Health Evidence Review Commission

August 8, 2019

1:30 PM - 4:30 PM

Clackamas Community College
Wilsonville Training Center, Room 111-112
29373 SW Town Center Loop E, Wilsonville, Oregon, 97070

Section 1.0

Call to Order

AGENDA

HEALTH EVIDENCE REVIEW COMMISSION

Clackamas Community College
Wilsonville Training Center, Rooms 111-112
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
August 8, 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 (5/16/19)	Kevin Olson	X
3	1:40 PM	Director's report	Darren Coffman	
4	1:45 PM	Value-based Benefits Subcommittee report	Ariel Smits Cat Livingston	X

5	2:15 PM	Proposed new coverage guidance topics
		• Review scoping statements
		  ○ Multicomponent Interventions to Improve Screening for Breast, Cervical or Colorectal Cancer
		  ○ Non-invasive Vagus Nerve Stimulation for Cluster and Migraine Headache (e.g., Gammacore)
		  ○ Percutaneous Occlusion of the Left Atrial Appendage in Atrial Fibrillation (e.g., Watchman)
		  ○ Patient and Radiologic Factors Influencing Outcomes in Total Knee Arthroplasty
		• Select and prioritize topics for coverage guidance development
			Cat Livingston
			Adam Obley
				X

6	2:45 PM	Status of the Health Technology Assessment Subcommittee	Darren Coffman	X
7	3:00 PM	Temporary Percutaneous Mechanical Circulatory Support with Impella Devices • Coverage guidance • Prioritized List changes	Cat Livingston Adam Obley	X
8	3:30 PM	Community Health Workers for Patients with Chronic Disease • Multisector intervention report	Adam Obley Cat Livingston	X
9	4:00 PM	Commissioner travel reimbursement policy	Jenny Osbourne	
10	4:20 PM	Next steps • Schedule next meeting – TBD	Kevin Olson	
11	4:30 PM	Adjournment	Kevin Olson	

Note: Public testimony will be taken on each topic per HERC policy at the time at which that topic is discussed. Public testimony not related to a topic on the agenda will be taken at the end of the meeting.

MINUTES

HEALTH EVIDENCE REVIEW COMMISSION
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
May 16, 2019

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, Vice-Chair; Mark Gibson (departed at 3:30 pm); Leda Garside, RN, MBA; Angela Senders, ND; Gary Allen, DMD; Devan Kansagara, MD (arrived at 1:40 pm); Lynnea Lindsey, PhD; Leslie Sutton; Adriane Irwin, PharmD, Kevin Cuccaro, DO (by phone).

Members Absent: Michael Adler, MD.

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

Also Attending: Renae Wentz, MD, MPH, Dana Hargunani, MD, MPH and Lisa Shields (Oregon Health Authority); Laura Ocker, LAc; Mary Kelly Rolf; Douglas Carr, MD (Umpqua Health); Rika Bierek; Kelly Howard; Amara M and Wendy Sinclair (Oregon Pain Action Group); Kathy Spain; Noel Elliot; Joe Elliot; Jay Hall, Amit Shah, Marine Schmitt and Kali Schweitzer (CareOregon); Kim Blood (WVP Health Authority); Cherry Amabisca; Sue Griffin; Laurel Ramy; Kristian Foden-Vencil (OPB); Julia; Alan Chino, Ph.D.; Jacqueline Conner; Barbara C.; Tina M. Stanfa (Kieser); Jessica Riegel.

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 3/14/2019 meeting as presented. CARRIES 10-0. *(Absent: Kansagara)*

Director's Report

Staff changes:
Coffman said this meeting will be Wally Shaffer's last. He thanked him for his years or service. He will be missed.

Membership
Coffman said Dr. Kathryn Schabel, who has been serving on the Health Technology Assessment Subcommittee (HTAS), has been appointed to HERC and confirmed by the Senate. She is an orthopedic surgeon.

Legislative Reports
A draft biennial report is being worked on, waiting for the decisions of today's meeting. It will also be finalized and off to the Legislature soon.

The report on Extended Stay Centers is up for review today as part of the HTAS report and will be finalized and formatted for release to the Legislature soon.

Coverage guidance update
A topic, *Sacral Nerve Stimulation for Non-Obstructive Urinary Retention,* was approved in 2017 as a coverage guidance topic. There is good evidence from trusted sources showing that this is a good topic to handle at the Value-based Benefits Subcommittee (VbBS) level.

MOTION: To move the topic of Sacral Nerve Stimulation for Non-Obstructive Urinary Retention from HTAS to VbBS and not conduct a coverage guidance process. CARRIES 12:0.

Value-based Benefits Subcommittee (VbBS) Report on Prioritized List Changes
Meeting materials pages 44-225

Reprioritization of Certain Chronic Pain Conditions
Meeting materials pages 88-225

Dr. Dana Hargunani thanked the Commission for allowing a pause in their deliberations to allow for the third-party review. She has been pleased by the appraisal assessment by Aggregate Analytics Incorporated (AAI). She said her task to do a complete review of the conflict of interest policies is underway.

Hargunani thanked the staff and the members of the Chronic Pain Task Force (CPTF) who worked on this topic for +18 months. She thanked the public who have had tremendous engagement on this topic from near and far. This input, both from personal accounts and from professionals, has contributed significantly to the Commission's work.

She said the Commission was looking at opening the back-pain guideline, particularly around opioid prescribing. There is forthcoming evidence expected to be published later this year and expect to re-open the topic this coming winter.

Hargunani said OHA, separate from HERC, is developing a task force around opioid prescribing guidelines.

Dr. Andrea Skelly then gave a presentation on AAI's evidence appraisal. There were no questions from the Commission.

Smits gave a brief presentation (meeting materials, pages 88-112) of the history of the topic and summarized the options before the Commission. She said VbBS looked at rescoring the line for the 5 conditions under consideration and the prioritization level did not change, therefore they did not recommend moving it into the funded region. VbBS's recommendation is to adopt *OPTION 1: Do not reprioritize chronic pain syndrome, fibromyalgia and related conditions due to lack of evidence of*

effectiveness of available treatment modalities. Consider readdressing the prioritization of these conditions as part of the 2022 or 2024 Biennial Review.

Sutton asked if we wait, when would changes be effective? Smits said the next time we are able to add and move lines would be effective in 2022.

Public Comment:
Dr. Amit Shah, CareOregon, declared no conflicts of interest. He said he supports the VbBS recommendation of Option 1, to not reprioritize the 5 chronic pain conditions due to weak evidence. Adding coverage would add significant expense in medication costs and harms. His Coordinated Care Organization (CCO) has seen a great number of ICU admissions secondary to opioid prescription use.

Dr. Douglas Carr, CEO of Umpqua Health, the CCO for Douglas County, declared no conflicts of interest. He supports the VbBS recommendation of Option 1, to not reprioritize the 5 chronic pain conditions. He supports the changes to Guideline Note 60, abolishing the mandatory taper as well as allowing for short-term opioid flares. He looks forward to the winter review of the back-pain lines and alignment with the Oregon Opioid Prescribing Guidelines.

Cherry Amabisca, declared no conflicts of interest. She spoke about her brother's struggles with forced tapers. She urged the Commission to retroactively rescind Guideline Note 60 and to eliminate any part of the proposals that endorse mandatory tapers.

Sue Griffin is a chronic pain patient. She has many pain conditions and has needed greater than 90 MME to control her pain. She has been on OHP and had her medication tapered lower. She recommends adding massage to the treatment protocol.

Amara M, co-founder of the Oregon Pain Action Group, a volunteer, declared no conflicts of interest. She said she is encouraged that the Commission is re-opening Guideline Note 60 for conditions of the back and spine. She noted the AAI report found that the evidence studied was found inconclusive to exclude the use of opioids for the treatment of fibromyalgia. She asked that opioids for fibromyalgia be covered. She said she is in favor of Option 3C. She asked the Commission to consider additional opioid prescribing for flares.

Kelly Howard declared no conflicts of interest. She talked about flares leading to a decrease in a patient's quality of life and physiological condition. She said she has tried non-opioid treatments to little success. She said there is no real evidence proving that treating flares with short-term opioids is harmful. The CDC and the FDA have recently come out to say they did not mean to direct force-tapers, nor tapers to zero.

Wendy Sinclair thanked the Commission for agreeing to revisit Guideline Note 60. She questioned why the CPTF proposal went on so long if the conditions didn't warrant being brought above the line. She feels they are valid medical conditions that need medical treatment and that opioids should be allowed. After reading through the AAI report, she asked the Commission to vote in favor of Option 3C.

