.nccn.org.
 - c) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-~~81167~~, ~~81211-81217~~ ~~81212~~, ~~81215-81217~~) for women with a personal history of breast, ovarian, and or other associated cancers and for men with breast ~~cancer~~ or other associated cancers should be provided according to the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast and Ovarian. V2.2019 (7/30/18) ~~V1.2018 (10/3/17)~~. www.nccn.org.

Appendix B

New Guideline Notes

- d) PTEN (Cowden syndrome) services (CPT 81321-81323) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. [Genetic/Familial High-Risk Assessment: Breast and Ovarian. V2.2019 \(7/30/18\) or Genetic/Familial High-Risk Assessment: Colorectal Screening V1.2018 \(7/12/18\). V3.2017 \(10/10/17\).](#) www.nccn.org.
- 2) Genetic counseling should precede genetic testing for hereditary cancer whenever possible.
 - a) Pre and post-test genetic counseling should be covered when provided by a suitable trained health professional with expertise and experience in cancer genetics. Genetic counseling is recommended for cancer survivors when test results would affect cancer screening.
 - i) “Suitably trained” is defined as board certified or active candidate status from the American Board of Medical Genetics, American Board of Genetic Counseling, or Genetic Nursing Credentialing Commission.
 - b) If timely pre-test genetic counseling is not possible for time-sensitive cases, appropriate genetic testing accompanied by pre- and post- test informed consent and post-test disclosure performed by a board-certified physician with experience in cancer genetics should be covered.
 - i) Post-test genetic counseling should be performed as soon as is practical.
- 3) If the mutation in the family is known, only the test for that mutation is covered. For example, if a mutation for BRCA 1 has been identified in a family, a single site mutation analysis for that mutation is covered (CPT 81215), while a full sequence BRCA 1 and 2 (CPT ~~81214~~ [81163](#)) analyses is not. There is one exception, for individuals of Ashkenazi Jewish ancestry with a known mutation in the family, the panel for Ashkenazi Jewish BRCA mutations is covered (CPT 81212).
- 4) Costs for rush genetic testing for hereditary breast/ovarian and colon/endometrial cancer is not covered.
- 5) Hereditary breast cancer-related disorders genomic sequence analysis panels (CPT 81432, 81433, 81479) [are only included for patients meeting the criteria for hereditary cancer syndrome testing per NCCN guidelines](#)
 - ~~i) Includes at least 5 genes that the NCCN Clinical Practice Guidelines in Oncology—Genetic/Familial High-Risk Assessment: Colorectal V1.2018 (7/12/18) V3.2017 (10/10/17). and/or NCCN Clinical Practice Guidelines in Oncology—Genetic/Familial High-Risk Assessment: Breast and Ovarian V2.2019 (7/30/18) V1.2018 (10/3/17) include(s) with specific guidance on clinical management; and,~~
 - ~~ii) Includes no more than a reasonable number of genes (e.g. 40 genes total).~~

Appendix C
2019 CPT Codes

code	long_code_description	Placement
10004	Fine needle aspiration biopsy, without imaging guidance; each additional lesion (List separately in addition to code for primary procedure)	Diagnostic Procedures File
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	Diagnostic Procedures File
10006	Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion (List separately in addition to code for primary procedure)	Diagnostic Procedures File
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	Diagnostic Procedures File
10008	Fine needle aspiration biopsy, including fluoroscopic guidance; each additional lesion (List separately in addition to code for primary procedure)	Diagnostic Procedures File
10009	Fine needle aspiration biopsy, including CT guidance; first lesion	Diagnostic Procedures File
10010	Fine needle aspiration biopsy, including CT guidance; each additional lesion (List separately in addition to code for primary procedure)	Diagnostic Procedures File
10011	Fine needle aspiration biopsy, including MR guidance; first lesion	Diagnostic Procedures File
10012	Fine needle aspiration biopsy, including MR guidance; each additional lesion (List separately in addition to code for primary procedure)	Diagnostic Procedures File
11102	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); single lesion	Diagnostic Procedures File
11103	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); each separate/additional lesion (List separately in addition to code for primary procedure)	Diagnostic Procedures File
11104	Punch biopsy of skin (including simple closure, when performed); single lesion	Diagnostic Procedures File
11105	Punch biopsy of skin (including simple closure, when performed); each separate/additional lesion (List separately in addition to code for primary procedure)	Diagnostic Procedures File
11106	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); single lesion	Diagnostic Procedures File
11107	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); each separate/additional lesion (List separately in addition to code for primary procedure)	Diagnostic Procedures File
20932	Allograft, includes templating, cutting, placement and internal fixation, when performed; osteoarticular, including articular surface and contiguous bone (List separately in addition to code for primary procedure)	Ancillary Procedures File
20933	Allograft, includes templating, cutting, placement and internal fixation, when performed; hemicortical intercalary, partial (ie, hemicylindrical) (List separately in addition to code for primary procedure)	Ancillary Procedures File

Appendix C
2019 CPT Codes

code	long_code_description	Placement
20934	Allograft, includes templating, cutting, placement and internal fixation, when performed; intercalary, complete (ie, cylindrical) (List separately in addition to code for primary procedure)	Ancillary Procedures File
27369	Injection procedure for contrast knee arthrography or contrast enhanced CT/MRI knee arthrography	Diagnostic Procedures File
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming	Diagnostic Procedures File
33286	Removal, subcutaneous cardiac rhythm monitor	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

Appendix C
2019 CPT Codes

code	long_code_description	Placement
33440	Replacement, aortic valve; by translocation of autologous pulmonary valve and transventricular aortic annulus enlargement of the left ventricular outflow tract with valved conduit replacement of pulmonary valve (Ross-Konno procedure)	82 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS 106 CONGENITAL STENOSIS AND INSUFFICIENCY OF AORTIC VALVE 186 RHEUMATIC MULTIPLE VALVULAR DISEASE 189 CHRONIC ISCHEMIC HEART DISEASE 224 DISEASES AND DISORDERS OF AORTIC VALVE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 366 ALLERGIC BRONCHOPULMONARY ASPERGILLOSIS
33866	Aortic hemiarch graft including isolation and control of the arch vessels, beveled open distal aortic anastomosis extending under one or more of the arch vessels, and total circulatory arrest or isolated cerebral perfusion (List separately in addition to code for primary procedure)	284 DISSECTING OR RUPTURED AORTIC ANEURYSM 325 NON-DISSECTING ANEURYSM WITHOUT RUPTURE
36572	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; younger than 5 years of age	Ancillary Procedures File
36573	Insertion of peripherally inserted central venous catheter (PICC), without subcutaneous port or pump, including all imaging guidance, image documentation, and all associated radiological supervision and interpretation required to perform the insertion; age 5 years or older	Ancillary Procedures File
38531	Biopsy or excision of lymph node(s); open, inguinofemoral node(s)	Diagnostic Procedures File
43762	Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; not requiring revision of gastrostomy tract	Ancillary Procedures File
43763	Replacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; requiring revision of gastrostomy tract	Ancillary Procedures File

Appendix C
2019 CPT Codes

code	long_code_description	Placement
50436	Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, with postprocedure tube placement, when performed;	180 URETERAL STRICTURE OR OBSTRUCTION; HYDRONEPHROSIS; HYDROURETER 231 URINARY FISTULA 352 URINARY SYSTEM CALCULUS
50437	Dilation of existing tract, percutaneous, for an endourologic procedure including imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, with postprocedure tube placement, when performed; including new access into the renal collecting system	180 URETERAL STRICTURE OR OBSTRUCTION; HYDRONEPHROSIS; HYDROURETER 231 URINARY FISTULA 352 URINARY SYSTEM CALCULUS
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
76391	Magnetic resonance (eg, vibration) elastography	199 CHRONIC HEPATITIS; VIRAL HEPATITIS
76978	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
76979	Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); each additional lesion with separate injection (List separately in addition to code for primary procedure)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
76981	Ultrasound, elastography; parenchyma (eg, organ)	199 CHRONIC HEPATITIS; VIRAL HEPATITIS
76982	Ultrasound, elastography; first target lesion	199 CHRONIC HEPATITIS; VIRAL HEPATITIS
76983	Ultrasound, elastography; each additional target lesion (List separately in addition to code for primary procedure)	199 CHRONIC HEPATITIS; VIRAL HEPATITIS
77046	Magnetic resonance imaging, breast, without contrast material; unilateral	Diagnostic Procedures File
77047	Magnetic resonance imaging, breast, without contrast material; bilateral	Diagnostic Procedures File
77048	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral	Diagnostic Procedures File

Appendix C
2019 CPT Codes

code	long_code_description	Placement
77049	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral	Diagnostic Procedures File
81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis	Diagnostic Procedures File
81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)	Diagnostic Procedures File
81165	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis	Diagnostic Procedures File
81166	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)	Diagnostic Procedures File
81167	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)	Diagnostic Procedures File
81171	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81172	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; characterization of alleles (eg, expanded size and methylation status)	Diagnostic Procedures File
81173	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; full gene sequence	Diagnostic Procedures File
81174	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; known familial variant	Diagnostic Procedures File
81177	ATN1 (atrophin 1) (eg, dentatorubral-pallidoluysian atrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81178	ATXN1 (ataxin 1) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81179	ATXN2 (ataxin 2) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81180	ATXN3 (ataxin 3) (eg, spinocerebellar ataxia, Machado-Joseph disease) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File

Appendix C
2019 CPT Codes

code	long_code_description	Placement
81181	ATXN7 (ataxin 7) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81182	ATXN8OS (ATXN8 opposite strand [non-protein coding]) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81183	ATXN10 (ataxin 10) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81184	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81185	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; full gene sequence	Diagnostic Procedures File
81186	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; known familial variant	Diagnostic Procedures File
81187	CNBP (CCHC-type zinc finger nucleic acid binding protein) (eg, myotonic dystrophy type 2) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81188	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81189	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; full gene sequence	Diagnostic Procedures File
81190	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; known familial variant(s)	Diagnostic Procedures File
81204	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; characterization of alleles (eg, expanded size or methylation status)	Diagnostic Procedures File
81233	BTK (Bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F)	418 CHRONIC LEUKEMIAS WITH POOR PROGNOSIS
81234	DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; evaluation to detect abnormal (expanded) alleles	Diagnostic Procedures File
81236	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, myelodysplastic syndrome, myeloproliferative neoplasms) gene analysis, full gene sequence	Diagnostic Procedures File

Appendix C
2019 CPT Codes

code	long_code_description	Placement
81237	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, diffuse large B-cell lymphoma) gene analysis, common variant(s) (eg, codon 646)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81239	DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; characterization of alleles (eg, expanded size)	Diagnostic Procedures File
81271	HTT (huntingtin) (eg, Huntington disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81274	HTT (huntingtin) (eg, Huntington disease) gene analysis; characterization of alleles (eg, expanded size)	Diagnostic Procedures File
81284	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; evaluation to detect abnormal (expanded) alleles	Diagnostic Procedures File
81285	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; characterization of alleles (eg, expanded size)	Diagnostic Procedures File
81286	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; full gene sequence	Diagnostic Procedures File
81289	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; known familial variant(s)	Diagnostic Procedures File
81305	MYD88 (myeloid differentiation primary response 88) (eg, Waldenstrom's macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, p.Leu265Pro (L265P) variant	Diagnostic Procedures File
81306	NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis, common variant(s) (eg, *2, *3, *4, *5, *6)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81312	PABPN1 (poly[A] binding protein nuclear 1) (eg, oculopharyngeal muscular dystrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81320	PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81329	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis (eg, carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed	Diagnostic Procedures File

Appendix C
2019 CPT Codes

code	long_code_description	Placement
81333	TGFBI (transforming growth factor beta-induced) (eg, corneal dystrophy) gene analysis, common variants (eg, R124H, R124C, R124L, R555W, R555Q)	Diagnostic Procedures File
81336	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; full gene sequence	Diagnostic Procedures File
81337	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; known familial sequence variant(s)	Diagnostic Procedures File
81343	PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81344	TBP (TATA box binding protein) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	Diagnostic Procedures File
81345	TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81443	Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucopolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81518	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
81596	Infectious disease, chronic hepatitis C virus (HCV) infection, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver	199 CHRONIC HEPATITIS; VIRAL HEPATITIS
82642	Dihydrotestosterone (DHT)	Diagnostic Procedures File

Appendix C
2019 CPT Codes

code	long_code_description	Placement
83722	Lipoprotein, direct measurement; small dense LDL cholesterol	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
90689	Influenza virus vaccine, quadrivalent (IIV4), inactivated, adjuvanted, preservative free, 0.25 mL dosage, for intramuscular use	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
92273	Electroretinography (ERG), with interpretation and report; full field (ie, ffERG, flash ERG, Ganzfeld ERG)	Diagnostic Procedures File
92274	Electroretinography (ERG), with interpretation and report; multifocal (mfERG)	Diagnostic Procedures File
93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
95836	Electrocorticogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and written report, up to 30 days	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT

Appendix C
2019 CPT Codes

code	long_code_description	Placement
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 PARKINSON'S DISEASE 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
96112	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour	Diagnostic Procedures File

Appendix C
2019 CPT Codes

code	long_code_description	Placement
96113	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; each additional 30 minutes (List separately in addition to code for primary procedure)	Diagnostic Procedures File
96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour	Diagnostic Procedures File
96131	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)	Diagnostic Procedures File
96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour	92 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS 173 POSTTRAUMATIC STRESS DISORDER 193 AUTISM SPECTRUM DISORDERS 202 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS

Appendix C
2019 CPT Codes

code	long_code_description	Placement
96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)	92 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS 173 POSTTRAUMATIC STRESS DISORDER 193 AUTISM SPECTRUM DISORDERS 202 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS
96136	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes	Diagnostic Procedures File
96137	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)	Diagnostic Procedures File
96138	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes	Diagnostic Procedures File
96139	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)	Diagnostic Procedures File
96146	Psychological or neuropsychological test administration, with single automated, standardized instrument via electronic platform, with automated result only	Diagnostic Procedures File
97151	Behavior identification assessment, administered by a physician or other qualified health care professional, each 15 minutes of the physician's or other qualified health care professional's time face-to-face with patient and/or guardian(s)/caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.
97152	Behavior identification-supporting assessment, administered by one technician under the direction of a physician or other qualified health care professional, face-to-face with the patient, each 15 minutes	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.

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2019 CPT Codes

code	long_code_description	Placement
97153	Adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with one patient, each 15 minutes	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.
97154	Group adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with two or more patients, each 15 minutes	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.
97155	Adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.
97156	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (with or without the patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.
97157	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.
97158	Group adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes	193 AUTISM SPECTRUM DISORDERS 436 STEREOTYPED MOVEMENT DISORDER WITH SELF-INJURIOUS BEHAVIOR DUE TO NEURODEVELOPMENTAL DISORDER.
99451	Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician, including a written report to the patient's treating/requesting physician or other qualified health care professional, 5 minutes or more of medical consultative time	All lines with E&M codes
99452	Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified health care professional, 30 minutes	All lines with E&M codes

Appendix C
2019 CPT Codes

code	long_code_description	Placement
99453	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment	Ancillary Procedures File
99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days	Ancillary Procedures File
99457	Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month	Ancillary Procedures File
99491	Chronic care management services, provided personally by a physician or other qualified health care professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored.	All lines with E&M codes

Appendix D
2019 HCPCS Codes

HCPCS	Description	Placement
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads	174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 250 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS 361 SCOLIOSIS 440 TRIGEMINAL AND OTHER NERVE DISORDERS 527 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C8937	Computer-aided detection, including computer algorithm analysis of breast mri image data for lesion detection/characterization, pharmacokinetic analysis, with further physician review for interpretation (list separately in addition to code for primary procedure)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-d rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (ebus) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C9752	Destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C9753	Destruction of intraosseous basivertebral nerve, each additional vertebral body, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum (list separately in addition to code for primary procedure)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

Appendix D
2019 HCPCS Codes

HCPCS	Description	Placement
C9754	Creation of arteriovenous fistula, percutaneous; direct, any site, including all imaging and radiologic supervision and interpretation, when performed and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization, when performed)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
C9755	Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
G0068	Professional services for the administration of anti-infective, pain management, chelation, pulmonary hypertension, and/or inotropic infusion drug(s) for each infusion drug administration calendar day in the individual's home, each 15 minutes	All lines with E&M codes
G0069	Professional services for the administration of subcutaneous immunotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
G0070	Professional services for the administration of chemotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes	All lines with "chemotherapy" in the treatment description line
G0071	Payment for communication technology-based services for 5 minutes or more of a virtual (non-face-to-face) communication between an rural health clinic (rhc) or federally qualified health center (fqhc) practitioner and rhc or fqhc patient, or 5 minutes or more of remote evaluation of recorded video and/or images by an rhc or fqhc practitioner, occurring in lieu of an office visit; rhc or fqhc only	All lines with E&M codes
G0076	Brief (20 minutes) care management home visit for a new patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0077	Limited (30 minutes) care management home visit for a new patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List

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2019 HCPCS Codes

HCPCS	Description	Placement
G0078	Moderate (45 minutes) care management home visit for a new patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0079	Comprehensive (60 minutes) care management home visit for a new patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0080	Extensive (75 minutes) care management home visit for a new patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0081	Brief (20 minutes) care management home visit for an existing patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0082	Limited (30 minutes) care management home visit for an existing patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0083	Moderate (45 minutes) care management home visit for an existing patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0084	Comprehensive (60 minutes) care management home visit for an existing patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0085	Extensive (75 minutes) care management home visit for an existing patient. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List

Appendix D
2019 HCPCS Codes

HCPCS	Description	Placement
G0086	Limited (30 minutes) care management home care plan oversight. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G0087	Comprehensive (60 minutes) care management home care plan oversight. for use only in a medicare-approved cmmi model. (services must be furnished within a beneficiary's home, domiciliary, rest home, assisted living and/or nursing facility)	Ancillary List
G2000	Blinded administration of convulsive therapy procedure, either electroconvulsive therapy (ect, current covered gold standard) or magnetic seizure therapy (mst, non-covered experimental therapy), performed in an approved ide-based clinical trial, per treatment session	Excluded List
G2010	Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment	All lines with E&M codes
G2011	Alcohol and/or substance (other than tobacco) abuse structured assessment (e.g., audit, dast), and brief intervention, 5-14 minutes	All lines with G0396 and G0397
G2012	Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion	All lines with E&M codes

Appendix D
2019 HCPCS Codes

HCPCS	Description	Placement
G9978	Remote in-home visit for the evaluation and management of a new patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires these 3 key components: a problem focused history; a problem focused examination; and straightforward medical decision making, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are self limited or minor. typically, 10 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List
G9979	Remote in-home visit for the evaluation and management of a new patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires these 3 key components: an expanded problem focused history; an expanded problem focused examination; straightforward medical decision making, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of low to moderate severity. typically, 20 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List

Appendix D
2019 HCPCS Codes

HCPCS	Description	Placement
G9980	Remote in-home visit for the evaluation and management of a new patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires these 3 key components: a detailed history; a detailed examination; medical decision making of low complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate severity. typically, 30 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List
G9981	Remote in-home visit for the evaluation and management of a new patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires these 3 key components: a comprehensive history; a comprehensive examination; medical decision making of moderate complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate to high severity. typically, 45 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List

Appendix D
2019 HCPCS Codes

HCPCS	Description	Placement
G9982	Remote in-home visit for the evaluation and management of a new patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires these 3 key components: a comprehensive history; a comprehensive examination; medical decision making of high complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate to high severity. typically, 60 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List
G9983	Remote in-home visit for the evaluation and management of an established patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires at least 2 of the following 3 key components: a problem focused history; a problem focused examination; straightforward medical decision making, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are self limited or minor. typically, 10 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List

Appendix D
2019 HCPCS Codes

HCPCS	Description	Placement
G9984	Remote in-home visit for the evaluation and management of an established patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires at least 2 of the following 3 key components: an expanded problem focused history; an expanded problem focused examination; medical decision making of low complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of low to moderate severity. typically, 15 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List
G9985	Remote in-home visit for the evaluation and management of an established patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires at least 2 of the following 3 key components: a detailed history; a detailed examination; medical decision making of moderate complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate to high severity. typically, 25 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List

Appendix D
2019 HCPCS Codes

HCPCS	Description	Placement
G9986	Remote in-home visit for the evaluation and management of an established patient for use only in a medicare-approved bundled payments for care improvement advanced (bpci advanced) model episode of care, which requires at least 2 of the following 3 key components: a comprehensive history; a comprehensive examination; medical decision making of high complexity, furnished in real time using interactive audio and video technology. counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. usually, the presenting problem(s) are of moderate to high severity. typically, 40 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology	Ancillary List
G9987	Bundled payments for care improvement advanced (bpci advanced) model home visit for patient assessment performed by clinical staff for an individual not considered homebound, including, but not necessarily limited to patient assessment of clinical status, safety/fall prevention, functional status/ambulation, medication reconciliation/management, compliance with orders/plan of care, performance of activities of daily living, and ensuring beneficiary connections to community and other services; for use only for a bpci advanced model episode of care; may not be billed for a 30-day period covered by a transitional care management code	Ancillary List

Appendix E
2019 CDT Codes

CDT Code	Code description	Proposed Placement
D0412	blood glucose level test – in-office using a glucose meter	Diagnostic Procedures File
D1516	space maintainer – fixed – bilateral, maxillary	53 PREVENTIVE DENTAL SERVICES
D1517	space maintainer – fixed – bilateral, mandibular	53 PREVENTIVE DENTAL SERVICES
D1526	space maintainer – removable – bilateral, maxillary	53 PREVENTIVE DENTAL SERVICES
D1527	space maintainer – removable – bilateral, mandibular	53 PREVENTIVE DENTAL SERVICES
D5282	removable unilateral partial denture – one-piece cast metal (including clasps and teeth), maxillary	588 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH)
D5283	removable unilateral partial denture – one-piece cast metal (including clasps and teeth), mandibular	588 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH)
D5876	add metal substructure to acrylic full denture (per arch)	451 DENTAL CONDITIONS (E.G., MISSING TEETH, PROSTHESIS FAILURE)
D9130	temporomandibular joint dysfunction – non-invasive physical therapies	547 TMJ DISORDER
D9613	infiltration of sustained release therapeutic drug – single or multiple sites	Excluded File
D9944	occlusal guard – hard appliance, full arch	644 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT
D9945	occlusal guard – soft appliance, full arch	644 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT

Appendix E
2019 CDT Codes

CDT Code	Code description	Proposed Placement
D9946	occlusal guard – hard appliance, partial arch	644 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT
D9961	duplicate/copy patient's records	Excluded File
D9990	certified translation or sign-language services – per visits	Ancillary Procedures File

MINUTES

Evidence-based Guidelines Subcommittee

Clackamas Community College
Wilsonville Training Center, Rooms 111-112
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
November 1, 2018
2:00-5:00pm

Members Present: Devan Kansagara, MD, Chair; Alison Little, MD, MPH; Angela Senders, ND; Lynnea Lindsey, PhD (by phone); Leslie Sutton (by phone).

Members Absent: Eric Stecker, MD, MPH, Vice-Chair.

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

Also Attending: Adam Obley, MD, Moira Ray MD and Craig Mosbaek (OHSU Center for Evidence-based Policy); T.A. Merritt; Silke Akerson and Kelsey A. Fisher (Oregon Midwifery Commission); Mohamed Abdiasis and Shelly Das (Oregon Health Authority), Duncan Neilson (Legacy Health Systems); Amin Medjamia (Abiomed); Crispin Davies, MD (OHSU, by phone).

1. CALL TO ORDER

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

2. MINUTES REVIEW

Minutes from the 9/7/2018 meeting were reviewed and approved 5-0.

3. STAFF REPORT

Coffman had nothing to report.

4. SCOPE STATEMENTS FOR MULTISECTOR INTERVENTIONS

Livingston reviewed the draft scope statement for the topic of Multisector Interventions to Reduce the Frequency of Asthma Exacerbations. She reported that staff got a limited amount of conflicting feedback from the survey requested in June. Based on this feedback, staff eliminated several interventions including air quality alerts and reducing diesel emissions as they would be challenging for a CCO to influence. In addition, health behavior interventions were excluded and scope was limited to multisector interventions rather than clinical interventions.

Kansagara asked Livingston to explain the concept of multisector interventions. Livingston referenced a paper by the Centers for Disease Control, which describes three buckets of preventive interventions. The first is clinical prevention. The second is preventive interventions delivered to individuals in community settings, such as diabetes prevention programs or home assessments for asthma patients. The third category is community-wide interventions such as tobacco taxes or media campaigns. Much of the time the multisector interventions of interest to coordinated care organizations would be in the second category, though there may some interventions in the third category.

She said the asthma topic is of particular interest as there is an health plan incentive metric on-deck related to asthma. This report may be of interest as plans strategize efforts related to this metric.

Next was the scope statement on Community Health Workers for Patients with Chronic Disease. She said the population of high utilizers were added, and the language around substance use disorders was corrected to reflect contemporary usage. Obley recommended changing a period to a comma in the population description.

There was no public comment.

A motion was made to approve the draft scope statements as amended. **Motion approved 5-0.**

5. Newer Interventions for Osteoarthritis of the Knee

Adam Obley reported that there were no public comments. Livingston said staff recommends no changes to the coverage guidance.

A motion was made to refer the draft coverage guidance to HERC as presented. **Motion approved 5-0.**

DRAFT 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*).

6. Planned Out-of-Hospital Birth

Livingston told the history of the existing coverage on this topic. The original report took about a year and a half and was controversial. She said there was no evidence from randomized controlled trials, since women were not willing to be randomized. EbGS did an evidence review and came up with an extensive list of risk factors. If a woman had or developed one of these risk factors, then an out-of-hospital birth would not be covered by OHP, including prior cesarean section, prior uterine rupture, breech presentation and twins. In addition, based on guidelines, the coverage guidance includes recommendations for other risk factors that should lead to a transfer of care to a hospital setting or a consultation with a hospital provider.

She summarized the evidence from the previous review. There was evidence that out-of-hospital birth offers many better outcomes for the mother, including a lower risk of cesarean section. However, there was also evidence babies born as a result of a planned out-of-hospital birth faced an increased risk of neonatal death; the risk may be about double compared to babies born in a hospital setting. Though rare, this increased risk was reflected in Oregon vital records data from 2012.

Livingston said several groups of stakeholders have requested revisions to the current coverage guidance. Some stakeholders requested removing requirements for consultation or transfer for conditions such as obesity. Others requested requiring additional documentation at specific gestational ages. Still others requested adding additional high-risk exclusion criteria, such as not covering out-of-hospital birth for women over the age of 35, primiparous women, or women at 41 or more weeks of gestation. Another OHA workgroup also asked OHA to determine if there was sufficient new evidence to reopen the coverage guidance. These requests are the reasons for today's rescan. The subcommittee needs to recommend whether or not to reopen the coverage guidance.

Moira Ray reviewed the rescan document from the meeting materials. She said that overall the evidence is consistent with the current coverage guidance, though some evidence suggests increased risks of harm to certain groups of patients.

Little asked whether the Oregon-based study included in the rescan was included in the current version of the coverage guidance. Obley said he believes that the information was available from vital statistics, but it was not available in the peer-reviewed literature at that time.

Livingston discussed how an updated literature search could potentially change the current coverage guidance. She said there is only one study identified that may shift the coverage guidance for certain high-risk groups (nulliparous women, women at or beyond 41 weeks 0 days of gestation and women over 35 years of age). However, there are strong values and preferences favoring out-of-hospital birth, and these increased risks were known at some level at the time of development of the prior coverage guidance. In addition, some of the guideline-based consultation or transfer criteria may be updated based on a review of the updated guidelines from various other groups.

Kansagara said it's important to think about the level of evidence you'd need to re-open the coverage guidances based on the low event rates and the preference-sensitive nature of this service. You would need pretty compelling data to dive into it again. He expressed doubt about whether the evidence presented would meet that standard. Otherwise, the subcommittee would be wading into what should be part of shared decisionmaking.

Kansagara invited public testimony.

Silke Akerson, a licensed direct-entry midwife and director of the Oregon Midwifery Council, spoke first. She declared no other conflicts of interest. While she agreed with the overall assessment that there isn't a huge amount of new evidence about the high-risk exclusion criteria, there are a number of consultation requirements which are not evidence-based. These criteria are functioning more as a practice guideline more than as an evidence-based coverage guidance. The level of detail in the consultation requirements is actually taking the place of shared decisionmaking.

She said that because the cost of a birth is something that is paid in total, the criteria completely removes access to the option of out-of-hospital birth when the guideline criteria are met for most people on OHP. She would like to see the consult criteria based on strong evidence. For example, all the consult requirements currently require consultation with a provider with hospital privileges. In some cases this adds significant cost and stress for the patient. Some could be addressed by a primary care provider. In other cases, a provider is consulting with a provider with hospital privileges such as maternal fetal medicine, but OHA is saying it is not an appropriate consultation, and instead consulting with another type of provider. For example, a midwife consulted with maternal fetal medicine on a case with anemia, but OHA consulted with a hematologist-oncologist and overruled the consultation. There was no cancer involved. She said the way the guidance is implemented is resulting in increased costs and complications in some specific instances (though not in the majority of the consultation requirements).

She also clarified that the vital records report was reviewed during the original coverage guidance development before the Snowden study came out. At the time her group was concerned as the report looked at about 4000 births total (we have about 2000 out-of-hospital births per year in Oregon). Because the negative outcomes are rare, looking at only a few years' data can distort the picture. She said there has been a rigorous quality improvement program since the study period of 2012-2013. In

2012, the perinatal mortality rate was 3.9 per thousand for planned out-of-hospital births. In 2015 it was 0.98 per thousand; in 2016 it was 1.03 per thousand. She advised caution in looking at the Snowden study, or at small ranges of time for vital records. She said Oregon's data from birth certificates are more reliable in terms of correctly allocating outcomes by intended place of birth than birth certificates from other states. She also said that certified professional midwives are now regulated in 38 states and are not illegal in about half of states as previously stated.