Laura Ocker, declared conflicts of interest that she works full time at a Federally Qualified Health Center, is past-president of the Association of Acupuncture and Oriental Medicine, and is a part-time advisor to a study that is evaluating the back-pain changes that were implemented under OHP. She was also a member of the Chronic Pain Task Force and a past-VbBS member. She said she submitted a CMS Bulletin

dated February 2019 on opioid prescribing and wanted to make sure the Commission got that. She said that her intent on the CPTF was to open access to effective non-pharmalogical therapies for patients with chronic pain.

Julia said she has been following this topic for the past 18 months. She said she is glad the advocates have been able to prevent the Commission from voting for the past year. She supports Option 3C. She said she does not support tapers or trying to force people under 90 MME. She said she had never heard the Commission discuss the difference between addiction and dependence. She said not everyone who uses opioids is an addict.

Dr. Alan Chino identified himself as a clinical health psychologist who served two terms on the Oregon Pain Management Commission and a pain specialist and declared no conflicts of interest. He believes forced tapers are dangerous. People who are monitored in a multi-disciplinary way tend to do well on long-term opioids. He supports Option 3C and believes fibromyalgia should be above the line.

Jacqueline Conner declared no conflicts of interest. She is a pain patient. She said none of us can escape our own bias; we come at this from a human standpoint. This is a quality of life issue. She said she was force-tapered in 10 days based on her doctor saying she had to do what the CDC recommended. It took the CDC 3-years to come out and clarify their position. She said decisions like the one the Commission faces today cause patients to be abandoned by doctors and causes suicides.

Tina M. Stanfa is a chronic pain patient who has had many medical issues. She has been in chronic pain since 14-years old. She has tried every modality and they have not been effective. She said the CDC guideline started a problem that should never had happened. She said people who are not trained to prescribe pain medication should not make decisions about prescribing pain medications. She has had her medication cut in half which is only enough to just get by. She supports Option 3C.

Jay Hall has a genetic disease causing tumors all over his body and has had multiple surgeries. As a consequence of those surgeries he has been left with chronic pain. He was seen at the Mayo clinic and prescribed high doses opioids; his Oregon doctor tapered him off. He echoed the AAI presentation by saying statistical significance does not equal clinical effectiveness. He mentioned the CDC's recent clarification of their tapering statement.

Jessica Riegel is a chronic pain patient who is being treated with chiropractic and acupuncture. The number of treatments is very limited. She is totally off opioids. She has been granted more visits in the past but in the length of time it took to get the authorization she wound up in the emergency department. She advocated looking at patients on an individual basis.

Olson said public testimony and input has helped shape the conversation around this complicated topic.

Olson reviewed the prioritization methodology. Smits led a discussion about reprioritization of the five conditions. She showed the line scoring that VbBS recommends be used. They thought the best scores were to give a "4" to healthy life years, a "3" to suffering, a "0" to tertiary prevention (due to being unsure if treatment of chronic pain prevents development of any condition), a "1" to effectiveness and a "0.8" to need for service. These scores result in a line score of 112, which would keep any new line at about line 528, the current location of these conditions. Since the rescoring did not move the line, the VbBS voted 6-0 in favor of Option 1, which makes no change to coverage for these five specific chronic pain conditions.

Discussion:
Gibson said we use the prioritization methodology to treat everyone fairly, consistently and equitably. Given that there is high-quality research available to us soon VbBS felt that maintaining stasis was a legitimate conclusion to our deliberation.

Lindsey said this decision is not a hard-stop and the new studies may shift the paradigm of how we have this discussion in the future. She said that "no change" really isn't "no change" – we are going to get there.

Kansagara said he appreciated all the public testimony. He said he struggled with the scoring, particularly around effectiveness, suffering and vulnerable populations. It seems incongruent with the public testimony heard. The numbers seem subjective.

Hodges said VbBS went through the scoring very carefully in the morning meeting, striving for consistency with other conditions that scored similarly. For example, they scored the suffering category the same as the score for rheumatoid arthritis.

Kansagara asked if the Commission voted for Option 1, would there be any forced tapering requirement for these conditions. Hodges and Olson said no, it would just mean that the five unfunded conditions would remain unfunded.

Lindsey said she struggles with the lack of non-pharmalogical treatments for those who have had trauma and vulnerable pain patients. If we put this off another two years we are delaying access to patients who might benefit. She said she struggles with the issue of having lack of evidence for interventions that she has seen be effective in her clinical practice. Olson said there is a similar issue in oncology. There are interventions that work 10% of the time, but for those for whom it is effective it is a great intervention. To determine the 10%, it takes studies.

Allen said testimony heard from medical directors that the costs are not inconsequential.

MOTION: To accept the VbBS recommendation of Option 1, to table the CPTF report and make no changes to the Prioritized List at this time. CARRIES: 12-0.

Guideline Note 60 Discussion:
Smits said this guideline outlines when opioids would be covered for back and neck conditions. There is a section on acute prescribing and a section stating there should be no chronic prescribing. It stated if a patient were on long-term opioids they should be tapered off. The history of this decision is that the Back Pain Reprioritization Task Force found lack of evidence of benefit for long-term opioid use and found evidence of harms. The Task Force wrote a tapering plan so patients would not be cut-off without a taper, giving them an 18-month window. The Chronic Pain Task Force suggested to strike the language allowing for prescribing of opioids for flares. VbBS does not support that suggestion given that the topic will be opened again when the new studies are out this winter.

HERC's staff developed wording for the guideline for consideration. After a brief discussion about tapering, the Commission members edited the language slightly as listed below:

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

Coffman noted, if approved, this change would go into effect with the implementation of the next Prioritized List on October 1, 2019.

MOTION: To approve the amended language in Guideline Note 60 for patients on long-term opioid therapy as stated. CARRIES: 11-0 (*Absent: Gibson)*

Other VbBS Recommendations:
Ariel Smits reported the VbBS met earlier in the day, 5-16-2019. She summarized the subcommittee's recommendations.

RECOMMENDED CODE MOVEMENT (effective 10/1/2019)
- Add the procedure code for injections for plantar fasciitis to an uncovered line
- Add the procedure code for radiofrequency ablation for knee osteoarthritis to an uncovered line
- Add the procedure code for pneumatic compression devices for lymphedema therapy to an uncovered line
- Make various straightforward coding changes

RECOMMENDED GUIDELINE CHANGES (effective 10/1/2019)
- Make various straightforward guideline note changes

2020 BIENNIAL REVIEW (effective January 1, 2020)
- Create a new line for liver transplantation for hepatic malignancies in the funded region

MOTION: To accept the other VbBS recommendations on Prioritized List changes as stated. See the VbBS minutes of 5/16/2019 for a full description. Carries: 11-0. *(Absent: Gibson)*

Evidence-based report on Ambulatory Surgery Centers with Extended Stay Centers: Appropriate Procedures and Patient Characteristics
Meeting materials, pages 226-291

Shaffer gave a history of the report. Shaffer and Obley presented an overview of the evidence. Shaffer then read the proposed guideline from HTAS.

Shaffer reported on HB 2717, which is a bill that would eliminate the requirement for ASCs and ESCs to file ASC discharge abstract records with the Oregon Health Authority (OHA). Reports would still go to the Oregon Patient Safety Commission (OPSC), who would release its data to OHA. The bill has new timelines; HERC is to develop evidence-based guidelines by July 1, 2022 and to update those guidelines by July 1, 2025 based on data collected by the OPSC. The bill has passed through the House Health Care Committee and is in the Ways and Means Committee; it has not yet gone to the Senate. It may be amended along the way or may not be enacted at all.

There was no discussion.

MOTION: To approve the proposed report for Ambulatory Surgery Centers with Extended Stay Centers: Appropriate Procedures and Patient Characteristics as presented. Carries 11-0. *(Absent: Gibson)*

Approved Guideline:

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

Other topics: Coverage Guidance Topics

Smits said there are a few coverage guidance topics to address:

- Intermittent Pneumatic Compression Devices for the Treatment of Lymphedema
  - This topic was addressed at today's VbBS meeting
- Liposuction for the Treatment of Lymphedema
  - After staff review, no coverage guidance or prioritization change needed
- Extracorporeal Membrane Oxygenation
  - After staff review, evidence is not likely to produce a recommendation that would effectively reduce inappropriate utilization without adversely impacting patients who would need it
- Acellular Dermal Matrix for Post-Mastectomy Breast Reconstruction
  - VbBS would like to address this at the August 2019 meeting
- Interventional Treatments for Lower Extremity Chronic Venous Disease
  - VbBS would like to address this at the August 2019 meeting

MOTION: To remove these topics as potential coverage guidances. Carries 11-0. *(Absent: Gibson)*

Coffman said new potential coverage guidance topics will be presented in August.

Adjournment

Meeting adjourned at 4:30 pm. Next meeting will be from 1:30-4:30 pm on Thursday, August 8, 2019 at Clackamas Community College Wilsonville Training Center, Rooms 111-112, Wilsonville, Oregon.