Kelsey Fisher, a licensed direct entry midwife from Oregon, spoke next. She also serves as a member of the Board of Direct Entry Midwifery. She has no additional conflicts of interest. She said her board's rules are open right now. While she recognized that her board's roles are separate, she said there was evidence from the Midwives Alliance of North America (MANA) (which she described as a prospective data collection, typically looked at in an intention-to-treat model) showing that vaginal birth after cesarean can be safe for women who've previously had a successful vaginal birth. This data shows that risk for these women is much lower than for women without a prior vaginal birth. In fact, the outcomes are better than for primiparous women. The indication for cesarean can impact outcomes as well as other prior obstetrical history. She had a woman with several vaginal births, then a cesarean for breech who had to elect planned hospital birth despite a history of precipitous labor because OHP would not pay for out-of-hospital birth.

Ray said that the MANA study doesn't make comparisons to planned hospital birth so was not included in the scope for the draft review. In addition, providers voluntarily report data to this database in some states, though reporting is mandatory in Oregon.

Livingston introduced Duncan Neilson, who served as an appointed expert for the prior coverage guidance. He said his impression is that the literature since the last HERC review hasn't added anything substantive and he agrees with what he has read in the meeting materials. In another forum he has heard the concerns Akerson raised and they are real. But addressing these isn't the job of the HERC. He said that the remaining work in this area for Oregon is threefold: addressing implementation issues with the current prior authorization process, disseminating the evidence as it has been compiled by HERC and addressing perceptions among providers statewide and among payers about out-of-hospital births. He said some payers don't understand the actual risks and are reticent to get involved or to be constructive. His primary issue is patient safety, and if things aren't implemented well and if the delivery community doesn't understand what is and isn't safe, we have actually compromised patient safety. Specifically, he said developing relationships for transfer of care for patients who do risk out of out-of-hospital births is important as relationships are crucial to successful transfers.

Livingston said there is a group working to address the implementation issues discussed, and these would not be in HERC's purview, except for the suggestion to drop some consultation criteria. Coffman said that if the other workgroup requests changes in the HERC guideline note associated with the Prioritized List, HERC could consider that request.

The subcommittee also briefly reviewed the scope statement from the meeting materials. The scope statement is new to the process since the 2015 report was initiated. If the coverage guidance were to be re-opened, this scope statement would be used for the new review, and it was used for conducting the rescanned evidence search.

During this discussion, staff discovered that an old version of the scope statement had made its way into the rescanned document. The correct version has delivery mode as a critical outcome rather than an

important outcome, and adds breastfeeding as an important outcome. There is a new key question about whether the harms vary by provider characteristics and a contextual question about the expected rate of transfer to hospital for out-of-hospital birth.

A motion was made to approve the staff recommendation not to re-open the coverage guidance. **Motion approved 5-0.** (Note: On November 8, 2018, HERC did not accept the EbGS recommendation and asked EbGS to re-open this coverage guidance.)

After a break, another motion was made to approve the scope statement as corrected, including the revisions mentioned by Livingston and displayed during the meeting (rather than the version from the meeting materials). **Motion approved 5-0.**

7. Temporary Percutaneous Mechanical Circulatory Support with Impella Devices

Livingston reviewed the discussion questions from the public comment disposition as presented in the meeting materials. Livingston clarified one item in the public comment disposition (the last item in the discussion table); there *were* inoperable patients in the PROTECT II study, but no subgroup analysis of these patients was performed. She also noted that Dr. Stecker was not able to be present but sent a letter (included in the meeting materials) suggesting revisions to the staff proposal, and reviewed this letter with the subcommittee.

Coffman introduced Crispin Davies, the appointed expert for this topic who reported no conflicts of interest. Davies said the issue of surgical turndowns is partially addressed by the Society of Thoracic Surgery (STS) score but not in the way you would expect. People with higher STS scores who could not have coronary artery bypass grafting (CABG) actually do worse. This could be because if you're more sick you might not do well with anything. He also echoed Stecker's concern about the proliferation of medical devices where we don't have good evidence. He acknowledged the cost of about \$25,000 per device.

Despite that, he said he worries that Impella may be a useful tool. It's difficult when you're examining something that is like a seatbelt or airbag, when it may not be deployed for an individual. He believes PROTECT II is so poor it doesn't provide useful information. He would like to see a better study with the correct endpoint (not changed mid-trial) and using the Impella 3.5, which could make quite a bit of difference. Such a study may also include interventionalists who are more skilled in placing the device. He said that a national payer might force the company to conduct a better study but that Oregon on its own may harm Oregonians by denying payment for this device without motivating the manufacturer to conduct a trial. He said that he found the previous indication for the device somewhat troubling, but the extension of the FDA indication in February to those with normal left ventricular function even more disturbing, as this opens it up to all comers. A small change in these criteria can make a big difference in terms of population. He would not recommend coverage be extended to patients with normal ventricular function.

Little requested Obley give a brief recap regarding the PROTECT II trial. Obley reviewed the inclusion criteria, interventions and results from PROTECT II. Kansagara noted that the cardiologists did more rotational atherectomy on patients with Impella. Kansagara said that additional rotational atherectomy may open the arteries more, benefitting patients, but may also have harms by sending material downstream. He also noted that need for revascularization was the primary demonstrated benefit (and

was not originally included). Obley said that most people would prefer to avoid repeat revascularization but that it would not generally be considered a critical outcome. In addition, an elective decision in an unblinded trial can introduce an element of bias. Davies said that revascularization can be important to patients, as it can affect employment. In addition, blinding a trial with Impella is not possible because the device is visible on procedure-related x-rays.

Kansagara also noted that the study was stopped for futility. Davies noted that about 200 additional patients were randomized before the study was stopped, and that there was a temporal trend which might have produced a more positive result if the study had been allowed to continue. Obley agreed that the improvements were better after the first year of the trial.

Obley then reviewed a table showing which populations have and have not been studied, including noncomparative data.

Amin Medjamia, MD, of Abiomed, offered public testimony. He participated in the PROTECT II trial though he did not design it. He noted that, while the study was cancelled based on preliminary data from a smaller subset of patients, the results reviewed today include results from a larger group of patients, some of whom were randomized while the preliminary data was being analyzed. The larger data is more positive than the preliminary data. He also said Impella is different from other alternatives in that it reduces the ischemic threshold of the heart. It is difficult to conduct a clinical trial in an emergent setting. Out of 10 trials attempted, only 2 have completed, and these are only powered to show improved hemodynamic support. Others have stopped for low enrollment.

He focused on the high-risk percutaneous coronary interventions (PCI) population. He said it's a small population. It's the surgical turn-downs (those not eligible for surgery). In PROTECT II they asked the physicians to call for a surgical consult to see whether they were eligible for CABG. Sixty-seven percent were not eligible, but the remaining patients were so compromised that the physicians didn't bother to call for a surgical consultation; it was obvious. He said at the time the study was designed, the assumption was that the complication rate was really low in these patients. This was the reason for the composite outcome including 10 adverse events. He described several issues with the PROTECT II study which may have skewed the results towards ineffectiveness and harms. He said that a lack of coverage in Oregon would create tiered coverage, with the sickest, most vulnerable patients lacking coverage for this device. He also mentioned several professional societies which reference the device in guidelines.

Kansagara said that the subcommittee feels the responsibility to provide the best coverage. The approval of coverage for some things takes away from other things. Livingston asked Obley to address Medjamia's comments. Obley said that giving the most generous interpretation of the subsidiary analyses of the PROTECT II study, if you were to re-do PROTECT II and add an operator experience requirement, accept the newer definition of MI and include only the newer models of Impella, it might well be a very different trial, though he would not say whether it would be better or worse. However, post hoc analyses introduce bias. In particular, redefining MI post hoc is problematic as one could have chosen any enzyme cutoff which produced the most positive outcome.

Davies said post hoc analysis of a negative trial always makes him feel very uncomfortable. Obley addressed the ischemic protection in the cardiogenic population. He said the left ejection fraction didn't differ between those using balloon pumps and those using Impella. While he understands the concept, he doesn't know that it has been proven in the trials. He said there is an ongoing trial comparing venoarterial extracorporeal membrane oxygenation (ECMO) with Impella. It is a small trial.

Kansagara said the PROTECT II trial itself was reasonably well-designed, but the results may not be applicable to current practice. For instance, it didn't use the Impella 3.5 devices currently in use. In addition, the way the trial was conducted in such a way that it adds risk of bias for revascularization but not mortality. He also commented that it is replacing intra-aortic balloon pumps, though these have issues as well. Davies added that the intra-aortic balloon pumps don't work very well according to the hemodynamic analysis, though it could be that neither device works.

Referring to Obley's table, he said there are several populations for which there is essentially no trial evidence. Then there is elective high-risk PCI. The latter have not had a myocardial infarction, and who have stable coronary disease. He asked Davies about the prognosis for these patients, without PCI. Davies said they would have lifestyle-limiting angina, but their rate of death and myocardial infarction wouldn't change after PCI. He said this sort of chest pain is significant for patients, as it affects whether they can get to their mailbox or play with their grandchildren. Kansagara asked whether the PROTECT II patients had refractory angina. Davies said in theory yes, but it isn't clear how refractory it was. In 2018 the only patients who should get stenting are those whose symptoms can't be managed with medication.

Davies said there is another important group to consider which hasn't been studied, people requiring high-risk PCI who have non-ST elevation myocardial infarction (NSTEMI). These people have a small myocardial infarction (MI) and are then stuck in the hospital. These are about half of the people receiving PCI now, and the consensus is that for these patients, the procedure is lifesaving. He said this group is wholly unrepresented in the data, but is in the sweet spot for benefit from stenting.

Livingston said that you should be able to study this population. Davies agreed. He said for some reason it was an exclusion from PROTECT II because it has to be done in a limited timeframe while the patient is in the hospital. Obley asked whether in that scenario you would use Impella if the patient had a normal ejection fraction. Davies said it would be unlikely; generally you would use it only with ejection fraction of 30 or less and only after a diagnostic angiogram.

Kansagara reviewed the draft recommendation for coverage only as a bridge to transplant. He said this is based on broad clinical consensus about this population despite lack of evidence. Davies said this is an important population, especially in a state that now has no transplant program, so that patients can travel to a state where they can get a transplant. Livingston reviewed the staff recommendation for this population, which requires a team decision. The group agreed on this portion and went on to discuss other populations.

Discussion turned to additional populations. Livingston presented some options for additional language. Kansagara said that the committee needs to consider precedent. He said the decision is not dissimilar in terms of evidence from some other topics discussed earlier in the year. He wanted to make sure this decision doesn't disrupt our standards for evidence.

There was extensive discussion about adding coverage for two populations. For those with stable angina, the subcommittee found no rationale to add coverage, as this would go against previous decisions for nonfatal conditions. For the NSTEMI population, the subcommittee elected to add coverage based on the rationale that PCI is potentially lifesaving for this population. There is no current evidence but a compelling rationale for efficacy, and in the absence of Impella these patients may not

receive PCI due to liability concerns of providers. Additionally, given the widespread use of Impella devices, it is less likely that a randomized controlled trial would be published examining this population.

The draft coverage guidance will be referred to HERC as amended. **The motion was approved 4-0, with Sutton not present.**

[NOTE: Following the EbGS meeting, HERC staff decided that given the subcommittee decision to add coverage for NSTEMI, it was appropriate to add a GRADE table about the acute myocardial infarction population. This population was within scope, but a separate GRADE table was not initially included because of the lack of evidence found. By adding this GRADE table post-hoc, the evidence review and the rationale for including coverage of the NSTEMI population could be made more transparent].

8. Adjournment

The meeting was adjourned at 5:00 pm. Gingerich said that next topics depend on what HERC decides with regards to the scope statements discussed previously. The next meeting is scheduled for February 7, 2019 from 2:00-5:00 pm at Clackamas Community College, Wilsonville Training Center, Rooms 111-112, 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
November 15, 2018
1:00-4:00pm

Members Present: Kathryn Schabel, MD (acting chair); Leda Garside, RN, MBA; Mary Beth Engrav, MD; Mike Adler, MD, Vinay Prasad, MD, MPH (chair, by telephone); Brian Duty, MD, Kevin Cuccaro, DO (by phone).

Members Absent: none

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

Also Attending: Doug Riggs (Oregon Ambulatory Surgical Association); Mellony Bernal (OHA Public Health Division); Chris Skagen (Oregon Ambulatory Surgery Association, by phone); Adam Obley, MD & Craig Mosbaek (OHSU Center for Evidence-based Policy); Fouad Otaki, MD (by phone).

1. CALL TO ORDER

Schabel, who acted as chair since Prasad was attending by phone, called the meeting of the Health Technology Assessment Subcommittee (HTAS) to order at 1:00 pm.

2. MINUTES REVIEW

Minutes from the September 20, 2018 meeting were reviewed and approved 7-0 (Duty absent).

3. STAFF REPORT

Coffman welcomed Dr. Duty and Dr. Engrav to the subcommittee. Staff and members introduced themselves and welcomed the new members. Duty is a urologist at OHSU; he is also working on his healthcare MBA, and this is one of his first ventures into health policy. Engrav has a background in emergency medicine; she practiced 27 years at Legacy and Providence hospitals. Her biggest interest is integrated medical and behavioral care for patients with behavioral health or substance use disorders. She has specific interest in the opioid epidemic and fraud.

4. REVIEW PUBLIC COMMENT: NEWER INTERVENTIONAL PROCEDURES FOR GERD

Adam Obley reviewed the public comments and responses from the meeting materials. Shaffer introduced Fouad Otaki, an OHSU gastroenterologist with an interest in foregut disease, esophageal

disorders and Barrett's esophagus. Schabel asked for his views on the recommendation. He said that he agreed with the evidence review. He said transoral incisionless fundoplication has demonstrated effectiveness, and the MUSE system is an up-and-coming alternative technique but not in clinical use; magnetic sphincter augmentation has a bright future but at this time he agrees with the overall review.

Shaffer reviewed the revisions, which highlight that the evidence that was reviewed used the Esophyx device. The MUSE system is newer. The CPT code would likely be the same for both devices. He said that the MUSE system is different in device components and surgical technique, so the recommendation was altered so that the recommendation for coverage is now specific to the Esophyx device.

A motion was made to refer the draft coverage guidance to HERC. **Motion approved 8-0.**

DRAFT 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
 - 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*).

5. EXTENDED STAY CENTERS (ESCs) AND AMBULATORY SURGERY CENTERS (ASCs)

Doug Riggs offered public testimony. He is with the Oregon Ambulatory Surgery Center Association (OASCA). He helped draft the bill and worked since 2014 to get the bill adopted. He said by the end, the allies included Oregon Medical Association, Oregon Association of Hospitals and Health Systems as well as patient advocate groups and unions. He said that the bill would allow people to extend their recovery period after surgery. This was a key to address the deluge of joint surgeries that are needed with the aging of an active population. These surgeries are expected to double in the next 10 years.

He said there are two rulemaking processes ongoing within the Oregon Health Authority. One, with the Public Health Division is complete, related to licensing rules. Those should be effective in January. Another, related to facility guidelines (or an FGI process) to align building standards at the federal level, is nearing completion as well. A third provision in the statute is related to the HERC, which was adopted last. It's important to understand that one of the hospitals in Southern Oregon wanted this provision adopted. He and other proponents of the bill saw the provision shortly before a vote and didn't have a chance to change it. He said it wasn't quite what his group was hoping for. There are only a handful of states that have recovery facilities. What was intended was to begin to collect data on the outcomes from patients who use extended stay centers and develop evidence around outcomes for these patients. However, that's not quite what the bill says. He believes there will be a legislative effort to modify the bill, which he would share within a couple of weeks. He said Chris Skagen, executive director of OASCA, would testify later about the procedures that will be done related to extended stay centers and about profitability of ASCs. He said profitability is poor; the number of ambulatory surgery centers is actually contracting in Oregon because of low reimbursement. He offered to be a resource in the guideline development and continues to work with the hospital association and Oregon Medical Association. He said Colorado also has data that may be helpful.

Schabel asked about the goals of the legislative provision. He said he spoke with the hospital association and he thinks they agreed that the goal was to collect data about the procedures leading into an ESC, which will tend to be knee, spine, joint and shoulder surgeries. It won't be a lot of daily pain management or complicated surgery with higher morbidity. It will begin to look into the issue but collect data on actual results on the ground in Oregon. The bill set up the opportunity to create new licenses only for a five-year period. After that the legislature would need to act for new facilities to be approved, though existing facilities could continue operations. The existing bill appears to request the HERC to determine which procedures would be appropriate in an ASC that has an ESC. He said it shouldn't be the procedure that determines this but rather the patient and their needs. For example, an elderly patient may need a little extra time for managing pain or bodily functions. Another patient might not have a caretaker at home but need one after 23 hours and 59 minutes. Or if the caretaker can't arrive because it is 6 a.m. and snowing, an ESC would be available so that the patient could be stabilized and wouldn't need to be transferred to the hospital emergency room at higher cost.

Riggs also clarified that an extended stay center is not for a patient whose condition is deteriorating, but a patient that is recovering. He said the data from Colorado support that patients who encounter complications either have this happen in the surgery center or are transferred to the hospital.

Obley asked whether there are procedures that are not currently performed at an ambulatory surgery center which would be with the option of an extended stay center. Riggs said he doesn't think so. It would be the ability to perhaps expand the types of patients and life situations that people have and allow them to be 'screened in' to have surgery in an ASC. ASCs already have a good track record at

screening patients to make sure they are appropriate for surgery in an outpatient setting. He said he doesn't see the surgeries that will be performed expanding, except where technology improves. For example, spine surgery technology has improved greatly over the past 10 years.

Schabel asked to clarify, would it be that patients would be scheduled for an ESC or whether it would just be available for patients if needed for their recovery. Riggs said Skagen could better answer that question but that it would likely be a little of both. He said there are about 12 of these in Colorado and most tend to be midsized (10-15 beds). Some patients may know that an extra 6 or 12 hours of recovery could be of benefit because of the time of year or lack of a caregiver at home. In other cases a patient might have a little additional trouble managing pain or bodily functions after surgery. The ESCs aren't a profit center because most plans don't pay for this service, though they are working to get reimbursement. He said Medicaid hasn't approved the waiver yet. Shaffer added that the bill directs the Oregon Health Authority to apply for such a waiver. Adler asked about the location of extended stay centers. Others said that they would need to be on the same site, though they would be licensed separately.

Shaffer and Schabel thanked Riggs for his participation and offers of assistance. Shaffer said that it's good to know that there may be statutory revisions, but the HERC will proceed until instructed otherwise.

Shaffer then reviewed the status of the report. Today's meeting will be phase 1 of the evidence review. He is hoping to get further direction on looking for evidence and getting experts for advice. He said we don't want to go too far if there's a feeling that we won't have enough information on which to base evidence-based guidelines. He introduced Valerie Halpin, a bariatric surgeon who will be calling in while returning from a national conference on bariatric surgery. He said we have had challenges recruiting external experts. We have Adler for gynecologic surgery, Schabel for joint replacements, and Duty for urologic procedures. Cuccaro received training in anesthesia though his practice is more focused on pain management. We are still seeking experts on quality and safety monitoring, otorhinolaryngology, and recovery nursing.

Shaffer reviewed the requirements. The HERC's task is not to provide any regulations, as these were created by the Public Health Division. The scope of this work is to come up with patient characteristics and appropriate procedures for ambulatory surgery centers that have an associated extended stay center. We don't expect much evidence as similar models only exist in a few places. It's possible we will come up with insufficient evidence, but we need to look for it. Our main goal should be patient safety and avoidance of harms. The concern is that more complex procedures will be done on more complex patients. This may have benefits as the costs may be lower, but it also may be that the evidence will suggest some boundaries on what should be recommended.

Schabel said that the existing data for ambulatory surgery centers is cherry-picked and ASCs typically operate on less complex patients. Assuming that the high quality/low-cost results will continue in the changed model is definitely a leap. She asked whether there is a role for this committee in stipulating that data be collected. Gingerich explained that OHA has two rulemaking processes. The first is the licensing requirements. Mellony Bernal from the Public Health Division is here to provide any needed information on that rule. The statute authorizing ESCs also contains provisions requiring discharge data collection from ESCs. Another part of OHA has developed rules for re-initiating discharge data for ASCs (data collection stopped in 2014). Once ESCs are in operation a similar rule would be developed for ESCs.

Shaffer and Obley reviewed the facility rules and initial partial draft guideline provided in the meeting materials. Shaffer noted that the facility rules do have some limits on patient characteristics, including ASA Class I, II or III. Several members expressed concern that ASA class III patients have significant systemic disease. Schabel gave the example of a patient getting a colonoscopy in an ASC who also has heart failure that has been stable for a long time. Could this patient be admitted to an ESC? According to the rule, such a patient could be admitted to the ESC.

Duty asked whether the new Center for Health and Healing Building 2 at OHSU follows ASC rules. Schabel said no, because it is affiliated with a hospital. Duty said this facility has requirements about who can use the facility and it includes ASA class III patients. Shaffer also reviewed the staffing requirements in the licensing rule as well as the rules related to pharmacy, labs and imaging.

Garside asked whether there would be regulations requiring certain levels of nursing staffing. Bernal said that there would have to be nurses available at all times. The rule specifically says that the staffing levels should be based on the number and complexity of patients. Bernal said her section will visit ESCs. She said that the ESC rule uses identical language to the ASC rule. This was discussed at length. They reached out to the Bureau of Labor and Industries and the Board of Nursing and chose to keep it vague since Public Health doesn't relate to employment. The rule does, however, require an RN to be on duty at all times. Gingerich said that some ASCs do less invasive surgeries like cataracts, so staffing requirements may vary; some ASCs would have no interest in creating an extended stay center. Bernal clarified that the ASC rules are now out for public comment.

Obley asked specifically about the origin of the ASA classification part of the rule. Bernal said it was based on AORN and ASPEN guidelines. They did not receive any comments on that part of the rule during the rules advisory committee meeting. Schabel said it would be helpful to have quality and nursing experts to understand these issues.

She also asked about whether adverse events would be reported. Bernal said that there is voluntary adverse event reporting through the Oregon Patient Safety Commission (OPSC). Gingerich clarified that the requirement is that if you report, the report should contain all incidents. Bernal said this is how the requirement is for all health facilities in Oregon.

Skagen said that ASCs are required to report certain adverse events to the Center for Medicare and Medicaid Services Quality Reporting Program. Measures include falls, wrong site/wrong side/wrong patient incidents, transfers to hospital and other outcomes the subcommittee may have interest in.

Obley reviewed the evidence section of the partial draft report.

Prasad asked to review the goal of the report. Shaffer said the goal is to create a guideline on appropriate procedures and characteristics for the setting of an ASC with an ESC available. Schabel said that the question isn't whether an ASC can do a particular procedure, as that is a foregone conclusion. The data presented shows whether certain procedures can be performed safely at an ASC. One type of data that might be helpful is reporting on failed outpatient surgeries. What percentage of patients end up being transferred to a hospital or emergency department and what are the rates for various procedures. Comparative studies might not get us to the answer for this question.

Prasad said he wasn't sure it could be done. Even if you have data that shows that if a patient has a certain surgery in an ASC there is a 3 percent chance of hospital transfer. Is that acceptable or not acceptable? In the absence of comparative studies how can anyone know?

Engrav said ASCs have an interest as it would expand their patient population. Is this going to skew it to taking higher-risk patients? Schabel said having an ESC could result in boundaries being pushed both in patient selection and procedure type. However, there is very poor evidence to guide us here. For instance, in orthopedics one of the issues that pushes people to a hospital setting is urinary retention. She said without an ESC, an ASC would have to send the patient home fully catheterized and the primary care physician could remove the catheter a week later. With an ESC the patient could stay overnight, work on urinating and then go home without a catheter and avoiding a transfer to hospital. This isn't a complication with the procedure but rather the anesthesia. The methodology of these case series is generally poor as they aren't looking for all the potential emergency department visits a patient could require. The case series generally make the procedures appear safe, and collecting a robust data set is difficult. Looking at the pool of patients who fail attempted ASC or hospital outpatient-based surgeries would be interesting. Obley said this data is summarized in the appendices. In many cases the outcomes selected are things like patient satisfaction rather than safety or quality metrics.

Shaffer invited Dr. Halpin to testify about bariatric surgeries performed in ASC settings. She said there are two centers near Seattle doing bariatric procedures in ASCs. One of them presented data today at the American Metabolic and Bariatric Surgery meeting. About 2000 patients underwent laparoscopic sleeve gastrectomy at their ASC. Their rate of transfer to the hospital was about 1 percent. The hospitalizations were for things like bleeding and cardiac events. The readmission and complication rates were similar to what is seen in a hospital setting. Many complications occur after discharge, so the surgical setting doesn't make that big of a difference. Selection criteria were ages 18-65, with a BMI less than 55 for men or 60 for women. They did report one early death related to sleep apnea, so patients with sleep apnea now stay overnight (about 70% of bariatric patients have sleep apnea). She said they also do Roux-en-Y surgeries but didn't report those results today.

Schabel said there is some differentiation in patient population—BMIs will be higher in a hospital. You would expect the outcomes data to be improved, not similar. A group of younger, healthier patients should have lower—not equivalent—complication rates. Halpin said bariatric patients are at least ASA class II by definition. Without directly comparing them it is hard to say whether their outcomes should be better than what we see nationally. However, data collection in bariatric surgery is pretty robust, with the vast majority of surgeons contributing to a robust data set. She said the second group that did ASC bariatric surgery keeps all of their patients overnight. Schabel said that having an ESC could therefore expand the population eligible for bariatric surgery. Still, with little data it is a foreboding task to do what we've been asked to do from an evidence-based standpoint.

Gingerich said that staff have been instructed that it would be acceptable for the subcommittee to decide there is insufficient evidence on which to base a guideline.

Prasad asked about propensity-matched or instrumental variable studies. Obley said that if there were such studies they would have been identified in the search. Prasad said the best we can do is look for case series or cohorts that report complications or transfers. Obley said such studies do exist.

Prasad said one possibility would be to present a table listing different patient groups, with those with the lowest risk at the top. Over time as providers gain comfort performing surgeries for more complex patients in this setting they could move down the table.

Shaffer said that from reviewing the abstracts, an issue may be that the patients are “carefully selected”. He said reading the full articles may or may not reveal whether there were specific exclusion criteria or whether exclusions were based on clinical judgment. Prasad said that if the only answer is clinical judgment, we haven’t made any progress. There would need to have been a protocol for patient selection. Halpin said that in bariatric surgery they would have specific criteria.

Schabel said we may not have as robust data in orthopedics. There is a study that used risk calculators and case series analysis to estimate that about 15 percent of the Medicare population meets criteria for outpatient joint replacement. That’s a small but not insignificant percentage. Studies like this will also be important.

Prasad said the search could include only studies where there were delineated criteria for conducting the surgery in an ASC setting. Obley said a robust accounting of the patient characteristics might suffice; Prasad agreed.

Gingerich noted that one of the studies was an externally defined national dataset. Schabel said that the large databases come from hospitalized patients. Obley said he’d have to delve into the study more deeply to answer that question.

Coffman asked whether an additional search might need to be done. Obley said the search was conducted in such a way to pick up these kinds of studies if the surgeries were conducted in ASCs. For these, the remaining work would be to analyze them based on today’s discussion. There could be additional studies that would report on “outpatient” procedures without specifying ASC as the site of care.

Schabel said it’s becoming clear that developing a robust evidence-based guideline is out of reach but being able to state that the data isn’t there could be important. She said looking at 1-day hospital procedures versus an ASC is a very different thing, as the available services are very different. Obley recommended focusing on the ASC-based studies, and Schabel suggested that the subcommittee might state that there is no way to comment on expanding the eligible population, for which there is no data in an ASC setting.

Schabel asked Skagen what the goal of the ESC was? Was it to increase the number of patients? Skagen said that the goal was to enhance the patient experience and that the admission criteria for an ASC does not change based on the recovery center.

Shaffer asked Skagen to offer the rest of his comments. Skagen thanked Bernal for her work on the licensing rules. He has consulted with some of the firms in the Washington area. He offered the names of some experts who might be able to assist. He can also put the group in touch with physicians as well as CEOs in Colorado who could share their expertise. They may be able to report internal data, which would not be peer-reviewed. He said that having all ESCs report data is appropriate, but having all ASCs report discharge data would be going too far. Skagen said that with respect to the ASA classifications, the ASC facility medical board would approve procedures that would matriculate into a recovery center. The types of procedures include joint replacements (hip, shoulder, knee, ankle). Arthroscopies and

sports medicine, spinal fusion and hand and upper extremity surgeries are also common. He said there is a lot of data out there, but there will be a specific list for each facility, followed by a retroactive review of complications for each procedure. He said he has additional information and looks forward to continuing the dialog.

Engrav asked where the CMS quality data or LeapFrog data can be accessed. Gingerich explained that the workplan involves collecting available data from CMS quality reporting and the ASC Quality Collaboration Report. Gingerich also explained that facilities which accept Medicare payments must have uniform discharge criteria for all patients (not just Medicare patients) and prior to the surgery must reasonably expect discharge within 24 hours. However, procedures not on the Medicare ASC list can be done on patients who aren't on Medicare. He also said that the HERC public comment survey indicated concerns about surgeries including neck dissections and prostate surgery, but that the volume would likely be in hip replacements, knee replacement and spine surgery. Shaffer added that each ASC has a list of procedures allowed in that facility. Also, each insurer would need to approve procedures done in an ASC in order for the insurer to provide payment. Schabel said some major payers do follow the CMS rules about which procedures can be done in an ASC, so hip replacements aren't allowed, but knee replacements are newly allowed since they have been removed from the inpatient only list.

Adler said he is in favor of ESCs and said that they would expand gynecologic surgeries. There are certain hysterectomies, vaginal repairs and bladder surgeries that would benefit. It makes him wonder if there is any reason a gynecologist couldn't do an abdominal hysterectomy. Normally a patient would stay more than 24 hours and it wouldn't be done in an ASC. Obley said hysterectomies were included in this search, but the vast majority of procedures described were for vaginal hysterectomies, not abdominal hysterectomies. Adler said that knowing you had a 48 hour time period, a younger patient with a normal weight who has large fibroids may benefit from an abdominal hysterectomy in an ASC. Schabel said that the caveat is that not all hospital services are available. Also, CMS rules state that the patient would need to meet the criteria for reasonable probability of a 24-hour discharge. She said these are the slippery slopes that are going to happen with the development of ESCs.

Duty said he was hearing that the ESC is mostly a buffer for patients needing additional recovery time. For transurethral resection of the prostate (TURP), most patients spend one night in the hospital with a catheter and continuous bladder irrigation. The next day if things look OK, the catheter is removed, or the patient is discharged with the catheter. He said if the ESC is simply a buffer, it would not be appropriate for TURP to be done with an ESC. However, he said if we're looking at doing procedures we wouldn't typically do, a TURP would be reasonable in that setting since the vast majority of people go home within one day and certainly within 48 hours. Gingerich said we are hearing today that it's a buffer, but the public comments from the survey indicated that people were looking to expand the types of procedures offered. Schabel said we should consider for this guideline a recommendation for the ESC to be a buffer for patient comfort and experience rather than an expansion for criteria for an ASC. Duty said the new OHSU Center for Health and Healing (CHH2) would have a huge expansion in procedures offered. Schabel said she believes CHH2 is considered a hospital-affiliated facility. Obley asked whether CHH2 would have 24-hour anesthesia coverage. Schabel said no—it's essentially an ASC. Schabel suggested that HERC could put the 24-hour reasonable expectation of discharge in its guideline, even though it's already in the Medicare rules.

Duty asked whether it's more about anesthesia-related recovery. Schabel said that maybe it's more about patient characteristics, as Riggs suggested earlier in the meeting. The expansion of patient criteria

could now include patients with conditions like sleep apnea that may require nursing observation but not hospital care.

Gingerich gave the example of a TURP patient. If the patient was admitted at 10 a.m. on Monday with the expectation of discharge by 9 a.m. Tuesday, that would meet the ASC requirement, though a provider may be reluctant to do the surgery because it's close to 24 hours. Would the availability of an ESC change the calculus? Duty said it could. Duty said he found an article on hospital visits after urologic ambulatory surgery procedures. The article looked at TURP and there was a 12 percent rate of patients having unexpected hospital visits. With this procedure there is a significant risk of bleeding, so he would be concerned about having to guarantee they would be gone in 23 hours. Schabel said if the reason you are keeping people for observation is a serious condition requiring hospital care, that's not the kind of procedure you'd want to be expanded with an ASC+ESC because it's not a hospital. However, when the concern is sedation, airway protection and other conditions not requiring hospital-based care, expanding procedures or patient selection into those realms would be appropriate. If the potential complication is airway compromise from massive bleeding in the neck, that would not be appropriate. Duty said nursing staff might have perspective on which complications would be reasonable. He'd also have concerns about a catheter being maintained properly. He said it's a tough job for nursing staff to be specialists in all the different procedures.

He asked whether they could take patients back to the operating room in the middle of the night. Bernal said they can. For example, in a breast reconstruction, the patient could return to the operating room to fix the bleed, but the 48 hours provision doesn't restart. And if there is no surgeon and anesthesia coverage available they may need to be transported; Bernal didn't recall anything regarding night hours coverage for anesthesia or surgery.

Engrav said the 24 hours at a hospital is different than at an ASC. In a hospital, after 24 hours it would convert to inpatient, while at an ASC the patient would need to be transported. Because it's a one-day procedure at a hospital doesn't mean it would be appropriate in an ASC. Schabel said we need to discourage thinking that the presence of an ESC would expand the scope of services, though it might expand the scope of patients eligible when the additional care is nursing intensive.

Discussion turned to the risk calculators. The subcommittee looked at the results for several procedures using the ACS NSQIP surgical risk calculator, including laparoscopic Roux-en-Y bariatric surgery, sleeve gastrectomy and knee replacement. Two potential patients were reviewed for each procedure, one being ASA class 3 and under 65 with no other risk factors, and the other patient had a higher BMI, age over 65 and hypertension with a prior heart attack. Schabel noted that the hospital length of stay for knee arthroplasty made sense with data from a few years ago but not today.

Schabel asked about the age ranges. Obley said the ACS risk calculator is only for adults and it is by far the most comprehensive risk calculator available. There are additional procedure-specific calculators.

The subcommittee suggested a few other procedures for the calculator. Schabel said that the utility of this is for hospitalized patients. Gingerich asked about other risk factors that might be tenable for ASC patients. Schabel said only a few—possibly systemic steroid use. Many of the risk factors would preclude ASC surgery. Patients over 85 wouldn't likely be appropriate for an ASC+ESC.

Shaffer asked whether the complication rates that are reported would be helpful for decisionmaking? There was agreement that only complications that would arise during the ESC stay would affect

decisionmaking. Schabel said predicted length of stay may not be helpful as the ASC is a different environment and patient optimization can reduce length of stay. Engrav said that those who own an ASC and have a financial interest in a skilled nursing facility sometimes perform a procedure at an ASC and transfer them to the nursing facility. This is completely unregulated and fraught with hazards and complications. This will likely continue no matter what. Schabel said patients are more often discharged from an ASC to a nursing facility on the East Coast.

Schabel said the whole ASC movement is a financial boon to the people doing it. In particular with arthroplasty, there is high profit potential for a well-run ASC. The conflicts of interest aren't in HERC's scope but they loom large.

Gingerich entered a hypothetical TURP patient in the calculator, undergoing the procedure described by CPT 52601, age 65-74, overweight male who uses tobacco with mild systemic disease, diabetes, and hypertension. The calculator returned a stay of 1.5 days. Duty said if that's the typical length of stay you would expect the patient to be in the hospital. But fundamentally the question is whether the ESC is a buffer or mechanism to do additional procedures. Engrav asked what would happen if the patient had a bleed at 2 a.m. in a hospital. Duty said the patient would return to the operating room. If that couldn't happen at the ASC in the middle of the night, there would need to be an emergency transfer.

Obley asked to put in a healthy patient for an anterior cervical discectomy and fusion (CPT 22551) on the healthiest possible patient. The calculator returned a 1-day length of stay with relatively low risk of complications. For neck dissection (CPT 38720) the length of stay was two days. Schabel said the potential complication is serious bleeding. Members were concerned about the potential risks to the patient. For abdominal hysterectomy (CPT 58150) on a healthy young woman of normal weight and no other risk factors the calculator returned a length of stay of two days.

Discussion turned to the selected procedures to search for observational data. The subcommittee selected five additional procedures. The subcommittee discussed arthroscopy, but decided not to select, since these have been done in ASCs for many years. The complete list of procedures selected is:

- Lumbar laminectomy/foraminectomy
- Cervical laminectomy/foraminectomy
- Lumbar fusion
- Total knee replacements
- total hip replacements
- Cholecystectomy
- Neck dissections
- Mastectomy
- Transurethral resection of the prostate
- Bariatric surgery
- Hysterectomy

Gingerich asked about cardiac catheterization, which is proposed for addition to the ASC list for 2019. Obley said generally you want a cardiothoracic surgeon onsite for these surgeries. Engrav said they have people do a catheterization in rural areas and if they find anything amiss they ship the patient to Portland. Obley said this might be for diagnostic angiograms, and the subcommittee decided not to include this.

Schabel returned to the discussion of what the purpose of the guideline is. Shaffer said it's patient safety. Though the ASC advocates are trying to reassure us, some hospital stakeholders were concerned it could also bring about more complex procedures on more complex patients. Despite the 24-hour box, the boundaries can be stretched. Schabel said we won't have data to specify the boundaries. Obley said the published peer-reviewed literature will be of little help. Schabel said if the literature is about patient experience this doesn't address the concern about expanding the boundaries into unsafe waters.

Schabel said we can let CMS rules guide, except for facilities which don't accept Medicare. It may be appropriate to have a separate section for these. Bernal said that an ESC can only be affiliated with an ASC that is certified by CMS, so they have to meet the Medicare criteria. Schabel said this helps and with that said, we could be done with this now if we want to acknowledge the limits of what evidence is available. We can focus most of our efforts around patient criteria.

Duty said we need anesthesia representation. Schabel also recommended nurses who work in these centers. Schabel asked Engrav whether she's seen patients transferred to the emergency room. Engrav said that she's seen neurosurgeons do a procedure then take the patients directly to a skilled nursing facility, creating a hazard. There have been some other transfers, but an ESC could reduce those transfers for young patients or rural patients. Duty said he has cancelled patients who don't have a ride home.

Schabel said that if we're doing this, it should be for patient comfort and convenience, not to expand the procedures. It could be for patients without a caregiver or a ride home. There was agreement that one day could make a difference.

Shaffer proposed that when using the calculator for the next meeting we design a healthy patient, then include some with some level of complications. There was agreement not to include septic patients, but include complications similar to those discussed earlier.

Shaffer said we will also include additional analysis of the other states' experience including any available data. Schabel said even rates of use or expansion over time would be useful. Obley said we may be able to get that data.

6. ADJOURNMENT

The meeting was adjourned at 4:00 pm. The next scheduled topic is spinal cord stimulators for chronic pain, but due to limited resources, this may not be discussed at the next meeting. The next meeting is scheduled for February 21, 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

MINUTES

Chronic Pain Task Force
Crowne Plaza
Plaza 2 & 3
14811 Kruse Oaks Drive
Lake Oswego, OR 97035
December 5, 2018
9AM-12PM

Members Present: Kevin Cuccaro DO; Laura Ocker Lac; Kim Jones PhD; Nora Stern; Tracy Muday MD; Cat Buist; Holly Jo Hodges MD; David Eisen; Lisa Boyle; Jim Shames MD (via phone); Amber Rose Dullea (via phone); Mitch Haas

Members Absent: David Sibell MD; Andrew Gibler; Amanda Risser MD; Jessica Gregg MD

Staff Present: Ariel Smits, MD, MPH; Darren Coffman; Jason Gingerich; Mark Altenhofen; Dana Hargunani, MD

Also Attending: Michele Koder, Multnomah County Health Department; Amara, Eve Blackburn, Wendy Sinclair, Jacqueline Conner and Caylee Crusta, Oregon Pain Action Group; Shanie Mason, Oregon Medical Association; Cherry Anabison; Amit Shah, MD; Allan Chino, PhD; Laura Stallard; Sue Griffin; Julie Walters; Lisa Shields, OHA

1. CALL TO ORDER

Smits called the meeting to order at 9:05 AM. Roll was called and the minutes reviewed; Haas noted that his name was misspelled. The misspelling will be corrected as soon as possible; the error was regretted. HERC staff will look at older minutes and ensure that his name was spelled correctly and change if needed.

Dana Hargunani, Chief Medical Officer for the Oregon Health Authority (OHA), provided opening remarks.

She expressed appreciation to the many people who have taken interest in the work of the Health Evidence Review Commission and the Chronic Pain Task Force. OHA believes transparency and public engagement lead to better policy.

She stated OHA's main mission is to transform health care to help Oregonians live healthier lives. At the heart of the Chronic Pain Task Force proposal is a goal to expand evidence-based treatment options for patients with 5 chronic pain conditions that are currently not covered by the Oregon Health Plan to improve patient health and safety.

The primary focus of the task force was to develop a recommended benefit package that includes a menu of evidence-based, non-pharmacological pain treatments that are currently unavailable to certain chronic pain patients and should be offered. As part of their work, the Task Force also had to consider

potential coverage of pharmacological treatments for these conditions as well, and to limit coverage of treatments that come with risks of harms.

She noted much of the public input received has been focused on opioid availability. In order to equip the task force with the adequate resources and information to consider and respond to these concerns:

- We have amended the makeup of the Chronic Pain Task Force to strengthen representation from experts in chronic pain and substance use disorder;
- We solicited expert testimony;
- We requested and received an updated evidence review on opioid tapering by OHSU's Center for Evidence-based Policy;
- We requested and received input from CCOs.

She said that we have listened and learned from this public input, expert testimony, additional evidence reviews and CCO feedback and made changes to the proposal being discussed today.

The bottom line is OHA believes that health care delivery depends on trusting and collaborative relationships between patients and providers. As we worked to revise this proposal, preserving that relationship has been on the top of our minds.

All of the proposal elements addressing opioid tapers- such as tapering timelines, rates or ultimate success in getting to zero- are intended to be flexible and able to meet individual patient needs.

She outlined some of the key changes to the proposal:

- Recognizing that long-term opioids may be an appropriate treatment for some patients, the proposal allows for safe and appropriate prescribing for these patients without a taper plan.
- For some chronic pain conditions, opioids have been found to be both ineffective and unsafe, and therefore a taper plan is appropriate. The new proposal recognizes that tapering is an individualized process with shared goals between patients and providers. For these patients, the proposal recommends a taper plan with the goal to zero but would not require a specific timeframe to achieve this goal.
- Based on expert and patient feedback, we emphasized the expectation that taper plans should be individualized with shared goals between patients and providers. The proposal's reference of a suggested taper rate of 5-10% per month was informed through expert input and is only intended to be a goalpost to help providers engage with their patients.
- The proposal now includes language about medication assisted treatment and substance use disorder treatment, which are both currently covered by the Oregon Health Plan. We recognize that some who need to taper may also need SUD treatment.
- To reflect this revised position on tapering, we will ask the HERC to adopt aligning language for the back-pain guidelines.

Dr. Hargunani closed by expressing appreciation for the Task Force's discussion she looks forward to hearing during the meeting.

Nora Stern, task force member and Chair of the Pain Management Commission, added a brief reflection on the work to date. She noted the challenge being faced by the community as the proposal is being developed. She shared that the members are deeply concerned about about this topic and that their main goal is in bringing better pain care to Oregon Medicaid patients.

Stern explained how, historically, we got pain wrong for 400 years. The belief was that pain could only be explained by what was happening to the body. If you couldn't cut out the source of the pain, numb it, or take an x-ray of it, the pain was less real, leading to a lack of coverage for many. Because of this, opioids were often seen as the only service that could be offered. This process is aiming to change that. She believes that this proposal will better align with the understanding of pain today. It is a complex experience that not only it is a result of information coming in from the body, but how the brain processes that information, how much sleep you get, what kind of food you are eating, the activity you are doing/not doing, and an individual's sense of hope/hopelessness. Treatments can now be geared towards addressing all of these pieces of the puzzle. The work of the task force gives us a chance to provide services that haven't previously been available.

Stern understands that some people have not had their pain treated adequately, often for many years, and have primarily been offered opioids. Further, making the prospect of not continuing to get that treatment as they are today a scary proposition. The task force hears these concerns from the community through the testimony received, as well as comments from researchers and clinicians. She hopes that the task force's efforts can act as bridge to get through this transition period towards providing more effective and safer care that is informed by this new understanding of pain. She thanked the community for the extensive public input that has been provided and the task force members and HERC staff for listening carefully and responding by reaching out to get the additional information being presented today to better inform the proposal.

2. REVIEW OF REQUESTED INFORMATION

Smits reviewed the summary of the CCO survey and the OHSU Center for Evidence-based Policy report on opioid tapering. She also reviewed the current fibromyalgia guideline on the Prioritized List that needs to be incorporated into the new proposal.

Kim Jones expressed concern regarding the Pharmacy and Therapeutics Committee review of tramadol for fibromyalgia. She noted several studies that supported use. Amber Rose Dullea noted that tramadol was an aid to help her do things like exercise which really addressed her pain; she felt that tramadol was a tool to an endpoint to manage pain. Dullea felt that tramadol can be really helpful in fibromyalgia even if not studied. Jones will provide the tramadol in fibromyalgia studies to HERC staff; HERC staff will then review with P&T staff to see if these studies should have been included in the P&T review.

3. REVIEW AND DISCUSSION OF POTENTIAL ALTERNATIVES TO THE JUNE CHRONIC PAIN TASK FORCE RECOMMENDATIONS

Smits reviewed the staff suggestions for changes to the Chronic Pain Taskforce recommendation that had been approved in June.

Stern asked whether group visits could be included in the CPT/HCPCS codes for the new line. Smits noted a lack of billing codes for these types of visits. Hodges noted that group visits were part of the contracts with CCOs. There was no discussion regarding the diagnosis codes proposed for the new line.

There was a robust discussion regarding the proposed new guideline. Muday requested that the guideline be formatted as an outline if possible, as this makes it easier for CCOs and reviewers to use. Stern requested that Tai Chi be included, as it is a type of mindful movement like yoga. Jones noted that there are several high quality studies on Tai Chi for fibromyalgia. Hodges noted that it would be very difficult to include a Tai Chi benefit from an administrative standpoint for the CCOs, due to lack of specific CPT code, issues with PAs, etc. Muday concurred that Tai Chi would be very difficult for CCOs to administer as a mandatory benefit. However, she noted that CCOs have the ability to develop community programs that could include Tai Chi. She recommended including it in the CCO flex benefits. Smits noted that Tai Chi could be included under the “supervised exercise” wording in the guideline. Gingerich suggested considering have EGBS or HTAS do a multisector intervention statement on modalities for treating fibromyalgia, to include consideration of Tai Chi. There was strong support for this suggestion among Taskforce members. HERC staff will include this among the recommendations forwarded to VBBS/HERC.

There was discussion about including the wording “or compendia” for non-opioid medications. Hodges wondered if the compendia were available to the CCOs. Gingerich replied that this wording is consistent with federal rebate laws for Medicaid medication benefits. The group was fine with leaving this wording as proposed.

Regarding the section on opioid pain medications, Muday asked whether the required 30% initial improvement should be reduced to 15% to align with the required improvement for non-pharmaceutical interventions. Shames noted that the overall benefits of opioids outweigh the harms at about a 30% improvement level. Cuccaro noted that this discrepancy should be noted and explained when this proposal is presented to VBBS/HERC.

There was discussion regarding whether marijuana use should be included in the opioid section along with “illicit drug use or active substance use disorder.” Some members felt that marijuana should be called out as ok if the use did not rise to a substance use disorder. Hodges noted that the evidence base for marijuana is very limited, so there is not a known safe level of use. The Oregon Medical Board has remained silent on marijuana use in their material risk documentation for opioid use. Muday and Hodges felt that operationally, adding in wording about alcohol or marijuana in this section would be difficult for CCOs. Jones noted that there was a large body of evidence for marijuana for chronic pain, although more studies have been conducted with synthetic cannabis than inhaled cannabis. The CPTF members decided to leave the proposed wording as is.

There was further discussion that the opioid section of the guideline did not require concurrent active therapy, unlike the non-opioid medication section. The CPTF members all felt that adding a clause requiring active therapy be done concurrently with opioids would be beneficial. Smits proposed a clause taken from the back conditions opioid guideline that the group approved.

Next, the group discussed the section indicating that opioid were contraindicated for fibromyalgia, centralized pain syndrome, and patients who do not meet the opioid criteria in the guideline. Haas asked about whether an exception should be made when a patient is stable on their current opioid dose, and when they cannot be tapered to zero. Smits noted that this section specifically addressed

patients for whom opioids are contraindicated; therefore, these patients could not be considered stable until they were on zero opioids. Muday felt that the 5-10% goal reduction would be reasonable for this population. Shames noted that buprenorphine is an option throughout the taper process for patients who are unable to taper further down on their opioids. Dullea stated that she felt the wording in this section, which is stated as a guideline rather than a requirement, was an improvement on the June proposal. The wording as proposed allows a patient and practitioner to work together. She felt that new evidence will hopefully lead to more safe and effective treatments for this population.

There was no discussion on the suggested line scoring or the suggested changes to the revised line 528. Similarly, there was no discussion to the suggested revisions to the back conditions guideline, back opioid guideline, acupuncture guideline or fibromyalgia guideline.

4. PUBLIC TESTIMONY

- 1) Wendy Sinclair: she read a letter from medical experts from Stanford University that had been sent to Gov. Brown.
- 2) Eve Blackburn, a chronic pain patient and advocate. Ms. Blackburn read a letter from the AMA, including their Resolution 235. This letter expressed concerns with forced tapers. She also expressed concern with the inclusion of centralized pain syndrome—how does restrictions on opioids work when a patient has both centralized pain syndrome and another diagnosis that qualifies for opioid therapy? She also requested information on the number of patients whose opioid prescriptions would be affected by the proposed new guideline.
- 3) Amara (no last name given) reviewed a study on opioids and depression and expressed concerns with the conclusions drawn by the Center for Evidence-based Policy (CEbP) regarding this study. She noted that no studies in the CEBP report were of high methodologic quality. She felt that the Task Force has been hearing misinformation of outcomes of taper to below 120 MED, or to zero.
- 4) Jaqueline Conner testified that she felt tapering should be individualized. She was concerned that only certain diagnoses were stated as appropriate for opioids, which is not individualized. She expressed concern that reducing to <50 MED would be individualized between patient and provider. Most patients on opioids long term are on >50 MED, and lower doses are just not enough. She also expressed concern for false positive UDS results. Substance use disorder allows use of methadone, which is an opioid, which is confusing to her.
- 5) Caylee Crusta testified that she benefits from high dose opioids. The guidelines do not take into account very rare conditions. She was also concerned that centralized pain conditions are a subjective term and could be applied to almost any painful condition. Taking away opioids from any person with centralized pain condition is dangerous. She reviewed the Washington Medical Condition guidelines for opioids. 90 MED is not effective for many patients. She requested data on the number of patients whose opioid prescriptions would be affected by the proposed changes. Patients won't know if they are going to be affected because you don't define centralized pain conditions. She felt that these policies will lead to loss of life.
- 6) Sue Griffin, a chronic pain patient, testified that she has taken opioids on and off for 27 years. She feels constant threat that she will have a forced taper based on a guideline. Guidelines don't work in real life as discretionary; doctors are following them due to concern for repercussion.

- 7) Shanie Mason testified on behalf of the Oregon Medical Association. She read a letter from the OMA/AMA regarding concerns with the Taskforce recommendations.
 - 8) Cherry Anabison, a caregiver for family members with severe pain issues, testified about her concerns that differences will be created between OHP coverage and private or Medicare coverage of chronic pain based on the proposed guideline. Oregon will be the only state in the country with such a punitive approach to opioids. Her brother had a forced taper in the VA, which she felt led to his suicide. She feels the Taskforce is underestimating benefits of opioids. What happens when alternate therapies don't work?
 - 9) Allan Chino, a psychologist and past Oregon Pain Management Commission member, testified regarding his work with chronic pain patients. In his experience, there is no problems with addiction to opioids for chronic pain. However, guidelines such as the Taskforce's creates fear among patients and clinicians, which makes outcomes worse. There is a sociocultural movement going on causing fear in patients who are remembering when their pain was not adequately treated.
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5. FINAL DISCUSSION REGARDING PROPOSAL

The group discussed that they felt the revised proposal gets several things right. These include the individualized plans for opioid treatment between prescribers and patients, the inclusion of pain education, the reinforcement that the proposal includes only five specific diagnoses, and that the requirement for providers and patients to review OPMC modules would increase pain knowledge in the medical and patient communities.

Jones felt the lack of inclusion of tramadol for fibromyalgia was something the proposal did not get right. Ocker was concerned that the requirements for non-pharmacologic treatments would create delays in care due to prior authorization issues.

Dullea reflected the fear she heard in the public testimony. The Taskforce has an opportunity to address this fear, but she is afraid that the increase in coverage is not being heard. Many treatments will now newly be available to patients. She also noted the need to be fiscally responsible in our recommendations. She recommended communicating this complexity with the HERC.

6. ADJOURNMENT

The meeting was adjourned at 11:45 am.

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

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 Summary 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

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

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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 clinician-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.

Additional important information/resources

- 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		●
<ul style="list-style-type: none"> ● 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 FIBROMYALGIA, 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 FIBROMYALGIA, 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](http://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx). 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~~

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.

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, dapson, 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 suppurativa as a covered diagnosis for patients enrolled in your insurance plans.

This request is medically necessary for the following reasons:

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- 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 regrettably 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.

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

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-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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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

Hidradenitis Suppurativa

- 2) **Option 2:** add hidradenitis suppurativa to the new severe acne line created for the 2020 Biennial Review Prioritized List
- Rename this line to reflect the additional diagnoses, add ICD-10 and CPT codes as noted below
 - 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
 - Include the new guideline note for hidradenitis suppurativa as in option 1
 - 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

- ICD-10 codes: L70 (acne), L73.2 (Hidradenitis suppurativa)
- 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:

- a reduction of 25% or more in the total abscess and inflammatory nodule count, AND
- 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

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.

Sacroiliac Joint Dysfunction Prioritization

Evidence

Washington HTA 2018, Sacroiliac joint 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] -

Sacroiliac Joint Dysfunction Prioritization

- 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.

Letter from Dr. Saboe:

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

Sacroiliac Joint Dysfunction Prioritization

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.

Sacroiliac Joint Dysfunction Prioritization

Model Prioritization for Sacroiliac 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

Sacroiliac Joint Dysfunction Prioritization

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.

Sacroiliac Joint Dysfunction Prioritization

- 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.](#)

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

Donor Breast Milk Guideline Edits

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 \(HMBANA\).](#)

VbBS Issue Summaries 1/17/2019

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

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

	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

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

	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

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

HERC Staff Summary

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 \$\geq 85^{\text{th}}\$ 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

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.

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

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

Procalcitonin

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.

Procalcitonin

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.

Procalcitonin

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 calprotectin 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.

Fecal Calprotectin

- 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 patients)
 - 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

Fecal Calprotectin

probability of IBD in adults and children. Pre-test probabilities for IBD of $\leq 75\%$ in adults and $\leq 65\%$ in children made FC screening cost-effective, but cost ineffective if the probabilities were $\geq 85\%$ and $\geq 78\%$ 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 $\leq 75\%$ for adults and $\leq 65\%$ for children. The utility of the test is greater for adults than children. Increasing the FC cut-off level to $\geq 50 \mu\text{g/g}$ 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 $>100 \mu\text{g/g}$ indicate endoscopic recurrence with a sensitivity in the range of 89%. In patients with an infliximab-induced remission, fecal calprotectin of $>160 \mu\text{g/g}$ 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

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 FEV₁, 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.

Pulmonary Rehabilitation

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.

Pulmonary Rehabilitation

Expert guidelines

- 1) **ACCP/AACVPR 2007**, evidence based guideline on pulmonary rehabilitation [https://journal.chestnet.org/article/S0012-3692\(16\)30215-X/pdf](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)

Pulmonary Rehabilitation

- 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)

Other coverage policies

- 1) **CMS 2010**, NCD for pulmonary rehabilitation
 - a. Pulmonary rehabilitation is covered if it is 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

Pulmonary Rehabilitation

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*

Pulmonary Rehabilitation

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.

CCO feedback to proposed guideline:

- 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

Pulmonary Rehabilitation

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.

Section 3.0

**Temporary Percutaneous
Mechanical Circulatory
Support With Impella Devices**

Temporary Percutaneous Mechanical Circulatory Support with Impella Devices

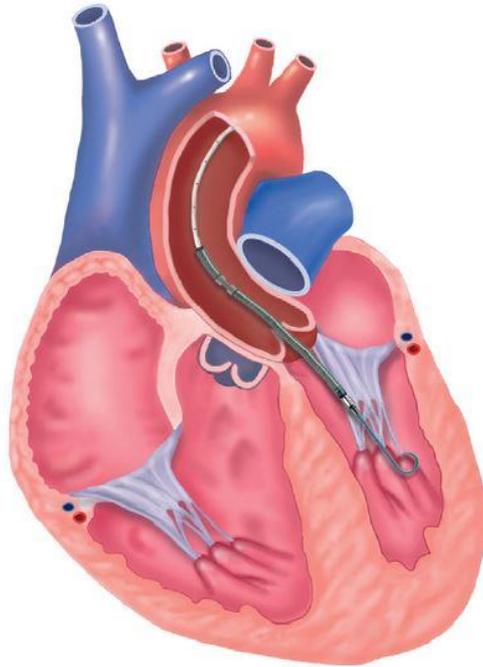
Draft Coverage Guidance for HERC Consideration

January 17, 2019

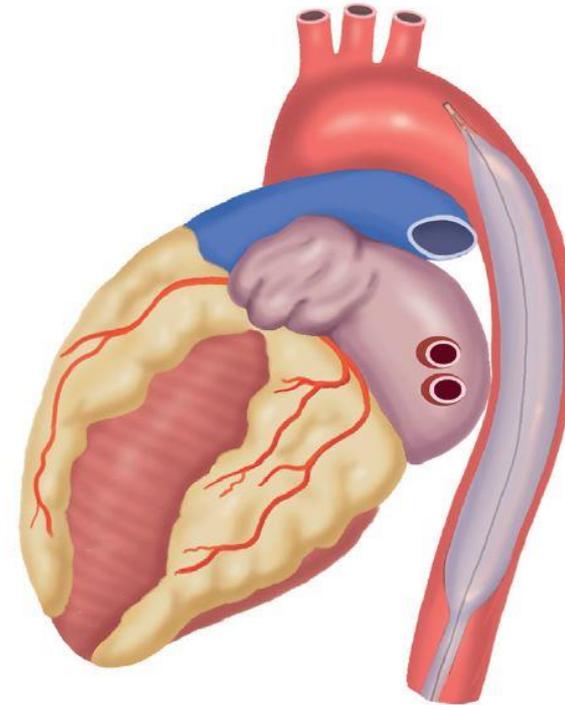
Background

- Temporary mechanical circulatory support (e.g., Impella) is used in patients with cardiogenic shock or who are undergoing elective high-risk coronary interventions
- Intra-aortic balloon pump (IABP) is the most frequently used ventricular assist device (since 1960s) because of ease of insertion and use
 - IABPs appear ineffective
- Impella may offer greater augmentation of cardiac output and left ventricular unloading
 - Decreasing myocardial oxygen consumption and pulmonary capillary wedge pressure, theoretically reducing the size of a myocardial infarction

Background



Impella device



Intra-aortic balloon pump

Source: Ouweneel et al., 2017

Impella has a small pump at one end of a thin, flexible tube with the other end connected to a system outside the body that controls pump rate

Background

- Impella has 5 models: 2.5, CP (or 3.5), RP, 5.0/LD
 - Most frequently used devices are Impella 2.5 and 5.0, capable of increasing cardiac output by up to 2.5 and 5.0 L/min, respectively
- Most Impella devices can be placed percutaneously through the femoral artery (or femoral vein for Impella RP)
 - Impella 5.0 typically requires an arterial cut-down procedure, and the Impella LD is placed during open chest procedures

Scope Statement

- Populations
 - Adults with cardiogenic shock or refractory heart failure (from right heart failure, left heart failure, or biventricular failure) and adults undergoing high-risk percutaneous coronary interventions (PCI)
- Interventions
 - Temporary percutaneous mechanical circulatory support devices (Impella)

Scope Statement

- Comparators
 - Usual care, inotropes, other forms of active circulatory support (i.e., IABP or more permanent left ventricular assist devices), extracorporeal membrane oxygenation (ECMO)

Scope Statement

- Critical Outcomes
 - Mortality
 - Major adverse cardiovascular events
- Important Outcomes
 - Successful bridge to transplantation or bridge to recovery
 - Length of hospitalization
 - Harms

Scope Statement

Key Questions

1. What is the comparative effectiveness of temporary percutaneous mechanical circulatory support in the management of adults with heart failure or cardiogenic shock, or undergoing high-risk PCI?
2. Does the comparative effectiveness of temporary percutaneous mechanical circulatory support vary by:
 - a. Indication for left ventricular support
 - b. Patient characteristics
 - c. Left ventricular function
 - d. Right ventricular function
 - e. Comorbid conditions
 - f. Device flow rate
 - g. Timing and duration of Impella placement
3. What are the harms of temporary percutaneous mechanical circulatory support?