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on May 16. 2019

For specific coding recommendations and guideline wording, please see the text of the 5/16/2019 VbBS minutes.

RECOMMENDED CODE MOVEMENT (effective 10/1/2019)

- Add the procedure code for injections for plantar fasciitis to an uncovered line
- Add the procedure code for radiofrequency ablation for knee osteoarthritis to an uncovered line
- Add the procedure code for pneumatic compression devices for lymphedema therapy to an uncovered line
- Move procedure codes for functional MRI (fMRI) from an unfunded line to the epilepsy surgery line
- Make various straightforward coding changes

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- Reprioritization of the chronic pain syndrome/fibromyalgia line was considered, but not recommended
- Preventive treatment of women at high risk for lymphedema was considered, but not recommended

RECOMMENDED GUIDELINE CHANGES (effective 10/1/2019)

- Edit the guideline for opioids for conditions of the back and spine to remove the requirement for those on long-term opioid therapy to be tapered off completely over a specified period of time *[Note: see the 5/16/19 HERC minutes for further changes made to the guideline]*
- Make various straightforward guideline note changes

2020 BIENNIAL REVIEW (effective January 1, 2020)

- Create a new line for liver transplantation for hepatic malignancies in the funded region

VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
May 16, 2019
8:00 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, Vice-Chair; Mark Gibson; Vern Saboe, DC; Gary Allen, DMD; Adriane Irwin, PharmD.

Members Absent: none

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

Also Attending: Renae Wentz, MD (Oregon Health Authority); Laura Ocker, LAc; Mary Kelly Rolf; Douglass Carr, MD (Umpqua Health); Jeanne Savage, MD (WVCH); Wendy Gordon; Larry Gordon; Rika Bierek (Oregon Medical Association); Kelly Howard; Len Ramey; Amara M; Kathy Spain; Noel Elliot; Joseph Elliot; Laura Dolph; Jay Hall.

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

The meeting was called to order at 8:05 am and roll was called. Minutes from the 3/14/19 VbBS meeting were reviewed and approved unanimously as submitted. Smits reviewed the errata document; there were no questions.

Coffman announced that Kathryn Schabel, MD, was confirmed this week by the Oregon Senate to a HERC position; she already serves on HTAS.

Ø **Topic: Straightforward/Consent Agenda**

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

Recommended Actions:

1) Add 11971 (Removal of tissue expander(s) without insertion of prosthesis) to lines 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER and 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
2) Add 96132 and 96133 (Neuropsychological testing evaluation services) to line 174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS Treatment: SINGLE FOCAL SURGERY
3) Remove M54.0 family (Panniculitis affecting regions of neck and back) from line 401 CONDITIONS OF THE BACK AND SPINE
    a. Add M54.0 family to line 519 PANNICULITIS
4) Add 19370 (Open periprosthetic capsulotomy, breast), 19371 (Periprosthetic capsulectomy, breast), and 19380 (Revision of reconstructed breast) to line 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER

5) Add G12.20 (Motor neuron disease, unspecified) to line 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
    a. Advise HSD to remove G12.20 from the Undefined Diagnosis File
6) The coding specification attached to line 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS was updated to include one additional CPT code (CPT 63650 Percutaneous implantation of neurostimulator electrode array, epidural):
    a. "Spinal cord stimulation (63650~~63655~~-63688) is not included on this line when paired with ICD-10-CM category G90.5 Complex regional pain syndrome/reflex sympathetic dystrophy…"
7) Add L8690, L8691, L8693, and L8694 (Auditory osseointegrated device) to lines 311 HEARING LOSS - AGE 5 OR UNDER and 444 HEARING LOSS - OVER AGE OF FIVE
8) Add HCPCS L8692 (Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment) to line 311 HEARING LOSS - AGE 5 OR UNDER
9) Modify GN103 as shown in Appendix A
10) Modify GN173 as shown in Appendix A
11) Remove ICD-10 M47.01 family (Anterior spinal artery compression syndromes) and the M47.02 family (Vertebral artery compression syndromes) from lines 346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS and 401 CONDITIONS OF THE BACK AND SPINE
12) Add ICD-10 M47.01 family (Anterior spinal artery compression syndromes) and the M47.02 family (Vertebral artery compression syndromes) to line 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
13) Recommend HSD add CPT 97033 (Application of a modality to 1 or more areas; iontophoresis, each 15 minutes) to the Ancillary File

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

Ø **Topic: 2020 Biennial Review: Reprioritization of certain chronic pain conditions**

Discussion: Dr. Dana Hargunani thanked the Commission for allowing a pause in their deliberations to allow for the third-party review. She has been pleased by the appraisal assessment by Aggregate Analytics Incorporated (AAI). She said her task to do a complete review of the conflict of interest policies is underway.

Hargunani thanked the staff and the members of the Chronic Pain Task Force (CPTF) who worked on this topic for +18 months. She thanked the public who have had tremendous engagement on this topic from near and far. This input, both from personal accounts and from professionals, has contributed significantly to the Commission's work.

She said the Commission was looking at opening the back-pain guideline, particularly around opioid prescribing. There is forthcoming evidence expected to be published later this year and expect to re-open the topic this coming winter.

Hargunani said OHA, separate from HERC, is developing a task force around opioid prescribing guidelines.

Dr. Andrea Skelly then gave a presentation on AAI's evidence appraisal and clarifying questions from the subcommittee were answered.

Smits gave a brief presentation of the history of the topic and summarized the three options included in the materials on the potential reprioritization of fibromyalgia and four additional chronic pain conditions.

Public testimony
Kelly Rolf, a fibromyalgia patient. Ms. Rolf testified about her various medical conditions, and how they responded well to opioid medications. These medications allowed her to function. She has had her opioid doses reduced, and now is having trouble functioning and is at times suicidal from the pain.

Douglas Carr, the CMO of Umpqua Health Alliance, testified about the sparse evidence to support the interventions being proposed for coverage for certain chronic pain conditions. He noted that high quality evidence will be available this winter on this topic. He noted that the non-pharmacologic interventions have slight or no long-term benefit. He recommended adoption of option 1 (no change from current coverage) and have the HERC review upcoming studies when they become available.

Larry Gordon, the husband of a chronic pain patient, testified about the unintended consequences and misinterpretations of the CDC opioid guidelines. His wife was forced tapered from opioids, and had negative consequences including suicidal ideation. He supports grandfathering in current chronic pain patients who are taking opioids appropriately. He also recommended considering coverage of opioids for patients not currently on them, as the CDC guidelines say that these types of patients can be treated with long-term opioids. He feels there is no evidence for forced tapers. He felt there should be no hard limits on opioid dosing as no evidence exists to support these limits. There are no studies finding that opioids don't work long term—there is just no study of long-term opioids at all. People have committed suicide and experienced other harms due to tapering. He recommended putting a hold on a decision and waiting for coming evidence.

Kelly Howard, a chronic pain patient, testified regarding coverage of additional opioids for pain flares. Breakthrough pain occurs 50-90% of the time for patients on opioids. Flares can increase stress and reduce a patient's medical status. Non-opioid treatments for flares may not be sufficient. She requested access to all tools to deal with breakthrough pain.

Amara M, the cofounder of the Oregon Pain Action Group, testified about being encouraged that the HERC was reopening guidelines on opioids for back conditions. She asked for an emergency halt/pause for opioid tapers for any conditions, including back and spine conditions. She noted that AAI found that evidence was missing for excluding fibromyalgia. She requested consideration of option 3C (allows opioid therapy for chronic pain consistent with national guidelines). She recommended not excluding any diagnosis (such as fibromyalgia) from opioid therapy based on diagnosis code. She also requested that the Commission not remove coverage of additional opioids for flares of chronic pain.

Kathy Spain, a chronic pain patient with fibromyalgia, testified that opioid pain medication was the only therapy that worked for her. Opioid therapy allowed her to function normally in daily life. With opioid therapy, she is able to work part time, do leisure activities and care for family. She has been

treated with opioids for 18 yrs. Without opioids, she would lose function and the ability to do things she enjoys. Pain medications are lifesaving. She feels that there is a stigma currently for being a chronic pain patient.

Laura Dolph, a chronic pain patient due to porphyria, testified in support of option 3c, but not in favor of removing coverage of flare for back pain opioid therapy. She feels that medications help flares, and that no evidence has been shown that treating flares is harmful. She testified against forced tapers. She has tried alternative pain therapies, which helped a bit mentally, but did not affect her pain. She attempted suicide twice due to pain. Pain management should be an exclusive arrangement between patient and provider.

Joseph Elliot, the husband of a chronic pain patient, testified about how opioid therapy has helped her for over 10 yrs. With opioid therapy, his wife is a normally functioning woman with some mobility limitations. If forced to taper off opioids, she would lose function, and has lost cognitive abilities when off opioids in the past. He urged the subcommittee to consider the impact on families and loved ones of removing opioid therapy.