Evidence Sources

- Health Quality Ontario review (2017)
 - High-quality systematic review of the benefits and harms of Impella for high-risk PCI or cardiogenic shock
 - Included studies for high-risk PCI: 1 RCT (PROTECT II), 2 comparative observational studies, 8 non-comparative observational studies
 - Included studies for cardiogenic shock: 1 small RCT, 1 comparative observational study, 6 non-comparative observational studies
- Ait Ichou et al. (2017)
 - Fair-quality systematic review of the effectiveness and safety of Impella devices in patients undergoing high-risk PCI or with cardiogenic shock
 - Included studies: 4 RCTs, 2 comparative observational studies
 - 14 non-comparative observational studies
- Ouweneel et al. (2017)
 - Briefly reported meta-analysis of 3 small RCTs of Impella compared to IABP in patients with cardiogenic shock

Evidence Summary

- On the basis of a relatively small number of comparative studies, the use of Impella devices to support elective high-risk PCI or in the setting of ischemic cardiogenic shock did not improve clinical outcomes compared to IABP
- In some studies of patients with ischemic cardiogenic shock, Impella appears to increase the risk of bleeding and vascular complications compared to IABP, although a wide range of adverse effect rates are reported in the comparative studies
- There were no systematic reviews or RCTs of Impella in the setting of non-ischemic cardiogenic shock

GRADE Table: High-risk PCI

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
All-cause mortality (Critical outcome)	<p>No significant difference in all-cause mortality 7.6% for Impella vs. 5.9% for IABP at 30 days $p = 0.47$</p> <p>12.1% for Impella vs. 8.7% for IABP at 90 days $p = 0.244$</p> <p>●●○○ (Low confidence, based on 1 RCT, n = 448)</p>

GRADE Table: High-risk PCI

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Major adverse cardiovascular events (Critical outcome)	<p>No significant difference in composite outcome of major adverse events (including repeat revascularization): 35.1% for Impella vs. 40.1% for IABP at 30 days $p = 0.227$</p> <p>40.6% for Impella vs. 49.3% for IABP at 90 days $p = 0.066$</p> <p>●●○○ (Low confidence, based on 1 RCT, n = 448)</p>

GRADE Table: High-risk PCI

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Successful bridge to recovery (Important outcome)	Not applicable
Successful bridge to transplant (Important outcome)	Not applicable
Harms (Important outcome)	<p>No significant difference in major bleeding complications between Impella and IABP ●○○○ (Very low confidence, based on 1 observational study, n = 75)</p> <p>No significant difference in vascular complications between Impella and IABP ●○○○ (Very low confidence, based on 1 observational study, n = 75)</p>

GRADE Table: Cardiogenic Shock

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
All-cause mortality (Critical outcome)	<p>No significant difference in all-cause mortality 40.8% for Impella vs. 41.3% for IABP at 30 days RR 0.99 (95% CI 0.62 to 1.58, p = 0.95)</p> <p>46.9% for Impella vs. 41.3% for IABP at 6 months RR 1.15 (95% CI 0.74 to 1.48, p = 0.53)</p> <p>●●○○ (Low confidence, based on 3 RCTs, n = 95)</p>

GRADE Table: Cardiogenic Shock

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Major adverse cardiovascular events (Critical outcome)	<p>No significant difference in major adverse cardiovascular events</p> <p>26% for Impella vs. 33% for IABP at 4 months $p = 0.74$</p> <p>37% for Impella vs. 47% for IABP at 12 months $p = 0.72$</p> <p>●○○○ (Very low confidence, based on 1 RCT, $n = 21$)</p>

GRADE Table: Cardiogenic Shock

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Successful bridge to recovery (Important outcome)	Insufficient data
Successful bridge to transplant (Important outcome)	Insufficient data
Harms (Important outcome)	<p>Range of reported vascular complications Impella: 3% to 25% IABP: 0% to 6.4% ●○○○ (Very low confidence, based on 4 studies, n = 222)</p> <p>Range of reported bleeding complications Impella: 8% to 38.4% IABP: 0% to 32.2% ●○○○ (Very low confidence, based on 5 studies, n = 272)</p>

GRADE Table: PCI for acute myocardial infarction without cardiogenic shock

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
All-cause mortality (Critical outcome)	Insufficient data
Major adverse cardiovascular events (Critical outcome)	Insufficient data
Successful bridge to recovery (Important outcome)	Insufficient data
Successful bridge to transplant (Important outcome)	Insufficient data
Harms (Important outcome)	Insufficient data

Payer Policies

- Washington State Medicaid Program
 - Provides coverage for FDA-approved percutaneous left ventricular assist devices for these indications:
 - Short-term circulatory support in cardiogenic shock
 - As an adjunct to PCI in the following high-risk patients:
 - Clients undergoing unprotected left main or last-remaining-conduit PCI with ejection fraction less than 35%
 - Clients with three vessel disease and diastolic ejection fraction less than 30%
- Medicare
 - No Medicare National Coverage Determination or Local Coverage Determinations were found for percutaneous mechanical circulatory support

Payer Policies

- Private Payers
 - Aetna provides coverage for Impella for these indications:
 - Short-term circulatory support in cardiogenic shock
 - As an adjunct to PCI in high-risk patients
 - Cigna provides the following coverage for Impella:
 - Up to 14 days in a child or adult with a BSA $\geq 1.5\text{m}^2$ for the treatment of acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery
 - For the treatment of cardiogenic shock for up to 6 hours
 - Moda requires prior authorization for left ventricular assist devices
 - Regence policy on ventricular assist devices states that the policy does not address the use of percutaneous ventricular assist devices, which may be considered medically necessary

Guidelines

- 3 guidelines were identified:
 - Guideline for the Management of ST-Elevation Myocardial Infarction published in 2013 by the American College of Cardiology Foundation and American Heart Association Task Force on Practice Guidelines
 - Alternative left ventricular assist devices for circulatory support may be considered in patients with refractory cardiogenic shock
 - Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care published by the Society for Cardiovascular Angiography and Interventions, American College of Cardiology Foundation, Heart Failure Society of America, and Society for Thoracic Surgery
 - Percutaneous mechanical circulatory support may be considered in carefully selected patients with severe hemodynamically unstable cardiovascular presentations

Guidelines

- 3 guidelines were identified: *(cont.)*
 - 2013 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support
 - Use of temporary mechanical support should be strongly considered in patients with multiorgan failure, sepsis, or on mechanical ventilation to allow successful optimization of clinical status and neurologic assessment prior to placement of a long-term mechanical circulatory support device

Public Comment

- 8 public comments submitted, mostly from providers, and Abiomed (manufacturer of Impella)
- Comment: Concerns about comparing Impella 2.5 to those with greater circulatory support
 - Response: All Impella devices except the 5.0 (which requires an arterial cutdown) were included; no evidence was found on differential effectiveness of various models
- Comment: Some non-comparative studies showed improvements in outcomes
 - Response: Standard methodology does not include non-comparative case series

Public Comment

- Comment: Clinical practice guidelines recommend use of these devices; some guidelines were not included
 - Response: Guidelines from International Society for Heart & Lung Transplant were added to the coverage guidance; the other cited recommendations were not from guidelines
- Comment: Commercial payers cover this
 - Response: C5, E3, G2 Standard methodology is to include the coverage policies for Medicare, WA Medicaid, Aetna, Cigna and Moda, and these policies were considered in the deliberations of this coverage guidance.

Public Comment

- Comment: There are several RCTs of IABP in patients with cardiogenic shock that have shown no clinical benefit of IABP
 - Response: IABP was a comparator in all of the RCTs of Impella for ischemic cardiogenic shock, and Impella was not found to be superior to IABP
- Comment: Patients who are inoperable (i.e., not eligible for coronary artery bypass graft) could only have PCI with Impella support
 - Response: The studies did not include subgroup analyses for inoperable patients; with the noncoverage recommendation, patients may not have access to PCI without Impella support; however, there may be no mortality benefit to PCI for many of these patients

Discussion: High-risk PCI

Values and Preferences

Patients would strongly prefer interventions that improve their outcomes (with regard to death or MACE) and have fewer harms. The mechanism by which this is achieved (i.e., IABP or Impella) is unlikely to be important to patients. There is likely to be low variability in these values and preferences.

Resource Allocation

Impella is extremely expensive and may cost as much as 20 times more than an IABP.

Discussion: High-risk PCI

Balance of Benefits and Harms

We have low confidence that there is no difference between Impella and IABP in terms of all cause-mortality and MACE and very low confidence of no difference in complications between major bleeding and vascular complications. The balance suggests no net benefit and no net harms based on limited evidence.

Discussion: High-risk PCI

Rationale

We make a recommendation against coverage for elective high-risk PCI in stable coronary artery disease because there appears to be no benefit for Impella over IABP and no difference in complications. Impella is much more expensive than the comparator, and patient values and preferences would not lean toward either direction. It is a strong recommendation because Impella appears to offer no benefit over the current standard of care at a much greater cost.

Discussion: High-risk PCI

Temporary percutaneous mechanical circulatory support with Impella devices is not recommended for coverage in elective high-risk percutaneous coronary intervention (PCI) for patients with stable coronary artery disease (*weak recommendation*).

Discussion: Cardiogenic Shock

Values and Preferences

Patients would strongly prefer interventions that improve their outcomes (with regard to death or MACE) and have fewer harms. The mechanism by which this is achieved (i.e., IABP or Impella) is unlikely to be important to patients. There is likely to be low variability in these values and preferences.

Resource Allocation

Impella is extremely expensive and may be as much as 20 times more than an IABP.

Other Considerations

There was insufficient evidence to include in the GRADE table for non-ischemic cardiogenic shock. There were no studies found examining patients bridging to LVAD or transplant.

Discussion: Cardiogenic Shock

Balance of Benefits and Harms

We have low confidence that there is no difference between Impella and IABP in terms of all-cause mortality, and very low confidence that there is no difference in MACE. We have very low confidence that significant harms (such as bleeding, stroke, and vascular events) are greater with Impella compared to IABP. The evidence reviewed suggests that the balance is neutral to negative for Impella in ischemic cardiogenic shock. Insufficient evidence was found for non-ischemic cardiogenic shock to make an assessment of the balance of benefits and harms.

Discussion: Cardiogenic Shock

Rationale

We recommend against Impella for ischemic cardiogenic shock because of a lack of proven benefit, possibility of greater significant harms, and significant increase in resource allocation compared to IABP. No studies were found for non-ischemic cardiogenic shock, and so the recommendation applies to all types of cardiogenic shock.

Patients who are candidates for LVAD or bridging to a transplant are an unstudied population, but it might be appropriate to consider Impella on an individual basis, based on expert opinion.

Discussion: Cardiogenic Shock

Temporary percutaneous mechanical circulatory support with Impella devices is recommended for coverage (*weak recommendation*) only for patients with cardiogenic shock who might be candidates for left ventricular assist device (LVAD) (destination therapy) or transplant (bridge to transplant), AND an advanced heart failure and transplant cardiologist agrees that Impella should be used as a bridge to a decision for LVAD or a transplant.

Discussion: High-risk elective PCI

Values and Preferences

Patients with acute myocardial infarction would likely strongly prefer an intervention thought to result in survival benefit. If Impella were thought to be necessary to allow revascularization for high-risk patients, their preferences would likely be in favor of Impella.

Resource Allocation

Impella is extremely expensive and may be as much as 20 times more than an IABP.

Discussion: High-risk elective PCI

Other Considerations

An RCT of these populations is feasible, however, given widespread use of Impella in current practice, might not be performed.

Balance of Benefits and Harms

There is insufficient evidence to evaluate the balance of benefits and harms. Expert opinion indicates that protected PCI might provide a significant survival benefit in patients with NSTEMI who are not eligible for CABG.

Discussion: High-risk elective PCI

Rationale

Patients with NSTEMI and low ejection fraction are an unstudied population for whom expert opinion indicates that protected PCI might provide a significant survival benefit and PCI might not otherwise be done without Impella devices. Although resource allocation and the lack of evidence would argue against coverage, values and preferences and expert opinion suggest in this carefully selected population a true survival benefit may exist. The coverage recommendation is weak because of the lack of evidence.

There was no evidence in patients with NSTEMI without shock, but this population is very likely to be revascularized regardless of their risk. Given that the availability of Impella is unlikely to change whether or not a patient is going to be revascularized, and given the lack of evidence and the high cost, a recommendation is not made for coverage.

Discussion: High-risk elective PCI

Temporary percutaneous mechanical circulatory support with Impella devices during PCI is recommended for coverage (*weak recommendation*) only for patients with acute myocardial infarction when all of the following conditions are met:

- NSTEMI without cardiogenic shock
- A heart team discussion determines that the patient needs revascularization with CABG or PCI
- Two cardiothoracic surgeons are consulted and agree that the patient is inoperable (i.e., surgeons are not willing to perform CABG, but agree that revascularization is indicated)
- Patient has complex left main or last remaining conduit disease
- Ejection fraction less than 30%

Health Evidence Review Commission (HERC)

Coverage Guidance: Temporary Percutaneous Mechanical Circulatory Support with Impella Devices

DRAFT for 1/17/2019 VbBS/HERC meeting materials

HERC Coverage Guidance

Temporary percutaneous mechanical circulatory support with Impella devices is not recommended for coverage in elective high-risk percutaneous coronary intervention (PCI) for patients with stable coronary artery disease (*weak recommendation*).

Temporary percutaneous mechanical circulatory support with Impella devices during PCI is recommended for coverage (*weak recommendation*) only for patients with acute myocardial infarction when all of the following conditions are met:

- Non-ST-elevation myocardial infarction (NSTEMI) without cardiogenic shock
- A heart team discussion determines that the patient needs revascularization with CABG or PCI
- Two cardiothoracic surgeons are consulted and agree that the patient is inoperable (i.e., surgeons are not willing to perform CABG, but agree that revascularization is indicated)
- Patient has complex left main or last remaining conduit disease
- Ejection fraction less than 30%

Temporary percutaneous mechanical circulatory support with Impella devices is recommended for coverage (*weak recommendation*) only for patients with cardiogenic shock who might be candidates for left ventricular assist device (LVAD) (destination therapy) or transplant (bridge to transplant), AND an advanced heart failure and transplant cardiologist agrees that Impella should be used as a bridge to a decision for LVAD or a transplant.

Note: Definitions for strength of recommendation are in Appendix A. GRADE Table Element Description. 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.

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.

DRAFT

GRADE Table

Should temporary percutaneous mechanical circulatory support (i.e., Impella) be recommended for coverage for elective high-risk percutaneous coronary intervention?

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>	Resource Allocation	Values and Preferences	Other Considerations
All-cause mortality <i>(Critical outcome)</i>	No significant difference in all-cause mortality 7.6% for Impella vs. 5.9% for intra-aortic balloon pump (IABP) at 30 days p = 0.47 12.1% for Impella vs. 8.7% for IABP at 90 days p = 0.244 ●○○○ <i>(Low confidence, based on 1 RCT, n = 448)</i>	Impella is extremely expensive and may cost as much as 20 times more than an IABP.	Patients would strongly prefer interventions that improve their outcomes (with regard to death or major adverse cardiac events [MACE]) and have fewer harms. The mechanism by which this is achieved (i.e., IABP or Impella) is unlikely to be important to patients. There is likely to be low	

Should temporary percutaneous mechanical circulatory support (i.e., Impella) be recommended for coverage for elective high-risk percutaneous coronary intervention?

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>	Resource Allocation	Values and Preferences	Other Considerations
Major adverse cardiovascular events <i>(Critical outcome)</i>	No significant difference in composite outcome of major adverse events (including repeat revascularization): 35.1% for Impella vs. 40.1% for IABP at 30 days p = 0.227 40.6% for Impella vs. 49.3% for IABP at 90 days p = 0.066 ●●○○ (Low confidence, based on 1 RCT, n = 448)		variability in these values and preferences.	
Successful bridge to recovery <i>(Important outcome)</i>	Not applicable			
Successful bridge to transplant <i>(Important outcome)</i>	Not applicable			

Should temporary percutaneous mechanical circulatory support (i.e., Impella) be recommended for coverage for elective high-risk percutaneous coronary intervention?

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource Allocation	Values and Preferences	Other Considerations
Harms (Important outcome)	<p>No significant difference in major bleeding complications between Impella and IABP ●○○○ (Very low confidence, based on 1 observational study, n = 75)</p> <p>No significant difference in vascular complications between Impella and IABP ●○○○ (Very low confidence, based on 1 observational study, n = 75)</p>			

Balance of benefits and harms: We have low confidence that there is no difference between Impella and IABP in terms of all cause-mortality and MACE and very low confidence of no difference in complications between major bleeding and vascular complications. The balance suggests no net benefit and no net harms based on limited evidence.

Rationale: We make a recommendation against coverage for elective high-risk PCI in stable coronary artery disease because there appears to be no benefit for Impella over IABP and no difference in complications. Impella is much more expensive than the comparator, and patient values and preferences would not lean toward either direction. It is a strong recommendation because Impella appears to offer no benefit over the current standard of care at a much greater cost.

Recommendation: Temporary percutaneous mechanical circulatory support with Impella devices is not recommended for coverage for patients receiving elective high-risk PCI (*weak recommendation*).

Temporary percutaneous mechanical circulatory support with Impella devices during PCI is recommended for coverage for patients with acute NSTEMI without cardiogenic shock (*weak recommendation*) when all of the following conditions are met:

- A heart team discussion determines that the patient needs revascularization with CABG or PCI.
- Two cardiothoracic surgeons are consulted and agree that the patient is inoperable (i.e., surgeons are not willing to perform CABG, but agree that revascularization is indicated).
- Patient has complex left main or last remaining conduit disease
- Ejection fraction less than 30%

Should temporary percutaneous mechanical circulatory support (i.e., Impella) be recommended for coverage for cardiogenic shock?

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource Allocation	Values and Preferences	Other Considerations
All-cause mortality <i>(Critical outcome)</i>	No significant difference in all-cause mortality 40.8% for Impella vs. 41.3% for IABP at 30 days RR 0.99 (95% CI 0.62 to 1.58, p = 0.95) 46.9% for Impella vs. 41.3% for IABP at 6 months RR 1.15 (95% CI 0.74 to 1.48, p = 0.53) ●●○○ (Low confidence, based on 3 RCTs, n = 95)	Impella is extremely expensive and may be as much as 20 times more than an IABP.	Patients would strongly prefer interventions that improve their outcomes (with regard to death or MACE) and have fewer harms. The mechanism by which this is achieved (i.e., IABP or Impella) is unlikely to be important to patients. There is likely to be low variability in these values and preferences.	There was insufficient evidence to include in the GRADE table for non-ischemic cardiogenic shock. There were no studies found examining patients bridging to LVAD or transplant.
Major adverse cardiovascular events <i>(Critical outcome)</i>	No significant difference in major adverse cardiovascular events 26% for Impella vs. 33% for IABP at 4 months p = 0.74 37% for Impella vs. 47% for IABP at 12 months p = 0.72 ●○○○ (Very low confidence, based on 1 RCT, n = 21)			
Successful bridge to recovery <i>(Important outcome)</i>	Insufficient data			

Should temporary percutaneous mechanical circulatory support (i.e., Impella) be recommended for coverage for cardiogenic shock?

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource Allocation	Values and Preferences	Other Considerations
Successful bridge to transplant (Important outcome)	Insufficient data			
Harms (Important outcome)	<p>Range of reported vascular complications Impella: 3% to 25% IABP: 0% to 6.4% ●○○○ (Very low confidence, based on 4 studies, n = 222)</p> <p>Range of reported bleeding complications Impella: 8% to 38.4% IABP: 0% to 32.2% ●○○○ (Very low confidence, based on 5 studies, n = 272)</p>			

Balance of benefits and harms: We have low confidence that there is no difference between Impella and IABP in terms of all-cause mortality, and very low confidence that there is no difference in MACE. We have very low confidence that significant harms (such as bleeding, stroke, and vascular events) are greater with Impella compared to IABP. The evidence reviewed suggests that the balance is neutral to negative for Impella in ischemic cardiogenic shock. Insufficient evidence was found for non-ischemic cardiogenic shock to make an assessment of the balance of benefits and harms.

Rationale: We recommend against Impella for ischemic cardiogenic shock because of a lack of proven benefit, possibility of greater significant harms, and significant increase in resource allocation compared to IABP. No studies were found for non-ischemic cardiogenic shock, and so the recommendation applies to all types of cardiogenic shock.

Patients who are candidates for LVAD or bridging to a transplant are an unstudied population, but it might be appropriate to consider Impella on an individual basis, based on expert opinion.

Should temporary percutaneous mechanical circulatory support (i.e., Impella) be recommended for coverage for cardiogenic shock?

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>	Resource Allocation	Values and Preferences	Other Considerations
<p>Recommendation: Temporary percutaneous mechanical circulatory support with Impella devices is recommended for coverage (<i>weak recommendation</i>) in cardiogenic shock only in patients who might be candidates for LVAD (destination therapy) or a transplant (bridge to transplant), AND an advanced heart failure and transplant cardiologist agrees that Impella should be used as a bridge to decision for LVAD or a transplant.</p>				

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Should temporary percutaneous mechanical circulatory support (i.e., Impella) be recommended for coverage to support PCI for acute myocardial infarction without cardiogenic shock?

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>	Resource Allocation	Values and Preferences	Other Considerations
All-cause mortality <i>(Critical outcome)</i>	Insufficient data	Impella is extremely expensive and may be as much as 20 times more than an IABP.	Patients with acute myocardial infarction would likely strongly prefer an intervention thought to result in survival benefit. If Impella were thought to be necessary to allow revascularization for high-risk patients, their preferences would likely be in favor of Impella.	An RCT of these populations is feasible, however, given widespread use of Impella in current practice, might not be performed.
Major adverse cardiovascular events <i>(Critical outcome)</i>	Insufficient data			
Successful bridge to recovery <i>(Important outcome)</i>	Insufficient data			
Successful bridge to transplant <i>(Important outcome)</i>	Insufficient data			
Harms <i>(Important outcome)</i>	Insufficient data			

Balance of benefits and harms: There is insufficient evidence to evaluate the balance of benefits and harms. Expert opinion indicates that protected PCI might provide a significant survival benefit in patients with NSTEMI who are not eligible for CABG.

Should temporary percutaneous mechanical circulatory support (i.e., Impella) be recommended for coverage to support PCI for acute myocardial infarction without cardiogenic shock?

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>	Resource Allocation	Values and Preferences	Other Considerations
<p>Rationale: Patients with NSTEMI and low ejection fraction are an unstudied population for whom expert opinion indicates that protected PCI might provide a significant survival benefit and PCI might not otherwise be done without Impella devices. Although resource allocation and the lack of evidence would argue against coverage, values and preferences and expert opinion suggest in this carefully selected population a true survival benefit may exist. The coverage recommendation is weak because of the lack of evidence.</p> <p>There was no evidence in patients with NSTEMI without shock, but this population is very likely to be revascularized regardless of their risk. Given that the availability of Impella is unlikely to change whether or not a patient is going to be revascularized, and given the lack of evidence and the high cost, a recommendation is not made for coverage.</p>				
<p>Recommendation: Temporary percutaneous mechanical circulatory support with Impella devices during PCI is recommended for coverage (<i>weak recommendation</i>) only for patients with acute myocardial infarction when all of the following conditions are met:</p> <ul style="list-style-type: none"> • NSTEMI without cardiogenic shock • A heart team discussion determines that the patient needs revascularization with CABG or PCI • Two cardiothoracic surgeons are consulted and agree that the patient is inoperable (i.e., surgeons are not willing to perform CABG, but agree that revascularization is indicated) • Patient has complex left main or last remaining conduit disease • Ejection fraction less than 30% 				

Note: GRADE table elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.

Background

Temporary mechanical circulatory support may be needed in patients with cardiogenic shock or who are undergoing elective high-risk coronary interventions. The intra-aortic balloon pump (IABP) has been the most frequently used ventricular assist device since its introduction in the 1960s because of the ease of insertion and use (Ait Ichou, 2017). For some patients in severe cardiogenic shock with a systolic aortic pressure that cannot be improved to more than 60 mmHg by vasopressors, the IABP might not provide sufficient circulatory support (Ait Ichou, 2017). Temporary percutaneous mechanical circulatory support devices, such as Impella, offer greater augmentation of cardiac output and left ventricular unloading. It has been hypothesized that these hemodynamic advantages would result in improved clinical outcomes. Other circulatory support devices (not in scope for this Coverage Guidance) require open surgery or septal puncture, and could be appropriate for longer-term use.

Indications

Temporary percutaneous mechanical circulatory support devices are indicated for patients in cardiogenic shock and those undergoing elective high-risk percutaneous coronary interventions (PCI).

Technology Description

Impella is a device for mechanical circulatory support that has a small pump at one end of a thin, flexible tube and is implanted through an artery in the leg. The other end of the tube is connected to a control system outside the body that controls the pump rate (Health Quality Ontario, 2017). Impella works by increasing the maximal blood flow by unloading blood from the left ventricle into the ascending aorta, resulting in improved coronary perfusion pressure and end-organ perfusion. In addition to increasing cardiac output, it also decreases myocardial oxygen consumption and pulmonary capillary wedge pressure, potentially reducing the size of a myocardial infarction and accelerating its recovery (Ait Ichou, 2017).

Impella has four models: 2.5, CP (or 3.5), RP, and 5.0/LD (Abiomed, 2018). The most frequently used devices, Impella 2.5 and 5.0, are capable of increasing cardiac output by up to 2.5 and 5.0 L/min, respectively (Ait Ichou, 2017). Most Impella devices can be placed percutaneously through the femoral artery (or the femoral vein for Impella RP), but the Impella 5.0 typically requires an arterial cut-down procedure, and the Impella LD is placed during open chest procedures (Ait Ichou, 2017).

In 2015, the U.S. Food and Drug Administration (FDA) granted premarket approval to Impella 2.5 (FDA, 2015). This approval order stated that Impella was indicated for temporary (< 6 hours) ventricular support during high-risk PCI performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease and depressed left ventricular ejection fraction (LVEF) (FDA, 2015). A 2016 supplemental order from the FDA approved Impella for patients experiencing ongoing cardiogenic shock immediately (< 48 hours) after acute myocardial infarction or open-heart surgery for the Impella Ventricular Support Systems (FDA, 2016). A February 2018 supplemental order expanded the indications to include patients with ongoing cardiogenic shock in the setting of cardiomyopathy, including peripartum cardiomyopathy or myocarditis (FDA, 2018).

Evidence Review

Our search identified two systematic reviews and one briefly reported meta-analysis for inclusion. Because of the small number of comparative studies of Impella and because of the incomplete overlap of included studies (see Table 1) in the reviews, the individual comparative studies included in those reviews are summarized in Tables 2-4. The characteristics of the individual comparative studies are summarized in Table 2 and their relevant outcomes are summarized in Tables 3 and 4.

The Health Quality Ontario review (2017) is a high-quality systematic review and health technology assessment of the benefits and harms of Impella for high-risk PCI or cardiogenic shock. For the high-risk PCI group, the authors identified one randomized controlled trial (RCT) (O'Neill et al., 2012), two comparative observational studies (Boudoulas et al., 2012; Schwartz et al., 2011), and eight non-comparative observational studies. The authors assessed the risk of bias in the RCT to be moderate because of insufficient statistical power, concern for selection bias, and early termination of the trial due to futility. The comparative observational studies were limited by selection bias, insufficient adjustment for confounding, and high rates of loss to follow-up.

For the cardiogenic shock group, the authors identified one small RCT (Seyfarth et al., 2011), one comparative observational study (Manzo-Silberman et al., 2013), and six non-comparative observational studies. The RCT was assessed to be at high risk of bias due to small sample size and the risk of model misclassification, as well as imbalance in baseline characteristics. The comparative observational study was judged to be at moderate risk of bias because of selection bias (including an imbalance in baseline LVEF between cohorts) and potential treatment bias due to a high degree of physician discretion in managing the patients. The relevant results from the included comparative studies are summarized in Tables 3 and 4 below. Applying a GRADE methodology, the authors of the review concluded that there was:

- No difference in 30-day mortality or MACE between Impella 2.5 and IABP for high-risk PCI (low strength of evidence)
- No difference in bleeding or vascular complications between Impella 2.5 and IABP for high-risk PCI (very low strength evidence)
- No difference in 30-day mortality or MACE between Impella 2.5 and IABP for cardiogenic shock (low strength of evidence)
- Significantly higher rate of hemolysis with Impella 2.5 compared to IABP for cardiogenic shock (low strength of evidence)
- No difference in vascular complications between Impella 2.5 and IABP for cardiogenic shock (low strength of evidence)

The review by Ait Ichou et al. (2017) is a fair-quality systematic review of the effectiveness and safety of Impella devices in patients undergoing high-risk PCI. The review is mainly limited by incomplete reporting of risk of bias assessments. The authors identified four RCTs (Seyfarth et al., 2008; O'Neill et al., 2012; Ouweneel et al., 2017b; Ouweneel et al., 2016), two comparative observational studies (Boudoulas et al., 2012; Schwartz et al., 2011), and 14 non-comparative observational studies, for a total of 1,287 patients. The authors judged three of the RCTs to be at low risk of bias and one (Ouweneel et al., 2016) to be at high risk of bias due to early termination and changes to inclusion criteria during recruitment. The two comparative observational studies were considered to be at high risk of bias

because of their design and the likelihood of confounding by indication. All of the non-comparative observational studies were regarded as having serious or critical risk of bias. The relevant results from the included comparative studies are summarized in Tables 3 and 4 below.