Jeanne Savage, the CMO of Willamette Valley Community Health CCO and a family physician, testified. She noted that many conditions are not currently covered that we want to cover, like asymptomatic hernias, but OHP must balance what is not covered if you choose to cover these particular chronic pain conditions. CCOs have limits on what they can afford to pay for. She stressed the need for the subcommittee to consider fiscal responsibility.

VbBS Discussion:
Saboe requested information on the number of patients on OHP who have one of these 5 diagnoses under consideration. Gingerich replied that there appears to be about 7,000 OHP patients with one of these diagnoses and no other covered diagnosis. Coffman added that patients with only these diagnoses might or might not currently have medications covered, depending on comorbid conditions, lack of PA process in their CCO, etc. Gibson noted that the definition of some of these conditions are so poor that it is difficult to determine what we are treating. He also noted that the proposed interventions have low evidence of effectiveness.

VbBS then reviewed the line scoring for the proposed new line. They determined the most appropriate scores are a "4" for healthy life years, a "3" for suffering, a "0" for tertiary prevention (due to being unsure if treatment of chronic pain prevents development of any condition), a "1" for effectiveness and a "0.8" to need for service. These scores result in a line score of 112, which would keep any new line at about line 528, the current location of these conditions. Based on the fact that the rescoring did not move the line, the VbBS voted 6-0 in favor of option 1, which makes no change to coverage for these 5 specific chronic pain conditions.

The VbBS then discussed the proposed edits to Guideline Note 60, OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE. Hodges asked what evidence was used for the creation of GN60; the reply was expert opinion. Hodges suggested just deleting the dates in the previous taper wording that had already passed, rather than changing the entire taper language. Olson noted that the proposed wording resulted in no consequences for a patient who failed to taper off opioids. Hodges argued that the CCOs are using GN60 and having no issues with the current wording. She suggested waiting to make any changes to the GN60 wording until the global evaluation of the back line planned for this winter. Olson noted that we don't have evidence of how to safely taper patients, or whether

patients need to be tapered down to zero. Irwin was not comfortable leaving GN60 with the current wording. She noted that public comments have shown harms, and that it gives a bad message to leave tapering verbiage in our guideline. Irwin suggested simply deleting GN60. Hodges argued against the staff suggested wording changes, which included nothing about patient safety, harmful doses, or the need to taper patients to safer doses of opioids. Hargunani replied that the CDC guidelines do not actually recommend tapering a patient's opioid dose down if the patient is taking over a certain dose; rather the CDC guidelines just state that caution needs to be taken when considering increasing dose over a certain level. Olson expressed his concern for patient abandonment that might be an unintentional consequence of the current guideline. A recommendation was approved in favor of the staff suggested wording changes to the tapering paragraph in GN60.

Lastly, the VbBS discussed the proposed language regarding removal of additional opioids for treatment of flares of pain, as proposed by the CPTF. Irwin was concerned about the lack of evidence to support this change. Gibson noted that this type of change can be addressed when the VbBS looks at the entire guideline this coming winter. The decision was to make no change to flare language (continue to include in Guideline Note 60).

Note: further changes to Guideline Note 60 were made at the May 2019 HERC meeting. Please see the 5/16/19 HERC minutes for that discussion.

Recommended Actions:

1) No change to the current prioritization of 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)
2) Modify guideline note 60 as shown in Appendix A

MOTION: To recommend the changes to Guideline Note 60 as presented. CARRIES 5-1 (Nay: Hodges)

Ø **Topic: 2020 Biennial Review: Reprioritization of liver transplant for hepatic malignancies**

Discussion: Smits reviewed the summary document. There were no questions or discussion.

Recommended Actions:

1) A new line for liver transplantation for hepatic malignancies was created as indicated below with the line scoring shown, effective January 2020

Line: XXX
Condition: CANCER OF LIVER OTHER THAN ANGIOSARCOMA (See Guideline Notes 64,65)
Treatment: LIVER TRANSPLANT
ICD-10: C22.0 [Liver cell carcinoma], C22.2 [Hepatoblastoma], C22.4 [Other sarcomas of liver], C22.7 [Other specified carcinomas of liver], C22.8 [Malignant neoplasm of liver, primary, unspecified as to type],T86.40-T86.49,Z48.23,Z51.11,Z52.6 [transplant rejection codes, post transplant care visit codes]
CPT: 47133-47147,86825-86835,93792,93793,98966-98969,99051,99060,99070,99078,99184, 99201-99239,99281-99285,99291-99404,99408-99449,99451,99452,99468-99480, 99487-99491,99495-99498,99605-99607
HCPCS: G0068,G0071,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427,G0463-G0467,G0490,G0508-G0511,G0513,G0514,G2010-G2012

Line Scoring

	Line XXX
Category (Non-Fatal Condition)	6
Healthy Life Years (0-10)	7
Suffering (0-5)	4
Population effects (0-5)	0
Vulnerable population (0-5)	0
Tertiary prevention (0-5)	0
Effectiveness (0-5)	3
Need for service (0-1)	1
Net cost	0
Score	1320
Approximate line	264

2) The original line was modified as shown below, and kept at the current prioritization

Line: 560
Condition: ~~CANCER~~ ANGIOSARCOMA OF LIVER; ~~AND~~ INTRAHEPATIC BILE DUCT~~S~~ CARCINOMA
Treatment: LIVER TRANSPLANT
ICD-10: ~~C22.0 [Liver cell carcinoma],~~ C22.1 [Intrahepatic bile duct carcinoma], ~~C22.2 [Hepatoblastoma],~~ C22.3 [Angiosarcoma of liver], ~~C22.4 [Other sarcomas of liver], C22.7 [Other specified carcinomas of liver], C22.8 [Malignant neoplasm of liver, primary, unspecified as to type],~~T86.40-T86.49,Z48.23,Z51.11,Z52.6 [transplant care visit codes]
CPT: 47133-47147,86825-86835,93792,93793,98966-98969,99051,99060,99070,99078,99184, 99201-99239,99281-99285,99291-99404,99408-99449,99451,99452,99468-99480, 99487-99491,99495-99498,99605-99607
HCPCS: G0068,G0071,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427,G0463-G0467,G0490,G0508-G0511,G0513,G0514,G2010-G2012

MOTION: To recommend the new line and line scoring, and modifications of the old line as presented. CARRIES 6-0.

Ø **Topic: Functional MRI (fMRI) and epilepsy surgery**

Discussion: Livingston presented the issue summary.

Dr. David Spencer, from OHSU, was introduced on the phone. He declared no conflict of interest. He shared that the existing test, the Wada test, which is considered the gold standard, has some inherent difficulties. Limitations of the Wada test have also impaired developing a robust evidence base for fMRI. They have seen some adverse effects such as small strokes. fMRI can sometimes provide more specific localizing information than the Wada test.

Olson asked what percentage of time do you use fMRI instead of Wada? Spencer stated it is used to determine whether the language hemisphere is dominant. He is quite confident it does a good job or is equivalent to the Wada test. There is still evolving evidence. The Wada test used to be applied to every patient about to undergo epilepsy surgery, but now it is applied more selectively. There are some cases where neither fMRI or Wada is necessary. Sometimes fMRI is preferred, and other times the Wada test is preferred.

Attention turned to the proposed guideline limiting use to identify the eloquent cortex. Spencer clarified that eloquent cortex is about whichever part of the brain is primarily responsible and is not limited to language. They only have about 10 cases per year. Hodges clarified what exactly would be on the chart notes, whether information about identifying eloquent cortex would be documented and Spencer confirmed it would in the neurologist's notes. Spencer discussed that there is evidence for motor mapping as well. He recommended staying with the more general term of eloquent cortex rather than limiting to language. Subcommittee members debated the need for the guideline.

MOTION: To recommend the code and guideline note addition as presented. FAILED 1-4. (Nay: Allen, Hodges, Irwin, Saboe; Abstained: Olson)

MOTION: To recommend the code changes without the guideline. CARRIES 6-0.

Recommended Actions:

1) Add the following CPT codes to Line 174 GENERALIZED CONVULSIVE OR PARTIAL EPILEPSY WITHOUT MENTION OF IMPAIRMENT OF CONSCIOUSNESS Treatment: SINGLE FOCAL SURGERY
    a. CPT 70555 Magnetic resonance imaging, brain, functional MRI; requiring physician or psychologist administration of entire neurofunctional testing
    b. CPT 96020 Neurofunctional testing selection and administration during noninvasive imaging functional brain mapping, with test administered entirely by a physician or other qualified health care professional (ie, psychologist), with review of test results and report
2) Remove the Line 660 entries for CPT codes 70555 and 96020
3) Leave 70554 (Magnetic resonance imaging, brain, functional MRI; including test selection and administration of repetitive body part movement and/or visual stimulation, not requiring physician or psychologist administration) on Line 660, as it is not focused on language and does not involve physician or psychologist involvement

Ø **Topic: Injections for plantar fasciitis**

Discussion: Smits reviewed the summary document and noted that the podiatrists consulted on this topic agreed with the staff recommendation. There was no discussion.

Recommended Actions:

1) Add CPT 20550 (Injection(s); single tendon sheath, or ligament, aponeurosis (eg, plantar "fascia")) to line 537 LESION OF PLANTAR NERVE; PLANTAR FASCIAL FIBROMATOSIS, with the coding specification below:
    a. "CPT 20550 only appears on this line for corticosteroid injections."

MOTION: To recommend the code and coding specification changes as presented. CARRIES 6-0.

Ø **Topic: Radiofrequency ablation for knee osteoarthritis**

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

Recommended Actions:

1) Add radiofrequency ablation (standard, cooled or cryoablation) for knee arthritis to line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
2) Add an entry to Guideline Note 173 as shown in Appendix A

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

Ø **Topic: Non-LANA certification for lymphedema therapy**

Discussion: Smits introduced the topic. There was general agreement that the requirement for LANA certification for lymphedema therapists should be broadened to include other certifications if LANA certified providers were not available. However, the manner of the wording of the guideline was debated. The current guideline restricts coverage to providers who are LANA certified, or who have graduated from a certified program in the last 2 years. This second provision is to allow providers who are in the process of getting enough hours to become LANA certified to provide care to OHP patients. However, the wording was felt to be problematic, and various wording revisions were suggested. The decision was to table this topic and have HERC staff work on revising the wording and bring back to the August VbBS meeting.

Recommended Actions:

1) Staff to work on revised language to the lymphedema therapy guideline and bring back to a future VbBS meeting

Ø **Topic: Preventive lymphedema treatment for high risk women**

Discussion: Smits reviewed the summary document; there was no discussion.

Recommended Actions:

1) Make no change to the current coverage of lymphedema and the current limitation to lymphedema therapy to those patients with diagnosed lymphedema

Ø **Topic: Pneumatic compression devices**

Discussion: Smits reviewed the summary document; there was no discussion.

Recommended Actions:

1) Add HCPCS E0650-E0673 and E0676 (Pneumatic compressor; Segmental pneumatic appliance for use with pneumatic compressor) to line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS/GN173 as shown in Appendix A

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

Ø **Public Comment:**

No additional public comment was received.

Ø **Issues for next meeting:**

- Non-LANA certification for lymphedema therapists

Ø **Next meeting:**

August 8, 2019 at Clackamas Community College, Wilsonville Training Center, Wilsonville Oregon, Rooms 111-112.

Ø **Adjournment:**

The meeting adjourned at 12:30 PM.

Appendix A

Revised Guideline Notes

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

Lines 346,361,401,527

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

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

1) During the first 6 weeks opioid treatment is included on these lines ONLY:
   a) When each prescription is limited to 7 days of treatment, AND
   b) For short acting opioids only, AND
   c) When one or more alternative first line pharmacologic therapies such as NSAIDs, acetaminophen, and muscle relaxers have been tried and found not effective or are contraindicated, AND
   d) When prescribed with a plan to keep active (home or prescribed exercise regime) and with consideration of additional therapies such as spinal manipulation, physical therapy, yoga, or acupuncture, AND
   e) There is documented verification that the patient is not high risk for opioid misuse or abuse.
2) Treatment with opioids after 6 weeks, up to 90 days after the initial injury/flare/surgery is included on these lines ONLY:
   a) With documented evidence of improvement of function of at least thirty percent as compared to baseline based on a validated tools (e.g. Pain average, interference with Enjoyment of life, and interference with General activity" (PEG) Assessment Scale, Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
   b) When prescribed in conjunction with therapies such as spinal manipulation, physical therapy, yoga, or acupuncture.
   c) With verification that the patient is not high risk for opioid misuse or abuse. Such verification may involve
      i) Documented verification from the state's prescription monitoring program database that the controlled substance history is consistent with the prescribing record
      ii) Use of a validated screening instrument to verify the absence of a current substance use disorder (excluding nicotine) or a history of prior opioid misuse or abuse
      iii) Administration of a baseline urine drug test to verify the absence of illicit drugs and non-prescribed opioids.
   d) Each prescription must be limited to 7 days of treatment and for short acting opioids only
3) Long-term opioid treatment (>90 days) after the initial injury/flare/surgery is not included on these lines except for the taper process described below.

~~Transitional coverage for patients on long-term opioid therapy as of July 1, 2016:~~
~~For patients on covered chronic opioid therapy 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 developed by January 1, 2017 which includes a taper with an end to opioid therapy no later than January 1, 2018 and include a taper goal to zero. Tapering should be unidirectional, generally with a 5-10% decrease monthly and can be paused or slowed if the prescriber believes this is medically appropriate. Taper plans must include nonpharmacological treatment strategies for managing the patient's pain based on Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE. If a~~

~~patient has developed dependence and/or addiction related to their opioids, treatment is available on Line 4 SUBSTANCE USE DISORDER.~~

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

NOTE: Additional changes made at the May 16, 2019 HERC meeting are noted above in *[italics]*

GUIDELINE NOTE 103, BONE ANCHORED HEARING AIDS

Lines 311,444

Bone anchored hearing aids (BAHA, CPT 69714, 69715; HCPCS L8690-8694) are included on these lines when the following criteria are met:

A) The patient is aged 5-20 years for implanted bone anchored hearing aids; headband mounted BAHA devices may be used for children under age 5
B) Treatment is for unilateral severe to profound hearing loss when the contralateral ear has normal hearing with or without a hearing aid
C) Traditional air amplification hearing aids and contralateral routing of signal (CROS) hearing aid systems are not indicated or have been tried and are found to be not effective
D) Implantation is unilateral.

Use of BAHA for treatment of tinnitus is not covered

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:

69710 ~~HCPCS L8690-L8693~~	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone ~~Auditory osseointegrated device~~	Less effective than other therapies	June, 2014, Aug. 2015

Appendix A

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
E0650-E0673 and E0676	Pneumatic compressor Segmental pneumatic appliance for use with pneumatic compressor	Insufficient evidence of effectiveness	May, 2019
64640	Destruction by neurolytic agent; other peripheral nerve or branch	Insufficient evidence of effectiveness	May, 2019 (knee osteoarthritis)

MINUTES

Evidence-based Guidelines Subcommittee

Clackamas Community College
Wilsonville Training Center, Rooms 111-112
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
June 6, 2019
2:00-5:00pm

Members Present: Devan Kansagara, MD, Chair; Alison Little, MD, MPH; Angela Senders, ND; Lynnea Lindsey, PhD (by phone until 1:20 pm, then in person); Michael Adler, MD (arrived 1:15 pm)

Members Absent: Eric Stecker, MD; Leslie Sutton.

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

Also Attending: Stefanie Rogers, MD; Duncan Neilson, MD (Legacy Health); Jason Mandic (Exact Sciences); Sharron Fuchs; Silke Akerson (Oregon Midwifery Council); Adam Obley, MD, Moira Ray MD MPH, Val King MD, MPH, and Craig Mosbaek (OHSU Center for Evidence-based Policy).

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1. Call to Order

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

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2. Minutes Review

Minutes from the 4/4/2019 meeting were reviewed and approved as presented, 4-0 (Adler not present).

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3. Staff Report

Coffman reported that some topics were dropped from the potential coverage guidance topics list for EbGS; some of the new topics to be considered today will replace these topics, and others are more appropriately addressed through the Value-based Benefits Subcommittee (VbBS) rather than be a coverage guidance topic. Topics which were dropped, addressed at VbBS, or which may be addressed by VbBS include pneumatic compression devices for the treatment of lymphedema, liposuction for the treatment of lymphedema, extracorporeal membrane oxygenation, acellular dermal matrix and interventional treatments for lower extremity chronic venous disease.

Little asked about postmastectomy reconstruction using acellular dermal matrix. Gingerich said that Ariel Smits has prepared a recommendation. It will be a difficult topic as there are concerns about harms and a lack of benefit based on evidence, but it is widely used among surgeons. Livingston said that staff

didn't believe the coverage guidance process would help with resolving this issue, so it is going directly to VbBS.

Little asked whether Adler would be a permanent member of EbGS; Coffman said it would likely be permanent.

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4. New Topics

Adam Obley reviewed the scope statements.

On the Scope Statement for Non-Invasive Vagus Nerve Stimulation Devices for Cluster and Migraine Headache (e.g., Gammacore), Senders asked about headache severity and intensity, and whether they were factored into response rate. Obley said response rate is one of the commonly reported outcomes, and includes frequency, severity and duration based on patient report.