Overall, the authors concluded that there were no differences in all-cause mortality between Impella and IABP, but noted a possible reduction in major adverse events at 90 days in a per-protocol analysis of the PROTECTII trial (O'Neill et al., 2012). They observed high levels of clinical heterogeneity in the studies and that most studies were inadequately powered to detect differences in clinical events. Finally, the authors asserted the need for larger RCTs to better clarify the clinical effectiveness and safety of Impella, and noted that one such trial (DANSHOCK, NCT01633502) is currently underway.

The review by Ouweneel et al. (2017a) is a briefly reported meta-analysis that combines the results of the three small RCTs of Impella compared to IABP in patients with cardiogenic shock (Seyfarth et al., 2008; O'Neill et al., 2012; Ouweneel et al., 2017b; Ouweneel et al., 2016). The total population of these studies was 95 patients. In the meta-analysis (it is not stated whether a fixed or random effects model was used), there was no difference in all-cause mortality at 30 days (RR 0.99, 95% CI 0.62 to 1.58) or at six months (RR 1.15, 95% CI 0.74 to 1.48). There was also no difference in LVEF of survivors between the two groups at two to six months.

Our search did not identify any additional RCTs published after the most recent systematic review (Ait Ichou et al., 2017). Additionally, the search did not identify any systematic reviews or RCTs examining the use of Impella in the setting of acute non-ischemic cardiogenic shock.

Evidence Summary

On the basis of a relatively small number of comparative studies, the use of Impella devices to support elective high-risk PCI or in the setting of ischemic cardiogenic shock did not improve clinical outcomes compared to IABP. In some studies of patients with ischemic cardiogenic shock, Impella appears to increase the risk of bleeding and vascular complications compared to IABP, although a wide range of adverse effect rates are reported in the comparative studies. There were no systematic reviews or RCTs of Impella in the setting of non-ischemic cardiogenic shock.

Table 1. Studies Included in Systematic Reviews

	Seyfarth 2008 (Risk of bias assessment)	O’Neill 2012 (Risk of bias assessment)	Ouweneel 2017b (Risk of bias assessment)	Ouweneel 2016 (Risk of bias assessment)	Schwartz 2011 (Risk of bias assessment)	Manzo-Silberman 2013 (Risk of bias assessment)	Boudoulas 2012 (Risk of bias assessment)
Ait Ichou 2017	X (Low)	X (Low)	X (Low)	X (High)	X (Serious)		X (Serious)
Ouweneel 2017a	X (Not rated)		X (Not rated)	X (Not rated)			
Health Quality Ontario 2017	X (High)	X (Moderate)			X (Moderate)	X (Moderate)	X (Moderate)

Table 2. Characteristics of Individual Comparative Studies

	Study type Setting	Population	Intervention (N) Comparator (N)
Seyfarth 2008	Randomized controlled trial 2 centers in Germany	Adults with acute myocardial infarction < 48 hours and cardiogenic shock	Impella 2.5 (13) IABP (13)
Schwartz 2011	Retrospective cohort Single center	Adults undergoing high-risk PCI supported with Impella, IABP, or TandemHeart between 2008 and 2010	Impella 2.5 (13) TandemHeart (32) IABP (5)
Boudoulas 2012	Retrospective cohort Single center	All patients with ACS undergoing high-risk PCI supported with Impella 2.5 or IABP between 2008 and 2010	Impella 2.5 (12) IABP (62)

	Study type Setting	Population	Intervention (N) Comparator (N)
O'Neill 2012	Randomized controlled trial 112 centers in the US, Canada, and Germany	Adults undergoing high-risk elective PCI (defined as unprotected left main or last patent vessel with LVEF < 35% or 3 vessel disease with LVEF < 30%)	Impella 2.5 (225) IABP (223)
Manzo-Silberman 2013	Retrospective cohort Single center	Adult survivors of out-of-hospital cardiac arrest and post-resuscitation shock supported with Impella or IABP after coronary angiography between 2007 and 2010	Impella 2.5 (35) IABP (43)
Ouweneel 2017b	Randomized controlled trial	Adults with STEMI and severe cardiogenic shock (SBP < 90 mmHg for more than 30 minutes or need for inotropes or vasopressors to maintain SBP > 90 mmHg), and requiring mechanical ventilation	Impella CP (24) IABP (24)
Ouweneel 2016	Randomized controlled trial 5 centers	Adults with anterior STEMI and cardiogenic pre-shock (defined as HR > 100 and/or SBP < 100 mmHg with clinical signs of shock)	Impella 2.5 (11) IABP (9)

Table 3. Outcomes from RCTs

	All-cause mortality, 30 days	All-cause mortality, 90-360 days	MACE, 30 days	MACE, 90-360 days	Adverse events
Seyfarth 2008 n = 26	46% Impella 46% IABP	NR	NR	NR	1 case of acute limb ischemia following Impella removal RBC transfusion requirement (mean) 2.6 units Impella

	All-cause mortality, 30 days	All-cause mortality, 90-360 days	MACE, 30 days	MACE, 90-360 days	Adverse events
					1.2 units IABP
O'Neill 2012 n = 448	7.6% Impella 5.9% IABP	12.1% Impella 8.7% IABP (at 90 days)	35.1% Impella 40.1% IABP (outcome defined as major adverse events)	40.6% Impella 49.3% IABP (outcome defined as major adverse events at 90 days)	NR
Ouweneel 2017b n = 48	46% Impella 50% IABP	50% Impella 50% IABP	NR	NR	Stroke 4.2% Impella 4.2% IABP Major vascular event 4.2% Impella 0% IABP Bleeding 33.3% Impella 8.3% IABP
Ouweneel 2016 n = 21	NR	26% Impella 11% IABP (at 4 months)	NR	26% Impella 33% IABP (at 4 months)	Severe vascular events 25% Impella 0% IABP

	All-cause mortality, 30 days	All-cause mortality, 90-360 days	MACE, 30 days	MACE, 90-360 days	Adverse events
				37% Impella 47% IABP (at 12 months)	Need for renal replacement therapy 18% Impella 0% IABP Ventricular arrhythmias 8% Impella 11% IABP Stroke 8% Impella 0% IABP Severe bleeding 8% Impella 0% IABP Hemolysis 8% Impella 0% IABP

Table 4. Outcomes of Comparative Observational Studies

	All-cause mortality, 30 days	All-cause mortality, 90-360 days	MACE, 30 days	MACE, 90-360 days	Adverse events
Schwartz 2011 n = 50	15% Impella 13% TandemHeart 0% IABP	NR	15% Impella 19% TandemHeart 40% IABP	NR	Limb ischemia 0% Impella 6% TandemHeart 0% IABP Major bleeding 31% Impella 13% TandemHeart 20% IABP
Boudoulas 2012 n = 75	In-hospital mortality 0% Impella 20.9% IABP	15.3% Impella 25.8% IABP	NR	NR	Vascular complications 15.3% Impella 6.4% IABP Leg ischemia 15.3% Impella 3.2% IABP Mesenteric ischemia 0% Impella 1.6% IABP

	All-cause mortality, 30 days	All-cause mortality, 90-360 days	MACE, 30 days	MACE, 90-360 days	Adverse events
					<p>Aortic rupture</p> <p>0% Impella 1.6% IABP</p> <p>Bleeding</p> <p>38.4% Impella 32.2% IABP</p> <p>CVA</p> <p>0% Impella 3.2% IABP</p> <p>Bacteremia</p> <p>0% Impella 4.7% IABP</p>
Manzo-Silberman 2013 n = 78	<p>Survival at day 3</p> <p>34% Impella 67% IABP</p> <p>Survival with CPC score 1 at 28 days</p>	NR	NR	NR	<p>Hemolytic anemia</p> <p>6% Impella 0% IABP</p> <p>Sustained ventricular arrhythmias</p>

	All-cause mortality, 30 days	All-cause mortality, 90-360 days	MACE, 30 days	MACE, 90-360 days	Adverse events
	23% Impella 29.5% IABP				17% Impella 24% IABP Bleeding requiring transfusion 26% Impella 9% IABP Vascular complications 3% Impella 2% IABP

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Policy Landscape

Payer Coverage Policies

Medicaid

The [Washington State Medicaid Program billing guide](#) (7/1/2018) provides coverage for FDA-approved percutaneous left ventricular assist devices for these indications:

- Providing short-term circulatory support in cardiogenic shock
- As an adjunct to PCI in the following high-risk patients:
 - Clients undergoing unprotected left main or last-remaining-conduit PCI with ejection fraction less than 35%
 - Clients with three vessel disease and diastolic ejection fraction less than 30%

Medicare

No Medicare National Coverage Determination (NCD) or Local Coverage Determinations were found for percutaneous mechanical circulatory support. The [NCD on ventricular assist devices](#) provides coverage only for ventricular assist devices that are surgically attached to one or both intact ventricles.

Private Payers

The Aetna [policy on ventricular assist devices](#) (last review 3/22/18) provides coverage for Impella for these indications:

- Providing short-term circulatory support in cardiogenic shock
- As an adjunct to PCI in the following high-risk patients:
 - Persons undergoing unprotected left main or last-remaining-conduit PCI with ejection fraction less than 35%
 - Persons with three vessel disease and diastolic ejection fraction less than 30%.

The Cigna [policy on ventricular assist devices and percutaneous cardiac support systems](#) (effective 2/15/18) provides the following coverage:

- Impella RP System for up to 14 days in a child or adult with a BSA $\geq 1.5\text{m}^2$ for the treatment of acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery
- Impella Recover LP 2.5 Percutaneous Cardiac Support System, Impella 5.0 Catheters, or Impella 2.5 Plus for the treatment of cardiogenic shock for up to six hours

Moda's [list of procedures and services requiring prior authorization](#) (updated 7/1/2018) includes left ventricular assist devices.

The Regence [policy on ventricular assist devices and total artificial hearts](#) (effective 2/1/2018) states that this policy does not address the use of percutaneous ventricular assist devices, which may be considered medically necessary.

Recommendations from Others

Three guidelines were identified that include recommendations on temporary percutaneous mechanical circulatory support:

- Guideline for the Management of ST-Elevation Myocardial Infarction published in 2013 by the American College of Cardiology Foundation (ACCF) and American Heart Association (AHA) Task Force on Practice Guidelines (O'Gara et al., 2013)
- Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care published by the Society for Cardiovascular Angiography and Interventions, American College of Cardiology Foundation, Heart Failure Society of America, and Society for Thoracic Surgery (Rihal et al., 2015)
- The 2013 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support (Feldman et al., 2013)

The ACCF/AHA guideline includes a recommendation that alternative left ventricular assist devices for circulatory support may be considered in patients with refractory cardiogenic shock (O'Gara et al., 2013). The guideline from the Society for Cardiovascular Angiography and Interventions states that percutaneous mechanical circulatory support may be considered in carefully selected patients with severe hemodynamically unstable cardiovascular presentations. Suggested indications for percutaneous mechanical circulatory support include complications of acute myocardial infarction, severe heart failure in the setting of non-ischemic cardiomyopathy, acute cardiac allograft failure, post-transplant right ventricle failure, refractory arrhythmias, high-risk ablation of ventricular tachycardia, and high-risk PCI (Rihal et al., 2015).

The following recommendation from the International Society for Heart and Lung Transplantation guidelines is based on level of evidence C, or consensus agreement: “The use of temporary mechanical support should be strongly considered in patients with multiorgan failure, sepsis, or on mechanical ventilation to allow successful optimization of clinical status and neurologic assessment prior to placement of a long-term [mechanical circulatory support device]” (Feldman et al., 2013, p. 165)

Quality Measures

No quality measures were identified when searching the National Quality Measures Clearinghouse for percutaneous mechanical circulatory support or Impella.

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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 Elective High-Risk PCI							
No. of Studies	Study Design(s)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Factors	Quality
All-cause mortality							
1	RCT	Moderate	Not serious	Not serious	Serious		Low ●●○○
Major adverse events							
1	RCT	Moderate	Not serious	Not serious	Serious		Low ●●○○
Bridge to recovery							
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Bridge to transplant							
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Harms							
1	Observational	Moderate	Not serious	Not serious	Not serious		Very low ●○○○

Quality Assessment (Confidence in Estimate of Effect) for Ischemic Cardiogenic Shock							
No. of Studies	Study Design(s)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Factors	Quality
All-cause mortality							
3	RCTs	Moderate to high	Not serious	Not serious	Serious		Low ●●○○
Major adverse events							
1	RCT	High	N/A	Not serious	Very serious		Very low ●○○○
Bridge to recovery							
0	N/A	N/A	N/A	N/A	N/A	N/A	Insufficient data
Bridge to transplant							
0	N/A	N/A	N/A	N/A	N/A	N/A	Insufficient data
Harms							
4	Mix of RCTs and observational	Moderate to high	Serious	Not serious	Very serious		Very low ●○○○

Appendix C. Methods

Scope Statement

Populations

Adults with cardiogenic shock or refractory heart failure (from right heart failure, left heart failure, or biventricular failure) and adults undergoing high-risk percutaneous coronary interventions (PCI)

Population scoping notes: None

Interventions

Temporary percutaneous mechanical circulatory support devices (Impella)

Intervention exclusions: Devices not marketed in the U.S., TandemHeart, extracorporeal membrane oxygenation (ECMO).

Comparators

Usual care, inotropes, other forms of active circulatory support (i.e., intra-aortic balloon pumps or more permanent left ventricular assist devices), extracorporeal membrane oxygenation (ECMO)

Outcomes

Critical: Mortality, major adverse cardiovascular events

Important: Successful bridge to transplantation or bridge to recovery, length of hospitalization, harms

Considered but not selected for the GRADE table: None

Key Questions

KQ1: What is the comparative effectiveness of temporary percutaneous mechanical circulatory support in the management of adults with heart failure or cardiogenic shock, or undergoing high-risk PCI?

KQ2: Does the comparative effectiveness of temporary percutaneous mechanical circulatory support vary by:

- a. Indication for left ventricular support
- b. Patient characteristics
- c. Left ventricular function
- d. Right ventricular function
- e. Comorbid conditions
- f. Device flow rate
- g. Timing and duration of Impella placement

KQ3: What are the harms of temporary percutaneous mechanical circulatory support?

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)
- 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 Impella, ventricular support system, and axial flow pumps. The search was limited to publications in English published since 2013. In addition, a MEDLINE® search was conducted for randomized controlled trials published after 2013.

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.

Appendix D. Applicable Codes

CODES	DESCRIPTION
CPT Codes	
33990	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; arterial access only
33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transeptal puncture
33992	Removal of percutaneous ventricular assist device at separate and distinct session from insertion
33993	Repositioning of percutaneous ventricular assist device with imaging guidance at separate and distinct session from insertion

Note: Inclusion on this list does not guarantee coverage.

CG - Impella Devices

Question: How should the Coverage Guidance *Temporary Percutaneous Mechanical Circulatory Support With Impella Devices* be applied to the Prioritized List?

Question source: EbGS

Issue: EbGs approved a draft coverage guidance on Impella devices. There was extensive discussion between subcommittee members and the appointed expert about the challenges with the existing evidence and recommended subpopulations that are most likely to benefit. Subcommittee members discussed the fact that these devices have widely become standard of care despite the evidence base. They approved a draft coverage guidance that recommends coverage in 2 populations, high risk patients with acute NSTEMI, and those with cardiogenic shock who are candidates for bridge to transplant or LVAD.

EbGS Draft Coverage Guidance Box Language

Temporary percutaneous mechanical circulatory support with Impella devices is not recommended for coverage in elective high-risk percutaneous coronary intervention (PCI) for patients with stable coronary artery disease (*weak recommendation*).

Temporary percutaneous mechanical circulatory support with Impella devices during PCI is recommended for coverage (*weak recommendation*) only for patients with acute myocardial infarction when all of the following conditions are met:

- NSTEMI without cardiogenic shock
- A heart team discussion determines the patient needs revascularization with CABG or PCI
- Two cardiothoracic surgeons are consulted and agree the patient is inoperable (i.e., are not willing to perform CABG but agree revascularization is indicated)
- Patient has complex left main or last remaining conduit disease
- Ejection fraction (EF) < 30%

Temporary percutaneous mechanical circulatory support with Impella devices is recommended for coverage (*weak recommendation*) for patients with cardiogenic shock only in patients who may be candidates for Left Ventricular Assist Device (LVAD) (destination therapy) or transplant (bridge to transplant), AND an advanced heart failure and transplant cardiologist agrees that Impella should be used as a bridge to decision for LVAD or transplant.

Current Prioritized List Status:

CODES	DESCRIPTION		
CPT Codes		Current Placement	Code History
33990	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; arterial access only	82 MYOCARDITIS, PERICARDITIS, AND ENDOCARDITIS 98 HEART FAILURE 264 CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL	Added in 2013 as part of CPT 2012 code review without discussion

CG - Impella Devices

		HEART DISEASE	
33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transseptal puncture	82,98,264	Same
33992	Removal of percutaneous ventricular assist device at separate and distinct session from insertion	82,98,264	Same
33993	Repositioning of percutaneous ventricular assist device with imaging guidance at separate and distinct session from insertion	82,98,264	Same

Illustrative ICD-10 codes

Code	Code Description	Line Placement
R57.0	Cardiogenic shock	69 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION
T81.11XA	Postprocedural cardiogenic shock, initial encounter	69
T81.11XD	Postprocedural cardiogenic shock, subsequent encounter	69
I20.0	Unstable angina	69
I20.1	Angina pectoris with documented spasm	189 CHRONIC ISCHEMIC HEART DISEASE
I20.8	Other forms of angina pectoris	189
I20.9	Angina pectoris, unspecified	189
I25.110	Atherosclerotic heart disease of native coronary artery with unstable angina pectoris	69,264
I25.11X	Atherosclerotic heart disease of native coronary artery with angina pectoris...	189
I21.XX	ST elevation (STEMI) myocardial infarction	69
I21.4	Non-ST elevation (NSTEMI) myocardial infarction	69
I22.2	Subsequent non-ST elevation (NSTEMI) myocardial infarction	69

Recommendations:

- 1) Add 33990, 33991, 33992, and 33993 to Line 69 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION

CG - Impella Devices

- a. 33991 was out of scope, but confirmed with the expert that this is only for Tandem Heart and is no longer likely to be in use.
- 2) Remove 33990 and 33991 from Lines 82,98,264
- 3) Do NOT add 33990 to Line 189 CHRONIC ISCHEMIC HEART DISEASE as this would be for elective high-risk percutaneous coronary intervention (PCI) for patients with stable coronary artery disease
- 4) Create a new guideline note
GUIDELINE NOTE XXX TEMPORARY PERCUTANEOUS MECHANICAL CIRCULATORY SUPPORT WITH IMPELLA DEVICES
Line 69

Temporary percutaneous mechanical circulatory support with Impella devices is included on Line 69 only in the two following circumstances:

- 1) During percutaneous coronary intervention (PCI) in patients with acute myocardial infarction when all of the following conditions are met:
 - NSTEMI without cardiogenic shock
 - A heart team discussion determines the patient needs revascularization with coronary artery bypass graft (CABG) or PCI
 - Two cardiothoracic surgeons are consulted and agree the patient is inoperable (i.e., are not willing to perform CABG but agree revascularization is indicated)
 - Patient has complex left main or last remaining conduit disease
 - Ejection fraction (EF) < 30%
- 2) In patients with cardiogenic shock in patients who may be candidates for Left Ventricular Assist Device (LVAD) (destination therapy) or transplant (bridge to transplant), AND an advanced heart failure and transplant cardiologist agrees that Impella should be used as a bridge to decision for LVAD or transplant.

Temporary percutaneous mechanical circulatory support with Impella devices is not covered for elective high-risk PCI for patients with stable coronary artery disease.

HERC Coverage Guidance: Temporary Percutaneous Mechanical Circulatory Support with Impella Devices Disposition of Public Comments

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Discussion Table

IDs/#s	Summary of Issue	Subcommittee Response
A2, AF	Concerns about comparing Impella 2.5 to those with greater circulatory support	All Impella devices except the 5.0 (which requires an arterial cutdown) were included within scope, and evidence suggesting differential effectiveness would have been considered, if found.
A3, G2	Protect II clinical trial showed trend of improvement	Given the severity of outcomes, and the arguments from proponents of these devices that they are effective, one would expect to see significant differences in critical outcomes when these devices were used. The studies did not show that Impella is superior to intra-aortic balloon pump (IABP).
A5	Concern that the coverage guidance only addresses ischemic cardiogenic shock and does not address non-ischemic cardiogenic shock	There was very limited evidence on non-ischemic cardiogenic shock. Therefore, there is a recommendation against coverage for non-ischemic cardiogenic shock.
A5	Role of Impella as a bridge to left ventricular assist device (LVAD)	A weak recommendation for coverage has been made for selected patients, including bridge to LVAD where an advanced heart failure

**HERC Coverage Guidance:
Temporary Percutaneous Mechanical Circulatory Support with Impella Devices
Disposition of Public Comments**

IDs/#s	Summary of Issue	Subcommittee Response
		and transplant cardiologist agrees that Impella should be used as a bridge to decision for LVAD or transplant.
A5	The strength of the evidence is too weak to make a conclusion against the use of Impella	The strength of the evidence is too weak to make a recommendation for coverage. However, patients who are candidates for LVAD or bridging to transplant are an unstudied population but may be appropriate to be considered for Impella on an individual basis, based on expert opinion.
A5	Guidelines recommend use of these devices	These guidelines were included in the considerations.
B2, C2, D3, G2	Evidence from some uncontrolled studies shows improvements in outcomes	Non-comparative case series do not provide adequate comparative evidence of benefit. In the RCT, there was no difference in acute kidney injury.
C4, F4	Missing guidelines	The 2013 ISHLT guideline was added to the coverage guidance.
C5, E3, G2	Commercial payers cover this	The coverage policies of commercial and other payers were considered in the deliberations of this coverage guidance.
D2, D3, F3, G2, H2	Balloon pumps do not work well	The evidence review found no differences in outcomes between balloon pumps and Impella devices.
E1, E2	The Impella 5.0/Impella LD heart pumps are effective	These devices were outside the scope of this coverage guidance.
G2	Concerns with the included systematic review	The systematic review of concern was judged to be of value, and the results of the individual studies were individually included.

HERC Coverage Guidance: Temporary Percutaneous Mechanical Circulatory Support with Impella Devices Disposition of Public Comments

IDs/#s	Summary of Issue	Subcommittee Response
G4, H3	The cost-effectiveness considerations do not take into account the costs of other treatments and their complications	A cost-effectiveness analysis was not performed nor included. In considering resources, the comparative cost of the device was considered. If the Impella devices are effective, the higher cost may be justified in a coverage decision.
A3, B1, D2, D3, D4, F2	Patients who are inoperable (not eligible for coronary artery bypass graft (CABG)) and could only have PCI with Impella support	Studies did not specifically examine patients who had inoperable disease. These patients were included in the studied population, but no subgroup analysis was performed. The subcommittee acknowledges that with a noncoverage recommendation patients may not have access to PCI without Impella support. However, there is no mortality benefit to PCI for most of these patients, and no evidence that Impella would actually make PCI safer for these patients.

Commenters

Identification	Stakeholder
A	Todd A. Caulfield, MD, FACC, FSCAI, Medical Director, Quality; Medical Director, Providence Heart Clinics – West, Providence Heart Institute (PHI); Medical Staff President, Providence St. Vincent Medical Center <i>[Submitted September 25, 2018]</i>
B	Kevin H. Thompson, DO <i>[Submitted October 1, 2018]</i>
C	Richard C Padgett, MD <i>[Submitted October 8, 2017]</i>
D	Stephen L. Cook., MD <i>[Submitted October 10, 2017]</i>
E	Eric B. Kirker, MD <i>[Submitted October 10, 2018]</i>
F	Mark G. Moran, MD, FACC, FSCAI <i>[Submitted October 11, 2018]</i>
G	Stacey Bunk, MS, CPC, CCC, FABC, Director, Reimbursement & Healthcare Economics, ABIOMED, Inc. <i>[Submitted October 11, 2018]</i>
H	Amish J. Desai, MD <i>[Submitted October 12, 2018]</i>

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Public Comments

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A1	Thank you for calling our attention to the recent HERC document addressing Temporary Percutaneous Mechanical Circulatory Support with Impella Devices. As cardiac providers at a high volume center which regularly utilizes Impella technology, we believe that the conclusions of the HERC document are not justified nor reflective of our current practice.	<i>Thank you for your comments. HERC and its subcommittees value the input and experience of providers who use the interventions under review.</i>
A2	<p><u>Technologic Advance</u></p> <p>As you are aware, the field of mechanical circulatory support (MCS) has been rapidly evolving. The device referenced in the majority of studies cited is the Impella 2.5, smaller than the currently used Impella CP and Impella 5.0. There is much greater circulatory support with these devices, and in no way should outcomes with the Impella 2.5 be considered comparable to those obtained with devices which generate greater support.</p>	<i>The review included randomized trials and comparative observational studies using any of the Impella family of devices. One of the included studies used Impella CP. We did not find any data that directly compared Impella 2.5 to other Impella devices with respect to the outcomes included in the review. Lastly, the Impella 5.0, because it requires an arterial cutdown procedure for placement was not regarded, in the strictest sense, as a percutaneous procedure.</i>
A3	<p><u>PCI</u></p> <p>The first point to emphasize is that the utilization of Impella devices is very carefully considered and in no way reflexive. Only a very small percentage of PCI cases performed, even in the setting of high risk PCI, including those with cardiogenic shock and STEMI, utilize Impella. Careful case selection occurs, and patients frequently require complete support from the Impella device during the procedure (i.e., develop PEA) due to the severity of the disease being undertaken. These are inoperable patients that have no other options, and with our expertise, outcomes are excellent. Data supporting this assertion can be provided if helpful. Additionally this advance</p>	<i>The subcommittee had extensive discussion about the potential role of Impella to support PCI procedures that would not otherwise be offered or undertaken, as well as its value for patients who are not candidates for surgical revascularization. However, the subcommittee believed that the available randomized and comparative observational evidence (including the PROTECT II study) did not establish that Impella support was superior to IABP. The studies did not include selection criteria for</i>

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	<p>has allowed us to treat patients who previously went to CABG. This allows more conservative patient selection for our surgical colleagues, and at this institution, surgical outcomes for CABG are the best in our large system. Again, data to support this is available upon request.</p> <p>It is imperative to note that our professional societies and guidelines support the use of the Impella device in carefully selected patients in highly experienced centers. Additionally, the Protect II clinical trial did reveal a strong trend and possibly a statistically significant benefit when patients were followed for 90 days or more. This is the same data set that was used to support the recommendation against Impella use in the high risk PCI population.</p>	<p><i>"inoperable patients" (some 'inoperable patients' were included in the study but no subgroup analysis was performed.</i></p>
A4	<p>Secondly please recognize that the HERC recommendation on this topic is only weak in strength. In reviewing Appendix A, there can be two outcomes from this: In Favor and Against. We recommend voting against this recommendation at this time. In the language provided, there will be undesirable effects that outweigh the desirable effects, but acknowledge that further research could lead to a different conclusion.</p> <p>A document is attached to provide objective support for this conclusion, based on our own review of the data, some of which was also used to support the position presented in this HERC document.</p>	<p><i>Thank you for your comments.</i></p>
A5	<p><u>Cardiogenic shock</u></p> <p>The analysis is limited to patients with ischemic cardiogenic shock (CS). Notably, on the basis of the IABP-SHOCK II trial, the IABP has been downgraded to a Class IIIA recommendation for use in CS in the most recent European re-vascularization and NSTEMI ACS guidelines. Moreover, by limiting its focus on ischemic CS, the HERC document excludes a large proportion of cardiogenic shock due to non-ischemic etiologies, including decompensated chronic HF.</p>	<p><i>Our search did not identify any systematic reviews or randomized controlled trials of Impella for non-ischemic cardiogenic shock.</i></p> <p><i>We agree that the utility of IABP has been called into question by large-scale trials. However, IABP was a comparator in all of the randomized controlled trials of</i></p>

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	<p>The HERC review notes that there are insufficient data on the use of Impella as a bridge to recovery, bridge to transplant, and, presumably, bridge to durable left ventricular assist device. As the only advanced heart failure center in Oregon, these are important indications for use of temporary mechanical circulatory support (MCS).</p> <p>The studies cited in the HERC review are largely based on a comparison of the Impella 2.5 vs IABP. The Impella 2.5 provides inadequate hemodynamic support for moderate to severe cardiogenic shock, and thus the lack of clinic benefit vs IABP is not surprising. At Providence and most advanced HF programs, the Impella CP or 5.0 are utilized for shock. In support of this practice, the American Heart Association Scientific Statement on Contemporary Management of Cardiogenic Shock (Circulation 2017;136:e232-e268) suggests that the IABP be “considered in CS patients with acute mitral regurgitation or a ventricular septal defect, and <i>it can be considered in select patients with profound CS when other MCS devices are not available, are contraindicated, or cannot be placed.</i>” (emphasis added) The axillary 5.0 Impella approach, with which we have considerable experience at Providence, provides the important benefit of enabling ambulation during prolonged mechanical support and has been used to successful bridge a number of patients to durable LVAD or recovery.</p> <p>The management of cardiogenic shock is rapidly evolving. The population is markedly heterogeneous and notoriously difficult to study. The strength of studies cited in the HERC analysis are, in our opinion, too weak to make conclusions against the use of Impella or other temporary MCS, in cardiogenic shock. Systems of care, including the implementation of a shock team approach to rapidly identify appropriate candidates and implement MCS prior to irreversible organ dysfunction; after action reviews; and quality analysis; are critical components to the rational implementation of these technologies.</p>	<p><i>Impella for ischemic cardiogenic shock and the results did not show improved outcomes from Impella.</i></p> <p><i>Unfortunately, comparative evidence of Impella in ischemic cardiogenic shock is quite limited. However, one of the studies included in the review did compare Impella CP to IABP.</i></p>