For the scope on Percutaneous Occlusion of the Left Atrial Appendage in Atrial Fibrillation (e.g. Watchman), Kansagara said that the attraction is that patients might not have to use anticoagulation, but they still do need it in reality. He suggested an outcome of the ability to discontinue anticoagulation, or only including patients who aren't candidates for anticoagulation. Obley said that there is likely a nontrivial increased risk of stroke for patients who go off anticoagulation. If we do that, we wouldn't capture the stroke risk. If there is an analysis of patients who aren't candidates for anticoagulation or a separate analysis of patients who successfully go off anticoagulation vs. those who remain on it, he's happy to report those results. Kansagara said this is probably worth reporting. Livingston proposed merging bleeding events and other adverse events and add ability to discontinue anticoagulation as an important outcome. *(Note: following the meeting, staff also proposed an additional change to capture this discussion, which would add a question evaluating the impact of the device on patients with a contraindication to anticoagulation).* For harms, Kansagara said one may want to distinguish procedure-related harms from other harms. Kansagara said the best data on procedure-related harms would come from registries.

For Multicomponent Interventions to Improve Screening for Breast, Cervical or Colorectal Cancer, Kansagara raised concerns about the range of frequency in USPSTF recommendations for breast and colon cancer screening. Obley said the goal is to improve adherence to screening intervals recommended by the USPSTF, not more frequent screening. If evidence is found on increasing inappropriate screening, this would be captured.

For scoping Patient and Radiologic Factors Influencing Outcomes in Total Knee Arthroplasty, Coffman informed the group that this would normally be a topic for the Health Technology Assessment Subcommittee (HTAS) agenda, but that since the spinal cord stimulation topic was dropped, the June HTAS meeting was cancelled, and the scope was therefore being brought to this group. Staff has consulted with Kathryn Schabel, a joint replacement surgeon on HTAS. This topic was inspired by reports of poor satisfaction among some patients undergoing knee replacement. Obley addressed a concern about harms not being an outcome; for this topic, the general effectiveness and safety of knee replacement is accepted. This topic is about identifying the best candidates for knee replacements. In someone without strong indications, the balance of benefits and harms might not be favorable. Kansagara clarified that patient characteristics include comorbidities as well as demographic

characteristics and symptoms. Obley said he would report things related to any of these characteristics. Based on discussion, the subcommittee called out patient-reported disease characteristics in addition to radiological findings in Key Question 3. King said this is a prognosis question, which required adaptation of the GRADE methodology. It would be defined retrospectively by identifying patients who did not get pain or function improvement.

Livingston said the next step with these scope statements is to prioritize the topics and asked the subcommittee for feedback in ranking them in priority. Little said staff should consider the volume of utilization and cost. She asked about Watchman in particular. Livingston said it is expensive and reportedly increasingly common. New York Medicaid is looking into Watchman due to burgeoning use as well. Kansagara agreed this is an important topic; Gingerich agreed to look into the utilization of Watchman on the Oregon Health Plan prior to the August meeting. Senders expressed interest in the vagal nerve stimulation topic.

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5. Planned Out-of-Hospital Birth

Coffman read the following bios and conflict of interest statements for appointed ad hoc experts Duncan Neilson and Stefanie Rogers. Two other appointed experts, Melissa Cheyney and Alice Taylor, were not able to be at the meeting and did not call in. Fuchs inquired about participation of Dr. Amos Grunebaum, who wanted to participate but could not be heard when he called in. Coffman clarified that call-in testimony is only available to appointed experts, and Grunebaum has not been officially appointed. He clarified that the HERC policy is that unsolicited public commenters need to be present at the meeting to give testimony.

Dr. Duncan Neilson is an OB/GYN clinical vice president for Legacy Medical Group's surgical specialties division. He also serves as clinical vice president of Legacy's Women's Services and Surgical Services. He also chaired the Oregon Health Authority's Licensed Direct Entry Midwife Staff Advisory Workgroup. He declared the following conflicts of interest in addition to his employment:

- Chairs the graduate medical education committee and provides ongoing OB-GYN-related Continuing Medical Education, especially advanced fetal monitoring training.
- He leads outreach efforts to community midwives providing out-of-hospital births to improve hospital transfer processes.
- His employer, Legacy Health Systems receives payments for care related to childbirth services and payments related to his participation in OB-GYN educational programs.

He has served the commission as an expert on previous obstetric-related topics, including Elective Induction of Labor, Opportunistic Salpingectomy, Tobacco in Pregnancy and the previous review of Planned Out-of-Hospital Birth.

Stefanie Rogers, MD is board certified in pediatrics and neonatal perinatal medicine. She is the medical director of Providence St. Vincents Neonatal Intensive Care Unit, Northwest Mothers Milk Bank and is a neonatologist at Northwest Newborn Specialists. She declared no conflicts of interest.

Livingston reviewed the process. The draft is not complete and cannot be approved to be posted for comment today; the earliest it would be posted is the September 12 meeting. If it is posted for written comment then, written comments would be reviewed at the December meeting and subsequently

reviewed by the VbBS and HERC in January 2020. The June discussion will be reviewing the recommendations on risk factors from other bodies.

Ray reviewed the additions to the draft coverage guidance since the last meeting. Appendices I & J are based on a guideline from the NICE as well as other lower quality guidelines and standards. She briefly described the various sources of the recommendations, including system level recommendations, and the context for each.

Adler asked whether the direct-entry midwife licensing standards meet the requirement of the American College of Obstetricians and Gynecologists that the birthing attendant has training which meets global standards. King said that in most of the United States, if the state allows direct-entry midwives or licensed midwives to practice, they generally come via a certification which may, but does not necessarily, meet the International College of Midwifery (ICM) global standard. Adler requested clarification. Silke Akerson, director of the Oregon Midwifery Council, said that appointed expert Missy Cheyney is attending a birth and is hoping to call in. She reported that in the United States, most nurse midwives and direct-entry midwives don't meet the ICM standards. One of the main reasons for this is that the ICM standards say that midwives should be able to provide abortions. However, the majority of licensed direct-entry midwives in Oregon have a bachelor's degree in midwifery. There are ways to become an LDEM or CPM without a bachelor's degree.

Kansagara noted that this coverage guidance is different than from some other topics; part of the reason for doing this is that there is limited evidence, and we may need to rely on standards from other places with different healthcare systems to develop this coverage guidance. King said that staff is hearing comments related to concurrent processes for licensure for licensed direct-entry midwives. Those standards are separate from this coverage guidance. If there was agreement on those standards, the Oregon Health Authority could provide Medicaid coverage without needing all the detailed criteria in a HERC coverage guidance; however, there are significant differences. There may be stakeholders who are confused about the separate processes. Ray added that the rules for birthing center licensing are also under review concurrently.

Little asked about the difference between a certified midwife and a licensed direct-entry midwife. King said that a certified midwife is the equivalent of a certified nurse midwife that doesn't have a nursing degree but has equivalent training around childbirth and takes the same exam. There aren't very many certified midwives in America. Livingston referenced Table 2 and suggested we might compare the types of midwives in the table with the various standards. After discussion the subcommittee decided not to add certified midwives, as they are not licensed in Oregon.

Sharron Fuchs spoke from the audience, adding that chiropractic physicians with certification in natural childbirth are also licensed to attend births in Oregon. Others were not aware of this licensure.

Livingston reviewed the balance of benefits and harms, resource allocation, other factors and rationale sections of the GRADE table. Lindsey said that cultural preferences are not mentioned in the values and preferences statement. After discussion, the subcommittee didn't add this, as the values and preferences seem to be strong regardless of what's driving the values and preferences.

Kansagara asked to what extent we should think of these guidelines as an incentive to improve the system, or whether it should be thought of within the constraints of the system. Neilson said one of the charges is to figure out whether we in Oregon have done enough to assure safety through the

regulations or whether we have not. One of the main reasons for this review was the assertion that we have not done enough and therefore may be responsible for some measurable harms. The question is, do we need to change something? If we decide to do so, those various perspectives are useful in figuring out what we need to change. Kansagara said there are questions about the applicability of some of the guidelines, but part of the reason for doing this is to drive some system change. Neilson said it is a question whether we need to change; this process was initiated because of a question about whether we should change the recommendations, but this subcommittee had initially decided we don't need to change the coverage guidance.

Livingston highlighted that the rationale statement may need to be adapted based on the decisions that are made about indications covered in the evidence versus the guidelines. For instance, if the subcommittee decides to add risk criteria around nulliparity or maternal age, the rationale would need to be revised as these are mentioned in the evidence as having higher risks of neonatal harms.

Adler and Kansagara expressed support for the framework described in these sections. Kansagara asked about operational implementation. Livinston clarified that if, based on individual review, the birth attendant did not follow the coverage criteria, the provider would not be paid by the health plan. If the health plan is the Oregon Health Plan, the recipient could not be balance billed by the provider, just as is true with all providers in the Oregon Health Plan.

Livingston referred to the written comments posted on the member only website. Some of the comments addressed licensing issues and these have been forwarded to the appropriate bodies. Comments related to the evidence, including those by Dr. Grunebaum, will be incorporated into the next version of the draft coverage guidance to be released prior to the September meeting.

Fuchs asked whether Dr. Grunebaum would be allowed to comment by phone. Coffman explained that the Commission does not accept unsolicited comments from the public by phone. Instead, there is a 30-day written comment period, and brief in-person comments are taken at the meetings.

Akerson offered her comments and declared no conflicts of interest outside her employment. She expressed concern about adding extensive guidance when existing outcomes for out-of-hospital birth with midwives in Oregon are excellent. She said it is alarming to see the vast number of restrictions. In addition, the Commission is referring to professional societies external to midwifery with the exception of the American College of Nurse Midwives. The report doesn't refer to the standards or guidelines or statements of the National Association for Certified Professional Midwives, the Home Birth Summit standards about transfer, or the guidelines of the Naturopathic Obstetric Association. In particular, she called out the requirement by the American Academy of Pediatrics for a consultation with a pediatrician within 24 hours of delivery. These recommendations are from organizations that aren't familiary with midwifery. She also clarified that midwives have been licensed since 1993, with a change in licensure in 2012.

She said she has many concerns about the recommendations in the coverage guidance, but highlighted a few. Some items don't have time constraints. For instance, the line on inability to auscultate doesn't have a time attached, and anyone who attends people in labor knows that sometimes there can be difficulty in auscultation due to the woman's position or if she is screaming during pushing. The same is true about heart rate below 110 or above 160. Other requirements are vague. For instance, the hepatic disorders section includes abnormal liver function test as a contraindication without specifying which test or how abnormal the results would have to be. The same is true with "treated with any

medication." If there are changes made they should be about clarifying the current guidance and making it more functional rather than adding additional conditions.

Coffman said there will be additional opportunities to comment. Livingston explained the tables which appear in Appendices I and J of the coverage guidance. The grey cells are clarifications to existing criteria in the current coverage guidance and the blue cells would add new criteria. She said that only the blue and grey cells would be discussed unless a subcommittee member (or an expert or the public) wants to discuss another condition for which the staff recommendation is "no change."

Adler said he would like to add a requirement for transfer at less than 37 weeks 0 days with ruptured membranes, as the critical access hospital where he practices transfers such patients to a higher level of care. King suggested the gestational age limit for the use of steroids for fetal lungs has gone down, and hospitals may be transferring for that and for the need for higher level neonatal care.

For anemia, the subcommittee agreed to change the cutoff from 10.5 to 10 g/dL.

For cancer affecting site of delivery, there was discussion about whether low grade cervical lesions represent cancer; they do not. There was discussion also of adding "active cancer" but no change was made.

For maternal cardiovascular disease, the subcommittee recommended that cardiovascular disease with functional impairment be considered a risk criterion requiring transfer. Fetal cardiovascular anomalies are considered elsewhere in the table.

Under congenital or hereditary anomalies, the subcommittee decided to adopt the ACNM definition "Evidence of congenital anomalies requiring immediate assessment and/or management by a neonatal specialists" as a clarification, and to drop the existing risk factor of "life-threatening congenital anomalies."

Based on Akerson's comments, Livingston discussed the requirement around fetal heart rate. The subcommittee agreed to keep the existing language "repetitive or persistent abnormal fetal heart rate pattern during labor" and not to add language around specific heart rates. Neilson said that defining numbers or defining repetitive or persistent is a matter of active disagreement in the field, so we have to be a little bit vague. For inability to auscultate, the subcommittee changed it to "Inability to adequately follow an intermittent auscultation protocol." Akerson gave the example of a woman on hands and knees screaming, where it would be difficult to auscultate. Neilson said they have the same problem in the hospital, but they still do their best to follow the protocol; the requirement is around using the protocol and excluding women who really require an internal monitor. Akerson said most of the time this occurs during late-stage labor. Neilson agreed this would not be a situation where you would transfer the patient to the hospital. It would be more for patients requiring an internal monitor, usually due to an abnormally thick abdominal wall. Adler expressed support for the language.

The subcommittee also discussed the requirements around abnomally decreased fetal movement. Neilson said that movement is something that the mother perceives but the attendant can also confirm. He said if the provider confirms the fetus is not moving normally, it can be because of anemia due to fetal maternal hemorrhage, which urgently requires hospital care. Most of the time when the mother reports low fetal movement, the provider will detect fetal movement and nothing further is required, but if the lack of movement is confirmed it can be urgent. Adler suggested making it a consultation

requirement, suggesting a nonstress test may be indicated. Neilson said in these cases the fetal heart rate is one of the last signs to appear. Livingston said one of the issues may be that the requirement isn't different depending on when the decreased movement appears. Ray confirmed that the NICE requirement is at onset of labor. Based on discussion, the subcommittee decided to change "abnormally decreased fetal movement" to "abnormally decreased fetal movement antepartum" and leave it as a 2 (consultation), and to add a separate requirement for "abnormally decreased fetal movement at onset of labor" as a 3 (requiring hospital transfer). The subcommittee clarified that the consultation requirements may be a phone consultation by the provider, and not necessarily a visit by the patient to another provider.

The subcommittee decided to make hepatic disorders including uncontrolled intrahepatic cholestasis of pregnancy and/or abnormal liver function tests a consultation requirement, not a transfer requirement, based on the public comment that the definition was too vague.

For "actively being treated with prescription medication for any medical condition," the subcommittee discussed making it a consultation requirement, but decided it was overly broad and did not add it. They also dropped the proposed consultation requirement for "current medical conditions that may affect pregnancy or are exacerbated due to pregnancy" and "current medical conditions that may affect pregnancy or are exacerbated by pregnancy that require specialized medical care (e.g., cardiac disease, renal disease, pre-existing insulin-dependent diabetes mellitus)." King said the criteria from Canada were designed to pick up other serious conditions that may not be on the list. Livingston suggested that staff might draft similar language appropriate to this context.

There was significant discussion about the gestational age cutoff for postterm births. Neilson said that in well-dated preganancies, risk increases at 41 weeks. However, many women planning out-of-hospital births may not be getting the most accurate dating technology, and without the most accurate technology, menstrual date estimation is likely to overestimate, rather than underestimate, gestational age. After discussion, the subcommittee decided not to change the recommendation around late gestational age. Akerson said she believes the elevation of risk between 41 and 42 weeks is an appropriate amount for an informed consent discussion rather than a requirement to transfer, regardless of the dating method used. Kansagara said it magnifies the uncertainty if you don't know what the dates actually are. Livingston reviewed the two Grunebaum studies included in the coverage guidance, which showed an increased rate of neonatal mortality over 41 weeks. Ray said these studies also included women with previous cesarean sections and breech births. After discussion the subcommittee did not request a change based on the Grunebaum studies.

On page 221, for "history of postpartum hemorrhage or bleeding requiring additional procedures such as Bakri-balloon, dilation and curettage, transfusion, and manual removal of placenta," the subcommittee decided not to add the requirement for transfer. For "history of postpartum hemorrhage requiring intervention, transfusion or pharmacologic management," the subcommittee decided to change the definition to "history of postpartum hemorrhage requiring intervention" and make it a consultation requirement. Neilson said many, but not all, of these should be managed in the hospital.

The subcommittee ran out of time before beginning work on the section on hypertensive disorders and will continue discussion at the September meeting. Ray said staff will keep the document updated with the latest proposals/decisions from the board of direct-entry midwifery.