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A6	<p>In conclusion, we thank you for calling our attention to this HERC coverage guidance. As we increasingly provide advanced cardiac care to this diverse, vulnerable patient population, please understand that the Impella device is an integral part of the care that we provide and is standard of care in our community and nationwide.</p>	<p><i>Thank you for your comments.</i></p>
B1	<p>I am an interventional cardiologist at Salem Hospital in Salem, OR and have supported a number of my patients with a Percutaneous Ventricular Assist Device (pVADs) when there is or where there exists the potential for acute cardiac instability and for whom this treatment was medically necessary.</p> <p>Therefore, I am requesting reconsideration of the above-referenced coverage policy.</p> <p>There is a robust and growing body of literature and practice guidelines that substantiate the benefits of pVAD therapy.</p> <p>I can relay many patient stories where the PVAD, and specifically Impella therapy, saved the lives of my patients who were in critical condition and would not have survived without this emergent intervention. It has allowed high risk patients to receive critical procedures thereby extending the quality and duration of their lives.</p> <p>I regularly bill, and receive payment for the insertion of the Impella when used as support during both elective and emergent percutaneous coronary interventions. (I am also aware the hospital in which I perform the Impella procedure receives payment under the appropriate MS-DRG by these same payers).</p> <p>That is because these payers recognize the cost benefit of this therapy while providing the following clinical benefits: reduction in major adverse events, protection from acute kidney injury (AKI), and reduces repeat revascularizations.</p>	<p><i>Thank you for your comments. HERC and its subcommittees value the input and experience of providers who use the interventions under review. The subcommittee bases its decisions on the best available evidence. In this case, the randomized trials of Impella failed to show a benefit for the studied populations.</i></p>

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B2	Because these findings were not seriously considered in your coverage review, I would like to call your attention to a few of these publications noted below. <i>(see References Provided by Commenters below)</i>	<i>The PROTECT II study was reviewed in the coverage guidance. The manuscript by Maini et al. is a non-comparative consecutive case series from the USPELLA registry. The use of Impella 5.0 for post-pericardiotomy support was outside the scope of this coverage guidance. The manuscript by Flaherty et al. is a single-center retrospective cohort study; it should be noted that in the PROTECT II study, the rate of acute renal dysfunction did not vary between the Impella and IABP groups.</i>
B3	The Impella technology's clinical benefits and safety data have been consistently demonstrated across studies and patient risk levels, and it is considered an important therapeutic option. Please consider revising your Impella coverage policy in light of this information.	<i>Thank you for your comments.</i>
C1	I am an interventional cardiologist at the Oregon Heart and Vascular Institute, Sacred Heart Medical Center in Eugene/Springfield and have used Percutaneous Ventricular Assist Devices (pVADs) as an adjunct to both elective and urgent percutaneous coronary interventions (PCI) for those patients at high risk for surgery and for cardiogenic shock.	<i>Thank you for your comments. HERC and its subcommittees value the input and experience of providers who use the interventions under review.</i>
C2	I have reviewed HERC's coverage policy and was surprised on the Commission's conclusion that pVADs are essentially as effective as IABPs, and each stand on equal footing in regard to net outcome. As such, the Commission jumps to the conclusion that for patients in need of hemodynamic support, <i>"The mechanism by which this is achieved (i.e., IABP or Impella) is unlikely to be important to patients. There is likely to be low variability in these values and preferences."</i>	<i>The subcommittee believes that the comparative evidence for the use of Impella does not clearly support its benefit over IABP. Both of the references submitted by the commenter were included in the coverage guidance.</i>

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	<p>The Commission also writes <i>“Impella is extremely expensive and may be as much as 20 times more than an IABP.”</i></p> <p>I respectfully disagree with the justification behind this coverage policy. Not only is the Impella the only FDA approved therapy for both high-risk PCI and cardiogenic shock, there are numerous peer reviewed articles that pVADs such as the Impella improve health outcomes while reducing length of stay, repeat revascularizations, and readmissions.</p>	
C3	<p>I would also like to take this opportunity to help answer questions on how the benefits of pVAD therapy exceed those of an IABP. Studies such as Protect II showed a significant reduction in adverse events at 90 days for Impella versus the IABP,¹ while ISAR-SHOCK demonstrated the Impella provided superior hemodynamic improvement compared with the IABP for cardiogenic shock patients.²</p>	<p><i>Both the PROTECT II study and the ISAR-SHOCK study were included in the coverage guidance. The reduction in major adverse events in PROTECT II were only apparent in the per-protocol analysis at 90-day follow-up and were driven mainly by a reduction in repeat revascularization, as noted in the coverage guidance. In addition to the fact that repeat revascularization was not part of the original composite outcome, the decision of whether to revascularize in an unblinded trial heightens the risk of bias. Hemodynamic outcomes were not selected as critical or important outcomes for the coverage guidance.</i></p>
C4	<p>Moreover, only two (2) clinical practice guidelines were identified in the coverage policy, despite several other guidelines adopted by: Society for Cardiac Angiography and Interventions (SCAI), American College of Cardiology Foundation (ACCF), Heart Failure Society of America (HFSA), Society of Thoracic Surgeons (STS), the International Society for Heart & Lung Transplant (ISHLT), and Heart Rhythm Society (HRS).</p>	<p><i>The Clinical Expert Consensus statement from SCAI/ACCF/HFSA/STS was summarized in the coverage guidance.</i></p> <p><i>The 2013 ISHLT guideline has been added to the coverage guidance. We were unable to locate a relevant guideline from the Heart Rhythm Society, and no citation was provided.</i></p>

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C5	A number of commercial payers provide coverage for the Impella when medically necessary, including, but not limited to: Aetna, United Healthcare, and Regence.	<i>The coverage policies of Aetna, Cigna, Moda, and Regence, as well as Washington Medicaid, are included in the coverage guidance in accordance with our usual methods.</i>
C6	In conclusion, it is very concerning to me that this policy limits access for those patients covered under the Oregon Health Plan, placing patients that are otherwise surgically turned-down for their coronary artery disease or suffering from cardiogenic shock at a distinct disadvantage compared to the rest of the citizens of Oregon.	<i>Thank you for your comments.</i>
D1	I have been a practicing interventional cardiologist for 27 years, 16 at Sacred Heart Medical Center. In my work, I frequently treat patients who are in shock from a heart attack or patients who would benefit from bypass surgery or coronary artery stents but are at extremely high risk of complications or mortality.	<i>Thank you for your comments.</i>
D2	For many years, the only device available to support these patients has been the intra-aortic balloon pump. Although they are widely used, there is no good scientific evidence that balloon pumps actually improve patient outcomes. There have been several randomized clinical trials in patients with cardiogenic shock that have shown no clinical benefit. Because of this research, the guidelines published by the cardiology professional societies no longer recommend using a balloon pump routinely in this situation.	<i>We agree that the utility of IABP has been called into question. However, IABP was a comparator in all of the randomized controlled trials of Impella for ischemic cardiogenic shock, and Impella was not found to be superior to IABP</i>
D3	More recently, the Impella assist device has become available. Unlike balloon pumps, Impella directly increases the amount of blood that is being sent to the rest of the body. The amount of support provided by the Impella is remarkable. When performing angioplasty in high-risk patients, it's not unusual for the heart to temporarily stop providing any meaningful blood flow. However, if an Impella is used, blood pressure and perfusion to the rest of the body are maintained. This allows time	<i>The subcommittee acknowledges that Impella devices may improve hemodynamic parameters, but those outcomes were not selected as important health outcomes for this review. EbGS discussed that if those hemodynamic parameters were significant enough to affect outcomes, then the results should have shown</i>

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	<p>for a better, more complete procedure to be done, and, frequently, is the only reason that the procedure can be performed at all.</p> <p>Unlike with the balloon pump, a number of studies have shown benefit to using Impella in high risk or severely ill patients. A community-wide initiative in Detroit has shown significant improvements in survival in patients with cardiogenic shock. A randomized study showed that high-risk patients undergoing coronary stenting had much better outcomes when supported with Impella compared to a balloon pump.</p>	<p><i>improved patient-oriented outcomes. The commenter did not submit references for the two studies mentioned here. The Detroit Cardiogenic Shock Initiative is a consecutive case series compared to historical controls and the interventions extended beyond use of temporary mechanical circulatory support. It was designed to establish the feasibility of early mechanical circulatory support. Our review of the PROTECT II trial data would not support the commenter's assertion that "high-risk patients undergoing coronary stenting had much better outcomes when supported with Impella compared to a balloon pump."</i></p>
D4	<p>In my practice, we follow several patients who simply would not be alive today if they had not been treated with Impella. After decades of disappointing outcomes with balloon pumps, it's been a tremendous breakthrough to finally have a device that helps the sickest patients.</p> <p>In a time of tight health care budgets, we all must be careful stewards and use resources responsibly. Even though Impella is expensive, there is no other device that has been shown to improve outcomes in the relatively small group of patient in which it is being used. It's important to avoid creating a two-tier medical system, in which life-saving medical therapy is only available to patients with certain types of insurance.</p> <p>In general, the patients who receive the most benefit from bypass surgery and stenting are the sickest, but those are also the ones at highest risk from the procedures. Use of the Impella allows us to treat patients who otherwise would be at too high a risk. Without Impella, we would frequently have nothing to offer them.</p>	<p><i>Thank you for your comments. HERC and its subcommittees value the input and experience of providers who use the interventions under review, but must also weigh that experience against the outcomes of the published, peer-reviewed studies.</i></p> <p><i>The subcommittee had extensive discussion about the potential role of Impella to support PCI procedures that would not otherwise be offered or undertaken, as well as its value for patients who are not candidates for surgical revascularization. However, the subcommittee believed that the available randomized and comparative observational evidence did not establish that Impella support was superior to IABP.</i></p>

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	<p>The result would be even more expense for the health care system, with frequent and prolonged readmissions, referrals for permanent left ventricular assist devices and cardiac transplant, and death.</p> <p>It's likely that the result of denying coverage for Impella will be that the device will still be inserted, but only when all other options have been exhausted and have failed. Unfortunately, studies have shown that Impella is most effective when inserted early. If used as a last-ditch effort, the results are not nearly as positive. If the Impella is not reimbursed, hospitals will have to absorb the cost of the device, and patients will have worse outcomes.</p> <p>I urge you to reconsider your coverage decision so that beneficiaries of the Oregon Health Plan can receive the best, evidence-supported cardiac care.</p>	
E1	<p>I am writing in regard to your coverage decision for the above-referenced policy. I am a thoracic and cardiac surgeon in Portland, Oregon and currently practice at both Portland Veterans Affairs Medical Center and Providence Portland Medical Center. I have supported a number of patients with either the Impella 5.0 or Impella LD in the setting of post-cardiotomy cardiogenic shock (PCCS).</p> <p>Historically, the overall mortality rate for PCCS is high, as much as 50-80%, despite advanced surgical techniques, inotropic support, and counterpulsation intra-aortic balloon pumps (IABPs). The Impella 5.0/Impella LD (left direct) are designed as minimally invasive and benefit the patient by providing circulatory support to restore normal cardiac function.</p>	<p><i>Thank you for your comments. HERC and its subcommittees value the input and experience of providers who use the interventions under review.</i></p> <p><i>However, the use of Impella 5.0 or Impella LD in the setting of post-pericardiotomy cardiogenic shock was beyond the scope of this coverage guidance, which was limited to percutaneously placed devices.</i></p>
E2	<p>The RECOVER I study evaluated the safety and feasibility of Impella 5.0®/Impella LD® heart pumps in patients experiencing cardiogenic shock or low cardiac output syndrome following cardiac surgery. It concluded that the use of the Impella 5.0 is safe and feasible in patients presenting with PCCS, recovery of the native heart</p>	<p><i>See E1 above.</i></p>

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	<p>function was obtained in 93% of the patients discharged, and survival to 30 days, 3 months, and 1 year was 94%, 81%, and 75%, respectively.¹</p> <p>Moreover, Lemaire, et al. showed myocardial recovery was accomplished in most patients, and the 30-day, 90-day, and 1-year survival was 72.3%, 65.9%, and 63.8%, respectively.²</p>	
E3	<p>I have performed almost forty procedures over the past twelve months, and have billed, and received payment for, the Impella heart pump procedure by Medicare and other major commercial payers. (I am also aware the hospital in which I perform the Impella procedure receives payment under the appropriate MS-DRG).</p> <p>This is because these payers recognize the cost benefit of this therapy while improving the survival rate in the setting of PCCS. Importantly, as a heart surgeon for high acuity patients, who helps lead a multidisciplinary team, this gives me an opportunity to meaningfully help patients that perhaps previously had no surgical option. These patients were then relegated to medical management of heart failure from surgical disease, that is doomed to failure.</p> <p>Please consider revising your Impella coverage policy in light of this information</p>	<p><i>The coverage policies of Aetna, Cigna, Moda, and Regence, as well as Washington Medicaid, are included in the coverage guidance in accordance with our usual methods.</i></p>
F1	<p>I would like to provide my comments in regard to the Commission’s decision for non-coverage of the Impella device for any patient with Oregon Health Plan (OHP) as their medical insurance carrier.</p>	<p><i>Thank you for your comments.</i></p>
F2	<p>I have used Impella for patients with severely reduced left ventricular systolic function and triple-vessel coronary artery disease, who have otherwise been turned-down for surgical revascularization given their comorbidities. While an IABP is known to provide counterpulsation therapy, randomized clinical trials have not shown hemodynamic or mortality benefit when compared with Impella.¹ Interventional cardiologists and cardiothoracic surgeons at Rogue Regional Medical Center rely on</p>	<p><i>Thank you for your comments. HERC and its subcommittees value the input and experience of providers who use the interventions under review.</i></p> <p><i>We agree that the utility of IABP has been called into question by large-scale trials. However, IABP was a</i></p>

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	<p>Impella support for providing percutaneous revascularization in individuals who are denied bypass surgery due to prohibitive surgical risk. This technology is lifesaving in these patients who otherwise have no other options available to them for revascularization.</p>	<p><i>comparator in all of the randomized controlled trials of Impella for ischemic cardiogenic shock.</i></p> <p><i>The subcommittee had extensive discussion about the potential role of Impella to support PCI procedures that would not otherwise be offered or undertaken and its value for patients who are not candidates for surgical revascularization. However, the subcommittee believed that the available randomized and comparative observational evidence did not establish that Impella support was superior to IABP for the studied populations.</i></p>
F3	<p>As for cardiogenic shock, clinical outcomes remained poor prior to the availability of the Impella. Inotropes and vasopressors increase both contractility and overload, therefore increasing myocardial oxygen and mechanical work in an already compromised ventricle. Historically, the IABP is utilized in conjunction with an inotropic or vasopressor agent, but must be timed with precision to the patient's EKG to provide benefit. It is also not optimal in patients with tachycardia or heart rate irregularity. Studies have concluded no mortality benefit of IABP compared with medical therapy in the setting of AMI complicated by cardiogenic shock, and at 12 month follow-up of these patients, there no survival benefit observed between the IABP arm and control arm.² Major medical centers caring for shock patients increasingly rely on Impella support to provide effective hemodynamic support permitting patients sufficient time to recover myocardial function improving their chances of recovery and survival. We have personally seen multiple patients at Rogue Regional Medical Center who would not have survived had Impella support been unavailable to them.</p>	<p><i>The comparative evidence for the use of Impella in cardiogenic shock is quite limited (fewer than 100 patients) and does not clearly establish a benefit in this setting.</i></p>

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F4	<p>In addition, the Commission’s evidence review is not consistent with the consensus of clinical experts familiar with the Impella technology. For instance, several guidelines were omitted from the draft coverage document, including those by the: Society for Cardiac Angiography and Interventions (SCAI), American College of Cardiology Foundation (ACCF), Heart Failure Society of America (HFSA), Society of Thoracic Surgeons (STS), the International Society for Heart & Lung Transplant (ISHLT), and Heart Rhythm Society (HRS).^{3,4,5}</p>	<p><i>The Clinical Expert Consensus statement from SCAI/ACCF/HFSA/STS was summarized in the coverage guidance.</i></p> <p><i>The 2013 ISHLT guideline has been added to the coverage guidance. We were unable to locate a relevant guideline from the Heart Rhythm Society, and no citation was provided.</i></p>
F5	<p>Thank you for your time and reconsideration of the above-mentioned coverage policy. I strongly support the request that this life saving technology be made available to this group of patients.</p>	<p><i>Thank you for your comments.</i></p>
G1	<p>Abiomed, Inc. appreciates the opportunity to comment on the HERC Draft Coverage Guidance for Temporary Percutaneous Mechanical Circulatory Support with Impella Devices. As the manufacturer of Impella, we would like to respond to comments raised at the September 6 meeting of the Evidence-based Guidelines Subcommittee and in the Draft Guidance with additional clinical data demonstrating Impella's clinical effectiveness in comparison to an Intra-Aortic Balloon Pump (IABP).</p> <ul style="list-style-type: none"> • Impella is the only FDA PMA approved device proven safe and effective for Protected PCI and Cardiogenic Shock • Seven clinical society guidelines support the use of Impella in severely ill patient populations who have no other option for care 	<p><i>Thank you for your comments.</i></p>
G2	<p>The Draft Guidance does not reflect the published peer reviewed evidence and consensus clinical society guidelines, and would limit Oregon Health Plan beneficiaries' access to the only FDA approved medical device for cardiogenic shock.</p>	<p><i>Clinical society guidelines are considered as contextual information for every HERC coverage guidance. The most recent (2015) Expert Consensus Statement of SCAI/ACC/HFSA/STS was included in the coverage</i></p>

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	<p>We respectfully request that the HERC finalize Coverage Guidance consistent with the clinical society guidelines or withdraw the Draft Guidance.</p> <p><u>Impella Is A Well Validated Technology Supported By Consensus Clinical Guidelines</u></p> <p>Impella is the only FDA approved, PMA on-label therapy for patients with high risk PCI (HR-PCI) and cardiogenic shock (CGS). Impella heart pumps have the ability to stabilize a patient's hemodynamics, perfuse end organs, and allow for recovery of the native heart. Impella can be used as a bridge for many critically ill cardiac patients.¹⁻⁸</p> <p>Impella is recognized as the clinical standard for HR-PCI and CGS. In total, seven clinical society guidelines support the use of Impella in these severely ill patient populations.⁹⁻¹⁵</p> <p>In comparison to Impella, an IABP provides limited flow augmentation with more heart dysfunction and has shown risk of stroke with no improvement in hemodynamics or mortality in CGS. As a result, the American Heart Association has downgraded IABP from a Class I recommendation to Class IIB in its guidelines on hemodynamic support in post-MI CGS. Additionally, the 2015 SCAVACC/HFSA/STS clinical expert consensus statement on the use of percutaneous mechanical circulatory support devices in cardiovascular care states: <i>“In the setting of profound cardiogenic shock, IABP is less likely to provide benefit than continuous flow pumps including the Impella CP...”</i>¹⁶</p> <p>Reflecting this clinical consensus, any other government and commercial payers cover Impella for HR-PCI and CGS including Regence, United Healthcare, Aetna, Cigna, Humana, and Highmark. Multiple Medicare Administrator Contractors provide coverage policies for pVADs (including Impella). Moreover, no Medicare contractors non-cover Impella. Internationally, the Canadian Association of Interventional</p>	<p><i>guidance, as was the older AHA/ACCF guideline on the management of STEMI.</i></p> <p><i>The coverage policies of Aetna, Cigna, Moda, and Regence, as well as Washington Medicaid, are included in the coverage guidance in accordance with our usual methods.</i></p> <p><i>The overall results of the PROTECT II study, including the 90-day per-protocol findings, were reviewed in the coverage guidance. The subgroup findings by use of rotational atherectomy were not included in the initial report of this trial. Although this was a pre-specified subgroup analysis, in an unblinded trial like PROTECT II, the decision to use rotational atherectomy itself may have been influenced by the treatment allocation (i.e., Impella vs. IABP), which limits any conclusions regarding subgroup effects. The authors acknowledged this limitation: “Our study is limited by the nonrandomized comparison between nonatherectomy PCI, by the constraints of its open-label design, and by its small sample size. The nonblinded design of the study most likely increased operator bias in selecting rotational atherectomy and influenced the manner in which it was performed.”</i></p> <p><i>The ISAR-SHOCK trial was also included in the coverage guidance. The hemodynamic improvements observed in</i></p>

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	<p>Cardiology as well as government agencies in Germany, the United Kingdom, Japan and almost all other modern healthcare agencies provide coverage for Impella.</p> <p><u>Peer Reviewed Publications Support Coverage for Impella</u></p> <p>Multiple peer reviewed publications demonstrate that Impella optimizes conditions for native heart recovery and reduces major adverse events and repeat revascularizations.</p> <p>The PROTECT II study was a prospective, multi-center, randomized, open label, active controlled clinical study to assess the safety and efficacy of the Impella 2.5 System compared to IABP.¹⁷ At the 90-day study exit follow-up, there was an average 22% relative increase in LVEF from baseline and a 58% improvement in NYHA functional class III/IV. Within the (pre-specified) ITT population not treated with atherectomy, the Impella 2.5 patients had better outcomes compared to those who received an IABP, with a significant 25% relative risk reduction in MAE incidence at 90 days.</p> <p>The ISAR-SHOCK study showed a significant improvement of cardiac index in the Impella 2.5 arm compared to the IABP arm post-device insertion.¹⁸ After 24 hours of support, fewer patients supported with the Impella 2.5 required inotropes compared to patients supported with an IABP.</p> <p>Although we recognize the value of prospective randomized control trials to assess medical devices, real world evidence through observational patient registries provides additional validation of the benefits to this severely ill patient population. A recent registry demonstrated that modifiable treatment patterns are associated with higher survival when Impella is used.</p> <p>The attached appendix lists peer-reviewed publications supporting the use of Impella.</p>	<p><i>that trial did not correspond with selected outcomes for this coverage guidance.</i></p> <p><i>HERC methods rely on systematic reviews and randomized controlled trials. Observational studies, particularly non-comparative observational studies, are given lower weight, especially when RCT data exist.</i></p>

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G3	<p><u>Health Quality Ontario Assessment has limited reliability</u></p> <p>The Draft Guidance relies heavily on the Health Quality Ontario "Percutaneous Ventricular Assist Devices: A Health Technology Assessment." We have previously shared our concerns about the methodology of this assessment with HQO, and, as noted above, the HQO assessment contradicts the Canadian Association of Interventional Cardiology. We requested that the report searchable on PubMed be removed until methodological errors are corrected.</p> <p>The HQO Report includes serious methodological flaws and is not peer-reviewed. First, the review selectively removes positive efficacy studies, removes or has inconsistent use of studies' own conclusions, and does not follow PRISM compliant protocols. Second, the committee did not seek advice from physicians with extensive Impella experience to identify appropriate clinical use in HR- PCI and CGS. Lastly, the cost model is based on unique and unvalidated assumptions, adverse events not assessed in the trials referenced, and cost levels from other countries omitted.</p> <p>As a result, there is a significant difference in efficacy data in the HQO Report compared to data from other government agencies and clinical societies. In comparison to the extensive efficacy data from peer-reviewed studies in the United States, the HQO report must be weighed in context and should not be the basis for the coverage guidance.</p>	<p><i>The HQO review is presented as one line of systematically reviewed evidence in the coverage guidance, but other lines of evidence are also included. In addition, because of the incomplete overlap in the included reviews' analysis of comparative studies, we separately summarized the results of those studies in the data table.</i></p> <p><i>That said, we believe that the search strategy outlined in Appendix 1 of the HQO report was comprehensive and that the pre-specified inclusion and exclusion criteria they outlined were clear and fairly applied. A PRISMA flow diagram is on page 15 of the HQO report.</i></p> <p><i>The subcommittee did not consider the economic analysis performed by HQO in their deliberations.</i></p>
G4	<p><u>Draft Guidance Undervalues the Cost-Effectiveness Of Impella</u></p> <p>The Draft Guidance's cost-effectiveness analysis underestimates Impella's clinical benefits and overstates its costs by failing to consider the costs of other treatments and their complications. For example, the Draft Guidance suggests that Impella does not reduce MACCE, but the largest randomized controlled trial in setting of HR-PCI demonstrated a statistical difference in MACCE.²⁰⁻²¹ Impella has also proven cost</p>	<p><i>The draft coverage guidance did not seek to undertake a cost-effectiveness analysis, and HERC generally does not consider economic analyses when the supporting evidence is not judged to be sufficient to inform such analyses. In this case, the only statistically significant benefit addressing an outcome of interest in the RCTs</i></p>

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	<p>effective through reduction in complications, length of hospital stay, re- admissions, and overall costs compared with IABPs and other alternative treatments.²² The Draft Guidance does not account for the total costs of IABPs or other alternative treatments.</p>	<p><i>was for the composite outcome of major adverse events in the per-protocol analysis of PROTECT II. We are not aware of a cost-effectiveness model that is able to capture the economic effects of such a composite outcome.</i></p> <p><i>The reference cited here to establish a reduction in MACCE in the PROTECT II trial relies on a post-hoc analysis using a revised definition of periprocedural myocardial infarction in place of the definition used in the original protocol. Such an analysis should be regarded as exploratory rather than definitive.</i></p>
G5	<p>Abiomed appreciates the opportunity to provide written comments, and welcomes the opportunity to provide a detailed presentation about the clinical benefits of Impella in person at the next public meeting.</p>	<p><i>Thank you for your comments.</i></p>
H1	<p>I would like to submit my comments in regard to OHP’s current policy for the <i>Temporary Percutaneous Mechanical Circulatory Support with Impella Devices</i>. As an interventional cardiologist serving the patients of OHP, it is concerning to me that this subset of patients will not be provided access to the only FDA approved therapy for high risk PCI or Cardiogenic Shock.</p>	<p><i>Thank you for your comments.</i></p>
H2	<p>Except for its’ cost, the current policy concludes the Impella and the intra-aortic balloon pump (IABP) can be used interchangeably, “...Impella appears to offer no benefit over the current standard of care at a much greater cost.”</p> <p>The Commission theorizes, “Impella is much more expensive than the comparator, and patient values and preferences would not lean toward either direction.”</p>	<p><i>We believe that the available comparative evidence does not support a conclusion that Impella is superior to IABP for the patients and outcomes considered in the scope of the coverage guidance.</i></p> <p><i>The Stretch et al. manuscript referenced here is a non-comparative cross-sectional study of patients receiving</i></p>

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	<p>To explain, patients who receive active LV unloading by the Impella are more hemodynamically stable and allows for complete revascularization, which helps avoid unplanned, repeat, PCI or surgical interventions, ultimately adding costs and increased risk for complications (examples include stroke, death, and MI) in a future healthcare encounter. In the emergent setting, Stretch et al. (2014) showed that IABP increased cost and mortality, while pVADs including Impella decreased both in PCI patients and specifically in AMI cardiogenic shock.¹</p>	<p><i>mechanical circulatory support in the Nationwide Inpatient Sample. It essentially describes trends in the use of mechanical circulatory support between 2007 and 2011 and includes devices other than Impella. This report was not intended to compare IABP and Impella, and indeed the authors noted that even after adjusting for all other variables in their analysis, later calendar years were predictive of lower mortality, suggesting a secular temporal trend toward improved outcomes.</i></p>
H3	<p>Therefore, I would request the Commission reconsider its policy against Impella by evaluating the cost-effectiveness and long-term outcomes of Impella therapy versus the IABP, as opposed to the upfront costs within a single healthcare encounter.</p>	<p><i>Thank you for your comments.</i></p>

HERC Coverage Guidance: Temporary Percutaneous Mechanical Circulatory Support with Impella Devices Disposition of Public Comments

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Section 4.0
Newer Interventional
Procedures For GERD

Newer Interventional Procedures for GERD

Draft Coverage Guidance for HERC Consideration

January 17, 2019

Background

- Gastroesophageal reflux disease (GERD) is a long-lasting and more serious form of gastroesophageal reflux
 - The lower esophageal sphincter becomes weak or relaxes, allowing stomach contents to rise up into the esophagus
 - Common symptoms of GERD include heartburn, bad breath, nausea, pain in the chest or upper part of the abdomen, painful swallowing, and vomiting
 - Patients with GERD can sometimes breathe stomach acid into the lungs, provoking asthma, laryngitis, or pneumonia
 - GERD can also cause Barrett's esophagus, a precursor of esophageal adenocarcinoma

Background

- Lifestyle changes may improve or eliminate GERD:
 - Not overeating
 - Not eating 2 to 3 hours before sleeping
 - Quitting smoking and avoiding secondhand smoke
 - Wearing loose-fitting clothing around the abdomen
 - Sleeping on a bed that is on a slight angle
- Prescription and nonprescription medicines to treat GERD:
 - Antacids
 - Histamine 2 receptor antagonists
 - Proton pump inhibitors (PPI)
 - Prokinetic agents

Background

- Most common surgery for GERD is laparoscopic fundoplication
 - Top of the stomach is sewed around the esophagus to add pressure to the lower end of the esophagus and reduce reflux
 - Performed under general anesthesia, and most patients return to usual activities in 2 to 3 weeks
- The focus of this coverage guidance is 2 additional treatments for GERD:
 - Transoral incisionless fundoplication (TIF)
 - Magnetic sphincter augmentation (MSA)

Background

- Transoral incisionless fundoplication (TIF)
 - Minimally invasive, endoscopic technique to restore the valve at the gastroesophageal junction via endoluminal fundoplication
 - EsophyX® device is a fastener delivery system designed to reconstruct the gastroesophageal valve and help restore its function as a reflux barrier
 - Approximately 20 fasteners are implanted during the procedure to create fusion of the esophageal and fundus tissues and form the valve
 - First iteration (TIF 1.0) creates the fundoplication wrap around the gastroesophageal junction
 - Later version of the procedure (TIF 2.0) creates the wrap around the intraabdominal portion of the esophagus
 - Indications for TIF include intractable GERD symptoms, no or mild esophagitis with hiatal hernia < 2 cm, and abnormal acid reflux

Background

- Magnetic sphincter augmentation (MSA)
 - MSA is performed using the LINX Reflux Management System, approved by the FDA in 2012
 - Small, flexible ring of interlinked titanium beads with magnetic cores placed around the esophagus just above the stomach
 - Magnetic attraction between the beads helps the lower esophageal sphincter resist opening because of gastric pressures; swallowing temporarily breaks the magnetic bonds, allowing food and liquid to pass normally
 - Indicated for patients diagnosed with GERD as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximum therapy

Scope Statement

- Populations
 - Adults with GERD
- Interventions
 - Transoral incisionless fundoplication
 - Laparoscopic magnetic ring procedure for augmentation of the lower esophageal sphincter
- Comparators
 - Medical management
 - Nissen fundoplication
 - Interventions compared to each other
 - Sham interventions

Scope Statement

- Critical Outcomes
 - Incident Barrett's esophagus
 - Complications of GERD (e.g., stricture)
- Important Outcomes
 - GERD symptom scores
 - Change in PPI therapy
 - Harms (e.g., repeat interventions)

Scope Statement

Key Questions

1. What is the comparative effectiveness of MSA of the lower esophageal sphincter and TIF in the treatment of GERD?
2. How does the effectiveness of MSA of the lower esophageal sphincter and TIF in the treatment vary by:
 - a. Patient characteristics (e.g., age, gender, weight, tobacco use)
 - b. Comorbid conditions
 - c. Duration of symptoms
 - d. Response to prior treatments
 - e. Procedural technique
3. What are the harms of MSA of the lower esophageal sphincter and TIF in the treatment of GERD?

Evidence Sources: TIF

- Huang et al., 2017
 - Good-quality systematic review and meta-analysis of 5 RCTs (n = 343) using TIF compared to sham procedure or PPI therapy
- Richter et al., 2018
 - Network meta-analysis of TIF, laparoscopic Nissen fundoplication, and PPI therapy
 - No RCTs directly comparing TIF with laparoscopic Nissen fundoplication (LNF)
 - 120 patients in the TIF vs. PPI trials
 - 835 patients in the LNF vs. PPI trials

Evidence Summary: TIF

- There is no evidence that TIF reduces the rate of incident Barrett's esophagus or complications of GERD (e.g., stricture)
- There is low-certainty evidence that TIF improves treatment response compared with sham procedures and/or PPI, but the durability of that improvement beyond 36 months is less certain
- Many patients who underwent TIF were able to stop PPI treatment
- The overall rate of adverse effects with TIF is approximately 2.5% in the studies
- There are no direct randomized comparisons of TIF and laparoscopic fundoplication, but a network meta-analysis suggested there was no statistically significant difference between the 2 procedures in improving GERD health-related quality of life

Payer Policies: TIF

- Washington State Medicaid Program
 - No Washington Medicaid coverage policy was found for TIF
- Medicare
 - No National Coverage Determinations were found for TIF
 - 2 Local Coverage Determination provide coverage for TIF under certain conditions, such as
 - Symptoms must not be completely responsive to PPI as judged by GERD HRQL scores of ≤ 12 while on PPI and ≥ 20 when off for 14 days
 - Hiatal hernia ≤ 2 cm, if present
 - BMI ≤ 35 , esophagitis LA grade $\leq B$, Barrett's esophagus ≤ 2 cm

Payer Policies: TIF

- Private payers
 - Aetna, Cigna, and Regence do not provide coverage for TIF
 - Moda provides coverage for TIF when a number of conditions are met, including:
 - Confirmed diagnosis of esophageal reflux by endoscopy, ambulatory pH, or barium swallow testing
 - GERD symptoms for 1 year occurring 2 to 3 times per week
 - BMI \leq 35
 - History of daily PPI therapy for greater than 6 months
 - Absence of a hiatal hernia or 1 that is 2 cm or less
 - No esophagitis LA grade C or D
 - No Barrett's esophagus, or if present it is 2 cm or less
 - No achalasia, esophageal ulcer, or esophageal motility disorder
 - No previous failed anti-reflux surgery/procedure

Guidelines: TIF

- 2 guidelines were identified:
 - American College of Gastroenterology
 - TIF cannot be recommended as an alternative to medical or traditional surgical therapy
 - European Association of Endoscopic Surgery
 - Not enough evidence available to recommend an alternative option to laparoscopic fundoplication for severe GERD

Public Comment

- Public comments on TIF submitted by EndoGastric Solutions, manufacturer of the EsophyX[®] TIF device
 - Comment: Indications for use of TIF should be based on indications in FDA approval
 - Response: Our recommendations for TIF indications are based on the published literature as well as the policies of other insurers
 - Comment: RCTs of TIF used only EsophyX[®], so coverage guidance should only recommend EsophyX[®] and not other devices
 - Response: Coverage guidance revised to specify that EsophyX[®] is the only device identified in the evidence reviewed for this coverage guidance

Discussion: TIF

Values and Preferences

For patients with chronic GERD symptomatology, we would expect values and preferences to be highly variable between medical and surgical treatment options, depending on the severity of symptoms and disease complications. Most patients with symptomatic control on chronic PPI therapy would prefer to continue medical management, although some would choose surgery to avoid possible long-term harm associated with PPIs. GERD patients for whom PPI therapy isn't working or is needed twice daily would value surgical intervention if safe and effective. Many would prefer TIF as a less invasive procedure, but others would prefer the laparoscopic Nissen or Toupe procedures as better established.

Discussion: TIF

Resource Allocation

Professional fees for the TIF procedure are generally lower than the fees for laparoscopic surgical procedures, but when facility and ancillary costs are taken into account, the difference in total procedure costs may not be significant.

If lesser degrees of GERD severity are treated with TIF rather than chronic medical therapy, surgical treatment costs for the covered population will rise as TIF utilization increases. The magnitude of offsetting savings in PPI or other medical therapy will vary, depending on the pricing of generic and brand name drugs.

Discussion: TIF

Balance of Benefits and Harms

Based on low-certainty evidence, the TIF procedure using the EsophyX[®] device appears to be effective in improving GERD-related quality of life and reducing or eliminating the need for chronic PPI therapy. There is no evidence that TIF reduces the rate of incident Barrett's esophagus or complications of GERD (e.g., stricture). Serious adverse effects (including perforation, bleeding, and pneumothorax) do occur with TIF, but the overall 2.4% rate of these events suggests that, on balance, the benefits of TIF outweigh the harms.

Discussion: TIF

Rationale

Although there is no evidence directly comparing TIF with laparoscopic fundoplication procedures, overall the two surgical approaches appear to have similar effectiveness. Coverage of the TIF procedure will not significantly change resource allocation for GERD management, and values and preferences would favor inclusion of TIF coverage, especially as an option for GERD patients whose symptoms are not controlled on chronic medical therapy. Current published evidence supports the safety and efficacy of the EsophyX[®] device used in this procedure. EsophyX[®] was the only device included in the systematic reviews and randomized trials that were identified for this coverage guidance. Other TIF devices and systems are not recommended for coverage because there are no comparative data. Our recommendation to cover the TIF procedure is weak because of our low level of confidence in the evidence.

Discussion: TIF

Transoral incisionless fundoplication 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 (*see next slide*)

Discussion: TIF

- Absence of all of the following conditions:
 - Hiatal hernia larger than 2 cm
 - Esophagitis with LA grade of C or D
 - 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*).

Evidence Sources: MSA

- Aiolfi et al., 2018
 - Fair-quality systematic review and meta-analysis of 7 observational studies (n = 1,211) comparing MSA with laparoscopic fundoplication using Nissen or Toupe techniques
- Bell et al., 2019
 - Poor-quality RCT of MSA compared to PPI therapy (n = 152)

Evidence Summary: MSA

- There is no evidence that MSA reduces the rate of incident Barrett's esophagus or complications of GERD (i.e., stricture)
- There is very low-certainty evidence that MSA is not statistically significantly better than laparoscopic fundoplication for reducing GERD symptoms or stopping PPI therapy
- There is very low-certainty evidence from 1 small RCT with a high risk of bias that MSA is superior to twice-daily PPI therapy for improving GERD symptoms
- There is very low-certainty evidence that the need for endoscopic dilation or reoperation did not differ significantly between MSA and fundoplication

Payer Policies: MSA

- Washington State Medicaid Program
 - No Washington Medicaid coverage policy was found for MSA
- Medicare
 - No National Coverage Determinations were found for MSA
 - 1 Local Coverage Determination states that LINX[®] Reflux Management System is not considered reasonable and necessary for the treatment of GERD
- Private payers
 - Aetna, Cigna, Moda, and Regence do not provide coverage for MSA

Guidelines: MSA

- 3 guidelines were identified:
 - American College of Gastroenterology
 - More data are needed before widespread usage of MSA can be recommended
 - National Institute for Health and Care Excellence (NICE)
 - MSA should only be used with special arrangements for clinical governance, consent, and audit or research
 - European Association of Endoscopic Surgery
 - Not enough evidence available to recommend an alternative option to laparoscopic fundoplication for severe GERD

Public Comment

- Public comments on MSA submitted by Johnson & Johnson Medical Devices, manufacturer of LINX[®] Reflux Management System
 - Comment: Additional studies should be considered
 - Response: Standard methodology, including comparative studies and systematic reviews, was used
 - Comment: Additional recommendations by professional organizations and AHRQ should be considered
 - Response: 2017 NICE guidance states that evidence of long-term efficacy is inadequate; AHRQ inclusion in Horizon Scans should not be construed as endorsement; American Society of General Surgeons support statements are not from clinical practice guidelines

Discussion: MSA

Values and Preferences

Most GERD patients with symptomatic control on chronic PPI therapy would prefer to continue medical management, although some would choose surgery to avoid possible long-term harm associated with PPIs.

GERD patients for whom PPI therapy isn't working or is needed twice daily would value surgical intervention if safe and effective. The level of laparoscopic intervention would appear to be similar for MSA and Nissen procedures; therefore, many GERD patients might prefer the laparoscopic Nissen or Toupe procedures as better established.

Discussion: MSA

Resource Allocation

Similar to the considerations for TIF, if lesser degrees of GERD severity are treated with MSA rather than chronic medical therapy, surgical treatment costs for the covered population will rise as utilization increases. The magnitude of offsetting savings in PPI or other medical therapy will be variable. Overall, there would most likely be some increase in resource allocation for GERD management with the addition of MSA coverage.

Balance of Benefits and Harms

Although MSA appears to have similar effectiveness and similar adverse events and complications compared to laparoscopic fundoplication, we have very low confidence in the evidence.

Discussion: MSA

Rationale

Based on observational studies and one poor-quality RCT, the level of evidence is insufficient at present to establish the comparative effectiveness of MSA. Some additional costs would be likely with the addition of MSA coverage, and there are no strong values or preferences that would favor MSA over other available GERD treatment options. Our recommendation for non-coverage is weak because future studies may better establish the benefits of the MSA procedure.

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

Health Evidence Review Commission (HERC)

Coverage Guidance: Newer Interventional Procedures for GERD

DRAFT for VbBS/HERC meeting materials 1/17/2019

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
 - 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*).

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.

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.

DRAFT

GRADE Table

Should transoral incisionless fundoplication (TIF) be recommended for coverage for GERD?

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>	Resource Allocation	Values and Preferences	Other Considerations
Incident Barrett's esophagus <i>(Critical outcome)</i>	No data	Professional fees for the TIF procedure are generally lower than the fees for laparoscopic surgical procedures, but when facility and ancillary costs are taken into account, the difference in total procedure costs may not be significant. If lesser degrees of GERD severity are treated with TIF rather than chronic medical therapy, surgical treatment costs for the covered population will	For patients with chronic GERD symptomatology, we would expect values and preferences to be highly variable between medical and surgical treatment options, depending on the severity of symptoms and disease complications. Most patients with symptomatic control on chronic	
Complications of GERD (e.g., stricture) <i>(Critical outcome)</i>	No data			
GERD symptom scores <i>(Important outcome)</i>	Treatment response at 6 months 124/188 (66%) for intervention vs. 32/105 (30%) for control/sham ARD = 36% NNT = 2-3 RR 2.44 (95% CI 1.44 to 1.79, p = 0.02) ●●○○ (Low confidence, based on 4 RCTs, n = 293)			
Change in PPI therapy <i>(Important outcome)</i>	At 6 months, approximately 70% of patients reported PPI cessation ●●○○ (Low confidence, based on 9 observational studies, n = 439)			

Should transoral incisionless fundoplication (TIF) be recommended for coverage for GERD?

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>	Resource Allocation	Values and Preferences	Other Considerations
<p>Harms <i>(Important outcome)</i></p>	<p>Overall rate of serious adverse events was 2.4% ●●○○ (Low confidence, based on 12 observational studies and 4 RCTs, n = 781)</p>	<p>rise as TIF utilization increases. The magnitude of offsetting savings in PPI or other medical therapy will vary, depending on the pricing of generic and brand name drugs.</p>	<p>PPI therapy would prefer to continue medical management, although some would choose surgery to avoid possible long-term harm associated with PPIs. GERD patients for whom PPI therapy isn't working or is needed twice daily would value surgical intervention if safe and effective. Many would prefer TIF as a less invasive procedure, but others would prefer the laparoscopic Nissen or Toupe procedures as better established.</p>	

Should transoral incisionless fundoplication (TIF) be recommended for coverage for GERD?

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>	Resource Allocation	Values and Preferences	Other Considerations
<p>Balance of benefits and harms: Based on low-certainty evidence, the TIF procedure using the EsophyX[®] device appears to be effective in improving GERD-related quality of life and reducing or eliminating the need for chronic PPI therapy. There is no evidence that TIF reduces the rate of incident Barrett’s esophagus or complications of GERD (e.g., stricture). Serious adverse effects (including perforation, bleeding, and pneumothorax) do occur with TIF, but the overall 2.4% rate of these events suggests that, on balance, the benefits of TIF outweigh the harms.</p>				
<p>Rationale: Although there is no evidence directly comparing TIF with laparoscopic fundoplication procedures, overall the two surgical approaches appear to have similar effectiveness. Coverage of the TIF procedure will not significantly change resource allocation for GERD management, and values and preferences would favor inclusion of TIF coverage, especially as an option for GERD patients whose symptoms are not controlled on chronic medical therapy. Current published evidence supports the safety and efficacy of the EsophyX[®] device used in this procedure. EsophyX[®] was the only device included in the systematic reviews and randomized trials that were identified for this coverage guidance. Other TIF devices and systems are not recommended for coverage because there are no comparative data. Our recommendation to cover the TIF procedure is weak because of our low level of confidence in the evidence.</p>				
<p>Recommendation: Transoral incisionless fundoplication (TIF) is recommended for coverage for GERD treatment only when the following criteria are met (<i>weak recommendation</i>):</p> <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> ○ Hiatal hernia larger than 2 cm ○ Esophagitis with LA grade of C or D ○ Barrett’s esophagus greater than 2 cm ○ Achalasia ○ Esophageal ulcer ○ Esophageal motility disorder 				

Should transoral incisionless fundoplication (TIF) be recommended for coverage for GERD?

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource Allocation	Values and Preferences	Other Considerations
<ul style="list-style-type: none"> ○ Altered esophageal anatomy preventing insertion of the device ○ Previous failed anti-reflux surgery or procedure <p>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.</p> <p>For patients who have recurrent symptoms or fail the initial TIF procedure, repeat TIF is not recommended for coverage (<i>strong recommendation</i>).</p>				

Should magnetic sphincter augmentation (MSA) be recommended for coverage for GERD?

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource Allocation	Values and Preferences	Other Considerations
Incident Barrett's esophagus (Critical outcome)	No data	Similar to the considerations for TIF, if lesser degrees of GERD severity are treated with MSA rather than chronic medical therapy, surgical treatment costs for the covered population will rise as utilization increases. The magnitude of	Most GERD patients with symptomatic control on chronic PPI therapy would prefer to continue medical management, although some would choose surgery to avoid possible long-term	
Complications of GERD (e.g., stricture) (Critical outcome)	No data			
GERD symptom scores (Important outcome)	No statistically significant difference in GERD health-related quality of life scores with MSA compared to fundoplication at 6 to 12 months Mean difference -0.48 (95% CI -1.05 to 0.09, p = 0.10)			

Should magnetic sphincter augmentation (MSA) be recommended for coverage for GERD?

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource Allocation	Values and Preferences	Other Considerations
	<p>●○○○ (Very low confidence, based on 6 observational studies, n = 1,083)</p> <p>Significantly more patients reported > 50% improvement in GERD health-related quality of life score with MSA (84%) than PPI (10%) at 6 months (p < 0.001)</p> <p>●○○○ (Very low confidence, based on 1 RCT, n = 152)</p>	offsetting savings in PPI or other medical therapy will be variable. Overall, there would most likely be some increase in resource allocation for GERD management with the addition of MSA coverage.	harm associated with PPIs. GERD patients for whom PPI therapy isn't working or is needed twice daily would value surgical intervention if safe and effective. The level of laparoscopic intervention would appear to be similar for MSA and Nissen procedures; therefore, many GERD patients might prefer the laparoscopic Nissen or Toupe procedures as better established.	
Change in PPI therapy (Important outcome)	<p>No statistically significant difference in PPI cessation with MSA compared to fundoplication at 6 to 12 months OR 0.81 (95% CI 0.42 to 1.58, p = 0.55)</p> <p>●○○○ (Very low confidence, based on 6 observational studies, n = 1,098)</p> <p>91% of patients undergoing MSA reported PPI cessation at 6 months</p> <p>●○○○ (Very low confidence, based on 1 RCT, n = 50)</p>			
Harms (Important outcome)	<p>No statistically significant difference in need for endoscopic dilation with MSA compared to fundoplication at 6 to 12 months OR 1.56 (95% CI 0.61 to 3.95, p = 0.12)</p> <p>●○○○ (Very low confidence, based on 5 observational studies, n = 535)</p> <p>No statistically significant difference in need for reoperation with MSA compared to fundoplication at 6 to 12 months</p>			

Should magnetic sphincter augmentation (MSA) be recommended for coverage for GERD?

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>	Resource Allocation	Values and Preferences	Other Considerations
	<p>0.54 (95% CI 0.22 to 1.34, p = 0.18)</p> <p>●○○○ (Very low confidence, based on 3 observational studies, n = 1,187)</p> <p>32% of patients experienced dysphagia; 5% experienced persistent moderate or severe dysphagia at 6 months</p> <p>●○○○ (Very low confidence, based on 1 RCT, n = 50)</p>			

Balance of benefits and harms: Although MSA appears to have similar effectiveness and similar adverse events and complications compared to laparoscopic fundoplication, we have very low confidence in the evidence.

Rationale: Based on observational studies and one poor-quality RCT, the level of evidence is insufficient at present to establish the comparative effectiveness of MSA. Some additional costs would be likely with the addition of MSA coverage, and there are no strong values or preferences that would favor MSA over other available GERD treatment options. Our recommendation for non-coverage is weak because future studies may better establish the benefits of the MSA procedure.

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

Note: GRADE table elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.

Background

Gastroesophageal reflux disease (GERD) is a long-lasting and more serious form of gastroesophageal reflux (or acid reflux). The lower esophageal sphincter becomes weak or relaxes, allowing stomach contents to rise up into the esophagus. Common symptoms of GERD include heartburn, bad breath, nausea, pain in the chest or upper part of the abdomen, painful swallowing, and vomiting. Patients with GERD can sometimes breathe stomach acid into the lungs, provoking asthma, laryngitis, or pneumonia. GERD can also cause Barrett's esophagus, a precursor of esophageal adenocarcinoma (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDKD], 2018).

An estimated 20% of the U.S. population has GERD. Populations at higher risk for GERD include people who are overweight, pregnant women, people who smoke or are exposed to secondhand smoke, and people taking certain medicines (e.g., calcium channel blockers, antihistamines, sedatives, antidepressants, asthma medications, pain medications). GERD is often classified by the frequency and severity of symptoms. Procedures to test for GERD include upper gastrointestinal endoscopy and biopsy, x-rays of the upper gastrointestinal area, and esophageal pH and impedance monitoring (NIDDKD, 2018).

Lifestyle changes may improve or eliminate GERD, such as not overeating, not eating two to three hours before sleeping, quitting smoking and avoiding secondhand smoke, wearing loose-fitting clothing around the abdomen, and sleeping on a bed that is on a slight angle. Medicines (both prescription and nonprescription) to treat GERD include antacids, histamine 2 receptor antagonists, proton pump inhibitors (PPI), and prokinetic agents (NIDDKD, 2018).

The most common surgery for GERD is laparoscopic fundoplication, in which the top of the stomach is sewed around the esophagus to add pressure to the lower end of the esophagus and reduce reflux. Laparoscopic fundoplication is performed under general anesthesia, and most patients return to usual activities in two to three weeks (NIDDKD, 2018).

The focus of this coverage guidance is two additional treatments for GERD: transoral incisionless fundoplication (TIF) and magnetic sphincter augmentation (MSA).

Indications

Indications for TIF include intractable GERD symptoms, no or mild esophagitis with hiatal hernia < 2 cm, and abnormal acid reflux (Richter et al., 2018).

MSA is performed using the LINX Reflux Management System. This device was approved by the U.S. Food and Drug Administration (FDA) in 2012 and is indicated for patients diagnosed with GERD as defined by abnormal pH testing, and who continue to have chronic GERD symptoms despite maximum therapy for the treatment of reflux (FDA, 2012).

Technology Description

TIF is a minimally invasive, endoscopic technique that restores the valve at the gastroesophageal junction via endoluminal fundoplication using EsophyX (Huang et al., 2017). The EsophyX device is a fastener delivery system designed to reconstruct the gastroesophageal valve and help restore its function as a reflux barrier. Approximately 20 fasteners are implanted during the procedure to create

fusion of the esophageal and fundus tissues and form the valve (EndoGastric Solutions, 2016). The first iteration of TIF (sometimes called TIF 1.0) creates the fundoplication wrap around the gastroesophageal junction; the later version of the procedure (TIF 2.0) creates the wrap around the intraabdominal portion of the esophagus.

The LINX Reflux Management System is a small, flexible ring of interlinked titanium beads with magnetic cores that is placed around the esophagus just above the stomach during a laparoscopic procedure. A sizing tool is used to determine the appropriate size LINX System, and the device is positioned using sutures. The magnetic attraction between the beads helps the lower esophageal sphincter resist opening because of gastric pressures. Swallowing temporarily breaks the magnetic bonds, allowing food and liquid to pass normally into the stomach (Torax Medical, 2018).

Evidence Review

Huang et al., 2017

This is a good-quality systematic review and meta-analysis of prospective studies of TIF. The primary outcome measure for the meta-analysis was treatment response at six months defined as improvement of at least 50% in the GERD health-related quality of life score, or remission of heartburn and regurgitation, or complete cessation of PPI therapy; these outcomes were considered hierarchically in the order described (i.e., cessation of PPI therapy only contributed to the outcome if the other two outcomes were not reported). The authors identified five randomized controlled trials (total n = 343) published in 2014 and 2015, all of which used the TIF 2.0 procedure. Two of the RCTs compared TIF to a sham procedure, and three trials compared TIF to PPI therapy. The included trials were mainly low to moderate risk of bias, although one trial was deemed to be at high risk of bias due to concerns with blinding and attrition. Three of the five studies were sponsored by the manufacturer of the EsophyX TIF system. The authors also identified 13 prospective observational studies, but these were not included in the primary meta-analyses. In general, studies excluded patients with large hiatal hernias or BMI greater than 30 or 35 kg/m².

For the primary outcome of treatment response at six months, four studies with 293 patients contributed to the meta-analysis. Overall, in the intention-to-treat analysis, treatment response occurred in 124 of the 188 patients randomized to TIF (66%) compared to 32 of 105 patients randomized to the control group (30%) (RR 2.44, 95% CI 1.44 to 4.79, p = 0.02, I² = 70%). Data from the prospective observational studies were not meta-analyzed, but did allow for an assessment of the durability of treatment effects beyond six months. Based on these studies, the treatment response to TIF appears to be sustained through 36 months but then begins to decline, although estimates beyond 36 months are based on very small numbers of patients. Similarly, the analysis of PPI use in prospective observational studies shows a sustained effect for PPI cessation between 12 and 36 months of follow-up (rate of approximately 60%), but the rate of PPI cessation beyond 36 months falls to 30-50% (again based on a very small number of observations).

Five-year follow-up from one of the included RCTs was separately reported (Trad et al., 2018). In this study, all control group patients crossed over to TIF after six months (total n = 63, of whom 44 had available data for follow-up at five years). At five years, there was sustained improvement in GERD health-related quality of life score compared to baseline (22.2 at baseline to 6.8 at five years, p < 0.01), although the rate of PPI use steadily increased from 17% at one year to 34% at five years.

In a total of 16 studies (four RCTs and 12 observational studies), there were 19 serious adverse events among 781 patients who received the TIF procedure (2.4%). These events included seven perforations, five episodes of bleeding, four pneumothoraces, and one death (reported 20 months after the TIF procedure). In the five-year follow-up reported by Trad et al. (2018), there were no serious adverse events, but three patients (5%) did require reoperation.

Richter et al., 2018

Because there are no RCTs directly comparing TIF with laparoscopic Nissen fundoplication (LNF), Richter et al. undertook a network meta-analysis (NMA), which allows for indirect comparisons. The PPI node allowed for an indirect comparison of TIF and LNF (120 patients were included in the TIF vs. PPI trials, and 835 patients were included in the LNF vs. PPI trials). For the NMA outcome of improved GERD health-related quality of life, TIF was found to have the greatest probability of being the best treatment (surface under the cumulative ranking curve of 0.92) followed by LNF (surface under the cumulative ranking curve of 0.66), although in the pairwise comparison the difference between the two procedures was not statistically significant (OR 2.08, 95% CI 0.71 to 6.09) and the quality of evidence was judged to be very low. The authors of this study also queried the MAUDE database for reports on the TIF procedure and found 50 cases of device malfunction and 75 cases of injury including 36 perforations, 10 gastrointestinal bleeds, 8 esophageal lacerations, 8 pleural effusions, and 6 mediastinal abscesses (out of an unknown denominator of total TIF procedures).

Aiolfi et al., 2018

This is a fair-quality systematic review and meta-analysis of seven observational studies comparing MSA with laparoscopic fundoplication (Nissen or Toupe techniques). The review is mainly limited by incomplete reporting of the quality ratings of the included studies. One study was a prospective cohort and the remaining six studies were retrospective cohorts. The included studies were published between 2014 and 2017 and involved 1,211 patients in total; 686 patients (56%) were treated with MSA and 524 (44%) underwent laparoscopic fundoplication. The mean age of patients ranged from approximately 40 to 55 years old, the mean BMI ranged from 24 to 30 kg/m², and the mean hiatal hernia size ranged from 1 to 2 cm. Six studies with 1,083 patients contributed to the random effects meta-analysis of the pooled mean difference in GERD health-related quality of life score at six to 12 months, which found a non-statistically significant difference of -0.48 (95% CI -1.05 to 0.09, $p = 0.10$, $I^2 = 0\%$). Six studies with 1,098 patients contributed to the random effects meta-analysis of the pooled odds ratio of PPI cessation at six to 12 months, which found a non-statistically significant difference of 0.81 (95% CI 0.42 to 1.58, $p = 0.55$, $I^2 = 64\%$). Five studies with 535 patients contributed to the random effects meta-analysis of the pooled odds ratio of endoscopic dilation at six to 12 months, which found a non-statistically significant difference of 1.56 (95% CI 0.61 to 3.95, $p = 0.12$, $I^2 = 35\%$). Three studies with 1,187 patients contributed to the random effects meta-analysis of the pooled odds ratio of reoperation at six to 12 months, which found a non-statistically significant difference of 0.54 (95% CI 0.22 to 1.34, $p = 0.18$, $I^2 = 0\%$). In terms of harms, the authors observed that overall postoperative morbidity ranged from 0% to 3% in the MSA groups and 0% to 7% in the fundoplication groups. The ability to vomit or belch was better preserved in the MSA groups compared to the fundoplication groups.

Bell et al., 2019

This is a poor-quality randomized controlled trial of MSA compared to twice-daily PPI therapy for patients with persistent GERD despite once-daily PPI. Eligible patients were over age 21 and had moderate-to-severe regurgitation symptoms while taking once-daily PPI therapy for at least eight weeks. Patients who were already on twice-daily PPI, had hiatal hernias larger than 3 cm, BMI > 35 kg/m², or who had grade C or D esophagitis or Barrett's esophagus or esophageal strictures were excluded. Patients were mainly recruited from surgical clinics. Overall, 152 patients were enrolled and randomized in 2:1 fashion to twice-daily PPI or MSA after a one week washout period off their once-daily PPI treatment. In the intention-to-treat analysis, the primary endpoint of resolution of moderate-to-severe regurgitation at six months was achieved in 84% of the MSA group and 10% of the PPI group ($p < 0.001$). Similarly, the percentage of patients achieving > 50% improvement in the GERD health-related quality of life score was 81% in the MSA group and 8% in the PPI group ($p < 0.001$). In the MSA group, 91% of patients had stopped using PPI at six months. The main adverse effect of MSA was dysphagia, which occurred in 15 patients (32%). This dysphagia was reported as minimal or resolved for 13 patients by six months, but was persistent and moderate or severe in two patients at six months.

There were several methodological limitations to this trial. The manuscript does not describe methods for random sequence generation or allocation concealment. Study participants were not blinded to treatment group, which increases the risk of performance bias for subjectively reported outcomes. This concern about a placebo effect is heightened by the recruitment of participants from surgical clinics. Although the overall rate of attrition at six months was modest, it was different in the MSA group (0%) and the PPI group (14%). There was no statement in the manuscript regarding trial funding, sponsorship, or conflicts of interest.

Evidence Summary

There is no evidence that either TIF or MSA reduce the rate of incident Barrett's esophagus or complications of GERD (e.g., stricture). There is low-certainty evidence that TIF improved treatment response compared with sham procedures and/or PPI, although the durability of that improvement beyond 36 months is less certain. Many patients who underwent TIF were able to stop PPI treatment. The overall rate of adverse effects with TIF is approximately 2.5% in the studies. There are no direct randomized comparisons of TIF and laparoscopic fundoplication procedures, but a network meta-analysis suggested that there was no statistically significant difference between the two procedures in the odds of improving GERD health-related quality of life.

There is very low-certainty evidence that MSA is not statistically significantly better than laparoscopic fundoplication for reducing GERD symptoms or stopping PPI therapy. There is very low-certainty evidence from one small RCT with a high risk of bias that MSA is superior to twice-daily PPI therapy for improving GERD symptoms. There is very low-certainty evidence that the need for endoscopic dilation or reoperation did not differ significantly between MSA and fundoplication; the rate of dysphagia in the MSA group of the sole randomized trial was 32%, although only 5% had persistent moderate-to-severe dysphagia at six months.

Policy Landscape

Payer Coverage Policies

Medicaid

No coverage policies were found for Washington Medicaid for either TIF or MSA.

Medicare

No Medicare National Coverage Determinations were found for TIF or MSA, and two Local Coverage Determinations (LCD) were found for these procedures. Two LCDs provide coverage for TIF. [L34659](#) (revision effective 1/1/2018) provides coverage of TIF for treatment of patients in whom PPI therapy fails. The procedure must be done by a well-trained surgeon, and the patient must meet these conditions:

- Symptomatic chronic gastroesophageal reflux (defined as > 6 months of symptoms)
- Symptoms must not be completely responsive to PPI as judged by GERD HRQL scores of ≤ 12 while on PPI and ≥ 20 when off for 14 days (or difference ≥ 10 of the scores between off and on therapy)
- Hiatal hernia ≤ 2 cm, if present

Coverage is not extended for patients who have recurrent symptoms or fail this procedure, and repeat TIF is considered investigational. This LCD does not mention MSA.

The other LCD, [L35080](#) (revision effective 12/1/2017), provides coverage for TIF, except for patients:

- Who have recurrent symptoms or other evidence of failure following a prior TIF
- In which a staged procedure is being done (i.e., laparoscopic esophageal or paraesophageal diaphragmatic hernia/opening closure followed by a TIF endoscopically)
- Who have a preoperative hiatal hernia > 2 cm
- With BMI > 35, esophagitis LA grade > B, Barrett's esophagus > 2 cm, and presence of achalasia or esophageal ulcer or has not been on an appropriate trial of PPI

This LCD states that LINX® Reflux Management System, a MSA device, is not considered reasonable and necessary for the treatment of GERD.

A third LCD, [L33296](#) (revision effective 1/25/2018), states that transesophageal endoscopic procedures (e.g., TIF) for the treatment of GERD are not covered.

Private Payers

Coverage policies were searched for four private payers: Aetna, Cigna, Moda, and Regence. None of these private payers covered MSA, and only Moda covered TIF. The Moda policy on [endoscopic procedures for GERD](#) (effective 7/1/2018) provides coverage for TIF when all these conditions are met:

- a. 18 years of age or older
- b. Confirmed diagnosis of esophageal reflux by endoscopy, ambulatory pH, or barium swallow testing
- c. History of GERD symptoms for one year occurring two to three times per week
- d. GERD patients with body mass index (BMI) ≤ 35
- e. History of daily PPI therapy for greater than six months

- f. Absence of all of the following conditions:
 - i. Absence of a hiatal hernia or one that is 2 cm or less
 - ii. No esophagitis LA grade C or D
 - iii. Barrett's esophagus, or if present it is 2 cm or less
 - iv. Achalasia
 - v. Esophageal ulcer
 - vi. Esophageal motility disorder
 - vii. Altered esophageal anatomy preventing insertion of the device
 - viii. No [sic] previous failed anti-reflux surgery/procedure

This Moda policy considers MSA to be investigational.

The Aetna policy on [GERD treatment devices](#) (last review 5/24/18) does not cover StomaphyX or EsophyX (TIF devices) or LINX Reflux Management System (a sphincter augmentation device). The Cigna policy on [endoscopic anti-reflux procedures](#) (effective 3/15/18) does not provide coverage for TIF or injection/implantation of biocompatible material, such as the LINX Reflux Management System. The Regence policy on [transesophageal endoscopic therapies for GERD](#) (effective 3/1/2018) does not provide coverage for TIF, and the Regence policy on [MSA](#) (effective 3/1/2018) does not provide coverage for that procedure.

Recommendations from Others

The search for clinical practice guidelines found guidelines from three organizations: American College of Gastroenterology, National Institute for Health and Care Excellence (NICE), and European Association of Endoscopic Surgery. All of these guidelines generally recommended against the use of TIF or MSA.

The American College of Gastroenterology guidelines on diagnosis and management of GERD (Katz et al., 2013) states that TIF cannot be recommended as an alternative to medical or traditional surgical therapy. These guidelines discuss the LINX Reflux System and state that more data are needed before widespread usage of LINX can be recommended.

The NICE guidelines on GERD in adults do not mention TIF or MSA (NICE, 2014). A more recent interventional procedures guidance from NICE concludes:

There are no major safety concerns about laparoscopic insertion of a magnetic titanium ring for [GERD]. There is limited evidence of short-term efficacy, but evidence of long-term efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research (NICE, 2017, p.2).

The European Association of Endoscopic Surgery guidelines on GERD (Fuchs et al., 2014) conclude that there is not enough evidence available to recommend an alternative option to laparoscopic fundoplication for severe GERD.

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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.

DRAFT

Appendix B. GRADE Evidence Profile

Quality Assessment (Confidence in Estimate of Effect)							
Transoral Incisionless Fundoplication							
No. of Studies	Study Design(s)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Factors	Quality
Incident Barrett's esophagus							
0							No data
Complications of GERD							
0							No data
GERD symptom scores (Treatment response)							
4	RCTs	Moderate	Serious	Not serious	Not serious		Low ●●○○
Change in PPI therapy							
9	Observational	Low	Not serious	Not serious	Not serious		Low ●●○○
Harms							
12	Mixed	Low	Not serious	Not serious	Not serious		Low ●●○○

Quality Assessment (Confidence in Estimate of Effect)							
Magnetic Sphincter Augmentation Compared to Fundoplication							
No. of Studies	Study Design(s)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Factors	Quality
Incident Barrett's esophagus							
0							No data
Complications of GERD							
0							No data
GERD symptom scores							
6	Observational	Moderate	Not serious	Not serious	Serious		Very Low ●○○○
Change in PPI therapy							
6	Observational	Moderate	Not serious	Not serious	Serious		Very Low ●○○○
Harms							
Endoscopic dilation 5	Observational	Moderate	Not serious	Not serious	Serious		Very Low ●○○○
Re-operation 3							

Quality Assessment (Confidence in Estimate of Effect)							
Magnetic Sphincter Augmentation Compared to PPI							
No. of Studies	Study Design(s)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Factors	Quality
Incident Barrett's esophagus							
0							No data
Complications of GERD							
0							No data
GERD symptom scores							
1	RCT	High	N/A	Not serious	Not reported	Sparse data	Very Low ●○○○
Change in PPI therapy							
1	RCT	High	N/A	Not serious	Not reported	Sparse data	Very Low ●○○○
Harms							
1	RCT	High	N/A	Not serious	Not reported	Sparse data	Very Low ●○○○

Appendix C. Methods

Scope Statement

Populations

Adults with gastroesophageal reflux disease (GERD)

Population scoping notes: None

Interventions

Laparoscopic magnetic ring procedure for augmentation of the lower esophageal sphincter; transoral incisionless fundoplication

Intervention exclusions: None

Comparators

Medical management, Nissen fundoplication, interventions compared to each other, sham interventions

Outcomes

Critical: Incident Barrett's esophagus, complications of GERD (e.g., stricture)

Important: GERD symptom scores, change in proton pump inhibitor (PPI) therapy, harms (e.g., repeat interventions)

Considered but not selected for the GRADE table: None

Key Questions

KQ1: What is the comparative effectiveness of magnetic sphincter augmentation of the lower esophageal sphincter and transoral incisionless fundoplication in the treatment of GERD?

KQ2: How does the effectiveness of magnetic sphincter augmentation of the lower esophageal sphincter and transoral incisionless fundoplication in the treatment vary by:

- a. Patient characteristics (e.g., age, gender, weight, tobacco use)
- b. Comorbid conditions
- c. Duration of symptoms
- d. Response to prior treatments
- e. Procedural technique

KQ3: What are the harms of magnetic sphincter augmentation of the lower esophageal sphincter and transoral incisionless fundoplication in the treatment of GERD?

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)
- 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 gastroesophageal reflux disease (GERD) and magnetic or transoral fundoplication. The search was limited to publications in English published since 2012. 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.

Appendix D. Applicable Codes

CODES	DESCRIPTION
CPT Codes	
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed
43285	Removal of esophageal sphincter augmentation device

Note: Inclusion on this list does not guarantee coverage.

DRAFT

Coverage Guidance: Newer Interventional Procedures for GERD

Question: How should the draft Coverage Guidance **Newer Interventional Procedures for GERD** be applied to the Prioritized List?

Question source: HERC Staff, HTAS

Issue:

The HTAS approved the following draft “box language”:

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
 - 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*).

Rationale for Recommendations:

Transoral incisionless fundoplication (TIF) is a minimally invasive, endoscopic technique that restores the valve at the gastroesophageal junction via endoluminal fundoplication using the EsophyX device. Magnetic sphincter augmentation (MSA) is performed using the LINX Reflux Management System, which is a small, flexible ring of interlinked titanium beads with magnetic cores that is placed around the esophagus just above the stomach during a laparoscopic procedure.

Based on low-certainty evidence, the TIF procedure using the EsophyX® device appears to be effective in improving GERD-related quality of life and reducing or eliminating the need for chronic PPI therapy. Serious adverse events (including perforation, bleeding, and pneumothorax) do occur with TIF, but the

Coverage Guidance: Newer Interventional Procedures for GERD

overall 2.4% rate of these events suggests that, on balance, the benefits of TIF outweigh the harms. Although there is no evidence directly comparing TIF with laparoscopic fundoplication procedures, overall the two surgical approaches appear to have similar effectiveness. Values and preferences would favor inclusion of TIF coverage, especially as an option for GERD patients whose symptoms are not controlled on chronic medical therapy.

Current published evidence supports the safety and efficacy of the EsophyX® device used in this procedure. EsophyX® was the only device included in the systematic reviews and randomized trials that were identified for this coverage guidance.

Although the MSA procedure appears to have similar effectiveness and similar adverse events and complications compared to laparoscopic fundoplication, we have very low confidence in the evidence. Based on observational studies and one poor-quality RCT, the level of evidence is insufficient at present to establish the comparative effectiveness of MSA. Some additional costs would be likely with the addition of MSA coverage, and there are no strong values or preferences that would favor MSA over other available GERD treatment options.

Current Prioritized List Status: Codes

On the January 1, 2019 Prioritized List, transoral incisionless fundoplication (CPT 43210) is placed on lines 56 and 380. Magnetic sphincter augmentation (CPT 43284) does not appear on the List.

CPT Codes	
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed

Line: 56

Condition: ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE

Treatment: MEDICAL AND SURGICAL TREATMENT

Line: 380

Condition: ESOPHAGITIS; GERD

Treatment: SHORT-TERM MEDICAL THERAPY; SURGICAL TREATMENT

Current Prioritized List Guideline:

There are no current Guideline Notes related to transoral incisionless fundoplication or magnetic sphincter augmentation.

Coverage Guidance: Newer Interventional Procedures for GERD

HERC Staff Recommendations:

- 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) \leq 35, AND
- 6) Absence of ALL of the following conditions
 - a. Hiatal hernia larger than 2 cm
 - b. Esophagitis with 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.

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>.

- 3) Add CPT 43284 (magnetic sphincter augmentation) to Line 660, and add an entry to Guideline Note 173 as shown below:

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

Line 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:

Coverage Guidance: Newer Interventional Procedures for GERD

Procedure Code	Intervention Description	Rationale	Last Review
43284	Laparoscopy, surgical, placement of esophageal sphincter augmentation device (ie, magnetic band)	Insufficient evidence of effectiveness	January 2019 Coverage Guidance

HERC Coverage Guidance: Newer Interventional Procedures for GERD Disposition of Public Comments

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Commenters

Identification	Stakeholder
A	Craig Gonzales, RN, MBA, Director, Healthcare Economics, EndoGastric Solutions, Inc. <i>[Submitted October 26, 2018]</i>
B	Sudip K. Ghosh, PhD, Director, Health Economics & Market Access, Johnson & Johnson Medical Devices <i>[Submitted October 31, 2018]</i>

Public Comments

ID/#	Comment	Disposition
A1	<p>On behalf of EndoGastric Solutions (EGS), I am filing the following comments to the draft Coverage Guidance: Newer Interventional Procedures for GERD. EGS is the manufacturer of the EsophyX transoral incisionless fundoplication (TIF) medical device. Since 2005, EGS has marketed the EsophyX TIF surgical implant device for patients with chronic gastroesophageal reflux disease (GERD). All Medicare Administrative Contractors cover the transoral incisionless fundoplication implant procedure for symptomatic beneficiaries who have failed to respond to conservative lifestyle and pharmacologic measures.</p> <p>We understand that Health Evidence Review Committee’s (HERC) purpose is to review clinical literature to prioritize health spending in the Oregon Health Plan (OHP) and to promote evidence-based medical practice statewide through comparative effectiveness reports. EGS supports these goals, and we want to work with HERC to ensure that these goals are met while protecting beneficiaries’ access to innovative new technologies. To that end, we applaud HERC’s draft decision to recommend TIF for treatment of GERD.</p>	<i>Thank you for your comments.</i>

HERC Coverage Guidance: Newer Interventional Procedures for GERD Disposition of Public Comments

ID/#	Comment	Disposition
	<p>To ensure that the HERC continues to provide OHP with timely, clinically significant analysis, EGS asks HERC to take the following actions:</p> <p>I. HERC should modify the indications and contra-indications in the Coverage Guidance.</p> <p>II. HERC should specify which device is allowed to perform the procedure under the Coverage Guidance.</p> <p>The above issues will be discussed in detail in the following comments.</p>	
A2	<p>I. HERC should modify the indications and contra-indications in the Coverage Guidance.</p> <p>EGS urges HERC to modify the coverage guidance criteria to match that in the instructions for use (IFU) for the device as approved by the FDA. Suggested language is below:</p> <p>INDICATIONS</p> <p>The EndoGastric Solutions EsophyX Z+ Fastener Delivery Device with SerosaFuse® Fastener and accessories is indicated for use in transoral tissue approximation, full thickness plication and ligation in the GI tract and is indicated for the treatment of symptomatic chronic gastroesophageal reflux disease in patients who require and respond to pharmacological therapy. It is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia ≤ 2cm in size in patients with symptomatic chronic gastroesophageal reflux disease. Patients with hiatal hernias larger than 2cm may be included, when a laparoscopic hiatal hernia repair reduces the hernia to 2cm or less.</p> <p>CONTRAINDICATIONS</p> <p>Patients with bleeding disorders, strictures, severe esophagitis, esophageal diverticulae, obstructions, paraesophageal hernia, limited neck mobility, osteophytes of the spine, esophageal varices, esophageal infections or fungal disease, esophageal stenosis and any kind of normal or abnormal esophageal anatomy which would not permit insertion of a device of this size, chronic cough, BMI > 35 or hiatal hernia > 2cm.</p>	<p><i>The subcommittee based its recommendations for indications and contraindications on the published literature as well as the policies of other insurers. The question of whether laparoscopic hiatal hernia repair should be undertaken to permit the use of endoscopic fundoplication is beyond the scope of this coverage guidance, but adding a surgical procedure before endoscopic fundoplication would alter the balance of benefits and harms.</i></p>
A3	<p>II. HERC should specify which device is allowed under the Coverage Guidance.</p> <p>Aside from EndoGastric Solutions' EsophyX Device, the MUSE system from Medigus Ltd. may also be used to perform a variation of the TIF procedure. There are very few published clinical studies on the MUSE system. In fact, there are no published RCTs on the MUSE system. None of the three TIF-focused papers in the draft</p>	<p><i>EsophyX® was the only device that was included in the systematic reviews and randomized trials that were</i></p>

HERC Coverage Guidance: Newer Interventional Procedures for GERD Disposition of Public Comments

ID/#	Comment	Disposition
	<p>Coverage Guidance studied the MUSE system. These papers only studied the TIF procedure performed with the EsophyX device.</p> <p>We suggest that HERC specify which device is allowable under the Coverage Guidance to prevent the inadvertent use of the untested MUSE system. The guidance in Palmetto’s local coverage determination (LCD) provides a suitable template. Suggested language is below:</p> <p>D. Covered Transesophageal Endoscopic Procedure for the Treatment of GERD</p> <p>Transoral incisionless fundoplication (TIF) is a transesophageal endoscopic procedure for the treatment of GERD that is covered under this Local Coverage Determination (LCD). Current published peer reviewed literature supports the safety and efficacy of the EsophyX® device used in this procedure (CPT® Code 43210).</p> <p>EsophyX® is a device used in a transoral incisionless fundoplication (TIF®) procedure to repair the natural anti-reflux barrier and is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia = 2cm in size. EsophyX® includes SerosaFuse® Fasteners and consists of a flexible fastener delivery system comprised of three elements: a stylet, a pusher rod, and a delivery tube. The EsophyX® procedure is designed for use in transoral tissue approximation, full thickness serosa to serosa plications and to construct valves in the gastrointestinal tract which are used. The procedure is performed with the patient under general anesthesia.</p>	<p><i>identified for this coverage guidance.</i></p> <p><i>We have revised the draft recommendation to specify that EsophyX® is the only device identified in the evidence reviewed for this coverage guidance.</i></p>
A4	<p>Conclusion</p> <p>EGS appreciates this opportunity to comment on the HERC Coverage Guidance. We urge HERC to consider our recommendations carefully and make the changes necessary to ensure that Oregon patients have access to state-of-the-art care. As always, EGS looks forward to working with the state in the future to improve access to the best and innovative technologies that our company has to offer.</p> <p>The IFU [indications for use] and LCD referenced are attached to this comment.</p>	<p><i>Thank you for your comments.</i></p>
B1	<p>This communication will serve as a request for reconsideration of the decision noted in the draft coverage guidance for Newer Interventional Procedures for GERD. The decision applies to Magnetic Sphincter Augmentation (MSA) that is associated with the following two procedures:</p>	<p><i>Thank you for your comments.</i></p> <p><i>We believe our search and the included studies in the CG capture all of the available</i></p>

HERC Coverage Guidance: Newer Interventional Procedures for GERD Disposition of Public Comments

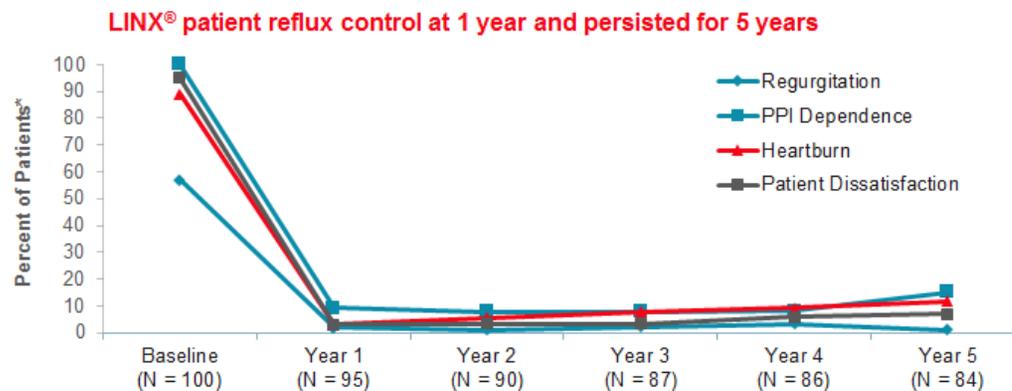
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	<p>43284: Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (i.e., magnetic band), including cruroplasty when performed</p> <p>43285: Removal of esophageal sphincter augmentation device</p> <p>Specifically, we request the above two procedures to be recommended for coverage for treatment of GERD. In total, over 50 peer-reviewed articles have been published on LINX, including 1 randomized control trial (RCT), 7 comparative, 11 single-arm, 3 meta-analysis. A few key published articles were not included in the sources of information in the basis for decision noncovered services. Therefore, to support reconsideration, additional sources of information that were not originally considered are included within this appeal. We believe that these new safety and efficacy data further reinforce the medical necessity of these procedures. In particular, you will find compelling evidence of long-term efficacy and safety of the LINX procedure, pursuant to the FDA approval. Furthermore, as a testimonial to its long-term outcomes, you will find a study recommending LINX be incorporated into the practice of National Health Service of UK following acceptable business plan and compliance.</p>	<p><i>comparative data. Single-arm (non-comparative) studies would not be included under usual HERC procedures except when they are summarized in systematic reviews.</i></p> <p><i>The SRs by Chen et al. (k = 4) and Skubleny et al. (k = 3) were identified in our search, but these were less comprehensive than the SR by Aiolfi et al. which summarizes 7 comparative observational studies of MSA, and includes all of the studies from both Skubleny et al. and Chen et al.</i></p> <p><i>Among the other manufacturer submitted citations, five are included in the Aiolfi et al. SR (Reynolds et al., 2015, Riegler et al., 2015, Warren et al., 2016, Louie et al., 2014, and Reynolds et al., 2016); seven are non-comparative studies (Ganz et al., 2016, Smith et al., 2017, Bonavina et al., 2013, Saino et al., 2015, Lipham et</i></p>

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		<p><i>al., 2015, Alicuben et al., 2018, and Prakash et al., 2017); and two are studies of LNF that are not pertinent to MSA (Draisma et al., 2006 and Lafullarde et al., 2001).</i></p> <p><i>Thus, the subcommittee is confident that it has considered the totality of comparative evidence for MSA.</i></p>
B2	<p>LINX® Reflux Management System-based MSA as an Alternative to LNF.</p> <p>LINX is a first line, fundic-sparing laparoscopic surgical treatment option for GERD. It consists of small, flexible band of titanium beads, with magnetic cores that augment the LES' ability to close while allowing food and liquid to pass through to the stomach. Approved via the most rigorous FDA PMA process, LINX is safe and efficacious, reversible and reproducible, and associated with fewer side effects and complications compared to LNF.¹⁻⁶</p>	<p><i>Thank you for your comments. We believe the relative merits of MSA and LNF were well summarized in the AioIfi SR which was considered by the subcommittee.</i></p>
B3	<p>LINX® is supported by clinical societies and HTA bodies</p> <p>Determinations made by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), Federal Agency for Healthcare Research and Quality (AHRQ), and the American Society of General Surgeons (ASGS) are testimonials to support of this technology by gastroenterologists, surgeons, and foregut experts.^{2,3,7} In their most recent Safety and Effectiveness Analysis statement (2017), the SAGES Technology and Value Assessment Committee performed an exhaustive and detailed review of the published literature available for LINX, with dozens of studies cited and detailed. This report concluded that “implantation of the LINX® device should be covered and reimbursed by insurance for appropriate patients who meet the selection criteria as described above.”</p>	<p><i>It is misleading to assert that AHRQ supports the use of this technology. AHRQ stated that Horizon Scans should “...not be construed as endorsements or rejections of specific interventions.”</i></p> <p><i>The statement by SAGES is noted, but LINX is not mentioned in the official clinical practice guideline for surgical</i></p>

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		<i>treatment of GERD that has been promulgated by SAGES. Similarly, the statement by ASGS is noted, but this organization does not appear to have a process for developing clinical practice guidelines.</i>
B4	<p>Updated LINX® Evidence Not Considered Previously</p> <p><u>Complications of GERD</u></p> <ul style="list-style-type: none"> • LINX patients experienced long term improvement in regurgitation, PPI dependence, heartburn, and patient satisfaction.¹ <ul style="list-style-type: none"> ○ Patients experienced significant and sustained improvement in regurgitation up to 5 years.^{1,8,9} 	<p><i>Thank you for your comments. We believe the relative merits of MSA and LNF were well summarized in the Aiolfi et al. SR, which was considered by the subcommittee. The data presented here were either included in the coverage guidance and informed the estimates of effect or are non-comparative studies as detailed above in B1.</i></p> <p><i>It should be noted that the NICE guidance issued in 2017 states that “...evidence of the long-term efficacy is inadequate,” and they recommend that the procedure “...only be used with special</i></p>



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	<p>○ Significantly less gas/bloating with LINX and greater ability to belch and vomit with LINX.^{6,10}</p> <div style="text-align: center;"> <p>Propensity matched studies: LINX® vs Nissen fundoplication Side-effect profile, 1-year follow-up</p> <table border="1" style="margin: 10px auto; border-collapse: collapse;"> <caption>Side-effect profile, 1-year follow-up</caption> <thead> <tr> <th>Side Effect</th> <th>Study</th> <th>LINX Procedure (%)</th> <th>Nissen fundoplication (%)</th> <th>p-value</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Ability to belch</td> <td>Warren, et al, N=114</td> <td>97.0%</td> <td>95.0%</td> <td>p<0.001</td> </tr> <tr> <td>Reynolds, et al, N=50</td> <td>91.5%</td> <td>74.5%</td> <td>p=0.028</td> </tr> <tr> <td rowspan="2">Ability to vomit</td> <td>Warren, et al, N=114</td> <td>88.0%</td> <td>40.0%</td> <td>p<0.001</td> </tr> <tr> <td>Reynolds, et al, N=50</td> <td>95.7%</td> <td>78.7%</td> <td>p<0.01</td> </tr> <tr> <td rowspan="2">Gas/bloating</td> <td>Warren, et al, N=114</td> <td>41.0%</td> <td>59.0%</td> <td>p<0.01</td> </tr> <tr> <td>Reynolds, et al, N=50</td> <td>27.7%</td> <td>36.3%</td> <td></td> </tr> </tbody> </table> </div> <p>○ Less regurgitation at one-year post-procedure.⁸</p> <p><u>GERD symptom scores</u></p> <ul style="list-style-type: none"> As measured by GERD-HRQL, LINX significantly improved quality of life.^{1,8,10,11,12,9,13} <p><u>Change in PPI therapy</u></p> <ul style="list-style-type: none"> Over 75% of patients experienced complete cessation of PPI at up to 5 years.^{1,8,10,11,12,9,13} Similar cessation of PPI usage found in patients undergoing LINX and LNF.⁵ <p><u>Harms</u></p> <ul style="list-style-type: none"> A 2014 study analyzed safety of LINX® procedure in the first 1000 patients worldwide at 82 institutions. While the intra/perioperative complication rates and device removal rates were 0.1% and 3.4%, respectively, the erosion rates were 0.1%.¹⁴ Most importantly, a recent seminal article analyzed FDA’s Manufacturer and User Facility Device Experience (MAUDE) database for data of 3283 patients who underwent LINX® procedure between March 2012-May 	Side Effect	Study	LINX Procedure (%)	Nissen fundoplication (%)	p-value	Ability to belch	Warren, et al, N=114	97.0%	95.0%	p<0.001	Reynolds, et al, N=50	91.5%	74.5%	p=0.028	Ability to vomit	Warren, et al, N=114	88.0%	40.0%	p<0.001	Reynolds, et al, N=50	95.7%	78.7%	p<0.01	Gas/bloating	Warren, et al, N=114	41.0%	59.0%	p<0.01	Reynolds, et al, N=50	27.7%	36.3%		<p><i>arrangements for clinical governance, consent, and audit and research.”</i></p>
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	<p>2016 across 165 institutes. The study showed no perioperative deaths and life-threatening complications, or device malfunctions.⁴ While the overall device explant rate was 2.7%, the erosion rate was 0.15%.</p> <ul style="list-style-type: none"> • Five-year reoperation rates were reported to be in the 13.1%-15.2% range with LNF,^{15,16} and in the 6.8%-7% range with LINX.^{1,11} • Importantly, another study that assessed the FDA’s MAUDE database for 9453 global implants of MSA device over the timeframe Feb 2007 – July 2017, reported device erosion of 0.3% with the median time to erosion of 26 months.¹⁷ • None of above studies reported MSA-associated mortality <p><u>Meta-analysis</u></p> <ul style="list-style-type: none"> • A recent meta-analysis of four databases compared LINX® to Nissen fundoplication by assessing 325 Nissen fundoplication and 299 LINX® procedures spanning 2005-2016. The publication reported that operating time with LINX® is in the 60-66 min range, which is 19.5%-29.5% shorter than Nissen fundoplication.¹⁸ <p><u>Recommendation of LINX® into the National Health Service (NHS) practice in UK</u></p> <p>In a study that prospectively evaluated 47 patients who underwent the LINX® procedure reported that reflux health-related quality of life (GERD-HRQL) was significantly improved after the procedure and maintained at one- and two-year (P < 0.0001) follow-up.¹⁹ Drug dependency went from 100% at baseline to 2.6% and 8.7% after one and two years. Importantly, the cost of the implant was offset against savings made from reduced usage of surgical equipment, operating time, inpatient stay/readmission.</p> <p>As such, the authors recommended LINX® to be incorporated into NHS practice.</p>	
B5	<p>Coverage Reconsideration</p> <p>We believe that the completion of two FDA trials providing significant long term follow up, as well as multiple studies, peer-reviewed articles, and support of key medical societies and HTA bodies indicate that the MSA has withstood appropriate scrutiny, and can no longer be considered experimental/investigational. As such, it should be considered a part of the armamentarium in the proven and effective surgical treatment of GERD in appropriate patients.</p>	<i>Thank you for your comments.</i>

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	We would be happy to further discuss this with you and support your efforts for evidence-based review of coverage guidance and answer any questions that you may have as you consider this request. Thank you for your consideration.	

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