6. Adjournment

The meeting was adjourned at 5:00 pm. The next meeting is scheduled for September 12, 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

Section 2.0

New Evidence-based Report Topics 2019

SCOPE STATEMENT FOR HERC MULTISECTOR REPORT

MULTICOMPONENT INTERVENTIONS TO IMPROVE SCREENING FOR BREAST, CERVICAL OR COLORECTAL CANCER

Population description	Adults eligible for breast, cervical, or colorectal cancer screening *Population scoping notes: None*
Intervention(s)	Multicomponent interventions to increase community demand for or access to USPSTF-recommended screening services (i.e., patient or clinician reminders, incentives, media campaigns, educational interventions, reducing or eliminating structural barriers, reducing out-of-pocket costs) *Intervention exclusions: None*
Comparator(s)	Care as usual, intervention components compared to each other
Outcome(s) (up to five)	Critical: Appropriate screening attendance, cancer stage at diagnosis, appropriate screening followup. Important: Harms (including overscreening or inappropriate screening), cost effectiveness *Considered but not selected for GRADE Table: Mortality, cancer specific incidence, cancer-related morbidity*
Key questions	1. What is the comparative effectiveness of multicomponent interventions to improve screening outcomes or attendance for breast, cervical, or colorectal cancer? 2. Does the comparative effectiveness of multicomponent interventions to improve screening outcomes or attendance for breast, cervical, or colorectal cancer vary by: a. Patient-level characteristics b. Community-level characteristics c. Intervention intensity d. Index screening vs subsequent screening 3. What are the harms of multicomponent interventions to improve screening outcomes or attendance for breast, cervical, or colorectal cancer?
Contextual questions	None

CHANGE LOG

Date	Change	Rationale

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

PATIENT AND RADIOLOGIC FACTORS INFLUENCING OUTCOMES IN TOTAL KNEE ARTHROPLASTY

Population description	Adults with osteoarthritis of the knee who are considering total knee arthroplasty *Population scoping notes: None*
Characteristics	Patient characteristics (e.g., age, gender, body mass index, comorbid conditions, baseline pain and function) Radiographic severity of osteoarthritis (e.g., as measured by Kellgren Lawrence grade)
Outcome(s) (up to five)	Critical: Long-term function Important: Long-term pain, quality of life, implant durability, cost-effectiveness *Considered but not selected for GRADE Table: None*
Key questions	1. Which prior interventions are associated with improved outcomes (reduced pain, improved function or quality of life, implant durability) at or beyond 12 months in those undergoing total knee arthroplasty for osteoarthritis? 2. What patient characteristics are associated with improved outcomes (reduced pain, improved function or quality of life, implant durability) at or beyond 12 months in those undergoing total knee arthroplasty for osteoarthritis? 3. What disease characteristics (patient-reported and radiological) are associated with improved outcomes (reduced pain, improved function or quality of life, implant durability) at or beyond 12 months in those undergoing total knee arthroplasty for osteoarthritis? 4. How do patient and disease characteristics influence the cost-effectiveness of total knee arthroplasty for osteoarthritis?
Contextual questions	1. What approaches have health insurers and health systems implemented to reduce the overuse of total knee arthroplasty?

CHANGE LOG

Date	Change	Rationale
6/6/19	Added patient-reported disease characteristics to key question 3.	

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

NON-INVASIVE VAGUS NERVE STIMULATION DEVICES FOR CLUSTER AND MIGRAINE HEADACHE (E.G., GAMMACORE)

Population description	Adults with cluster or migraine headache *Population scoping notes: None*
Intervention(s)	Non-invasive vagus nerve stimulation (e.g., Gammacore) *Intervention exclusions: None*
Comparator(s)	Abortive medication, preventive medication, acupuncture, no treatments, sham controls, behavioral interventions
Outcome(s) (up to five)	Critical: Headache frequency, headache response rate, headache duration Important: Quality of life, adverse events *Considered but not selected for GRADE Table: None*
Key questions	1. What is the comparative effectiveness of non-invasive vagus nerve stimulation for cluster and migraine headaches? 2. Does the comparative effectiveness of non-invasive vagus nerve stimulation vary by: a. Patient characteristics b. Baseline headache severity or frequency c. Other headache characteristics d. Response to prior or current treatments or prophylactic measures 3. What are the harms of non-invasive vagus nerve stimulation?
Contextual questions	

CHANGE LOG

Date	Change	Rationale

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

PERCUTANEOUS OCCLUSION OF THE LEFT ATRIAL APPENDAGE IN ATRIAL FIBRILLATION (E.G. WATCHMAN)

Population description	Adults with non-valvular atrial fibrillation *Population scoping notes: None*
Intervention(s)	Percutaneous occlusion of the left atrial appendage (e.g., Watchman device) *Intervention exclusions: None*
Comparator(s)	Oral anticoagulants (warfarin, direct oral anticoagulants), anti-platelet agents, no treatment, surgery
Outcome(s) (up to five)	Critical: Major adverse cardiovascular events, embolic stroke, major bleeding Important: Adverse events, ability to discontinue or avoid anticoagulation *Considered but not selected for GRADE Table: None*
Key questions	1. What is the comparative effectiveness of percutaneous occlusion of the left atrial appendage in adults with non-valvular atrial fibrillation? 2. Does the comparative effectiveness of percutaneous occlusion of the left atrial appendage vary by: a. Patient characteristics b. Duration or type of atrial fibrillation c. Left atrial morphology d. Risk of embolic stroke (as assessed by tools like CHADS2 or CHA2DS2-VASC) e. Risk of bleeding (as assessed by tools like HAS-BLED) f. History of bleeding while on oral anticoagulants g. History of embolic events while on oral anticoagulants h. Contraindications to anticoagulation 3. What are the harms of percutaneous occlusion of the left atrial appendage?
Contextual questions	

CHANGE LOG

Date	Change	Rationale
5/29/2019	Add “e.g.” before Watchman in title	Allow for other similar devices

Date	Change	Rationale
6/6/2019	Added discontinuation of anticoagulation as an important outcome.	Cessation of anticoagulation could be a significant benefit and a primary reason for choosing to undergo this intervention
6/19/2019	Added “contraindications to anticoagulation” to key question 2.	Alternative treatments would be of particular benefit to this population.

Topic	Disease Burden	Prevalence	Uncertainty in Efficacy/Harm	Variation from evidence	Economic Impact	Potential Health Benefit	Public/Prof. Interest	Potential to reduce disaparities	Total
Multicomponent Interventions to Improve Screening for Breast, Cervical or Colorectal Cancer	3	3	1	2	2	2	2	3	**18**
Multisector Interventions to Reduce the Frequency of Asthma Exacerbations	2	2	1	3	2	3	2	2	**17**
Patient and Radiologic Factors Influencing Outcomes in Total Knee Arthroplasty	2	3	1	3	2	1	2	0	**14**
Percutaneous Occlusion of the Left Atrial Appendage in Atrial Fibrillation (e.g. Watchman)	2	2	3	1	2	2	2	0	**14**
Non-Invasive Vagus Nerve Stimulation Devices for Cluster and Migraine Headache (e.g., Gammacore)	2	2	3	1	2	1	1	0	**12**
Hepatic Artery Infusion Pumps (2016)	3	1	3	2	1	1	1	0	**12**

Section 3.0

VBBS Report

Errata
August 2019

1) Two HCPCS codes were mistakenly added to the new liver transplant for hepatic malignancies line at the May, 2019 VbBS/HERC meetings. These codes were determined to belong only on line 3 at the January, 2019 VbBS/HERC meetings. These codes will be removed from the new liver transplant line when effective January 1, 2020.
    a. 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 prev
    b. 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 cod
2) The CPT codes representing applied behavioral analysis (ABA) in GN75 were not updated when these codes were replaced with new codes for 2019
    a. Excerpt of GN75 showing updated codes

GUIDELINE NOTE 75, APPLIED BEHAVIOR ANALYSIS FOR AUTISM SPECTRUM DISORDER

Line 193

Applied behavioral analysis (ABA), including early intensive behavioral intervention (EIBI), represented by CPT codes 97151-97158 ~~0359T-0374T~~, is included on Line 193 AUTISM SPECTRUM DISORDERS for the treatment of autism spectrum disorders.

ABA services are provided in addition to any rehabilitative services (e.g. physical therapy, occupational therapy, speech therapy) included in Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES that are indicated for other acute qualifying conditions.

Consent Agenda Issues—August 2019

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
58541-58544	Supracervical hysterectomy	464 UTERINE PROLAPSE; CYSTOCELE	Line 464 contains all hysterectomy CPT codes except for the supracervical hysterectomy codes	Add 58541-58544 to line 464
68720	Dacryocystorhinostomy (fistulization of lacrimal sac to nasal cavity)	393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN	Claims reconsideration for pairing of CPT 68720 with congenital lacrimal duct deformity diagnoses, which appear on line. 68720 is currently on line 508 DYSFUNCTION OF NASOLACRIMAL SYSTEM IN ADULTS; LACRIMAL SYSTEM LACERATION	Add 68720 to line 393
95012	Nitric oxide expired gas determination	9 ASTHMA	In March, 2018, HERC added 95012 to line 9 to allow use in asthma management. However, the January, 2018 HERC decision was to also allow use in diagnosis of asthma. To best accomplish both of these objectives, 95012 should be placed on the Diagnostic Procedures File.	Remove 95012 from line 9 Advise HSD to add 95012 to the Diagnostic Procedures File
97535	Self-care/home management training (eg, activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes	421 LYMPHEDEMA	HSD requested addition of CPT 97535 to line 421 as self-management is standard of care in this population. 97535 is on 50+ lines.	Add 97535 to line 421

Consent Agenda Issues—August 2019

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
99091	Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days	Ancillary	CPT 99453-99454 and 99457 were added to the Ancillary List as new codes for 2019. These codes are all for remote monitoring of physiologic data. These codes are all highly similar to CPT 99091, which has been a code for 20 years. 99091 has never previously been reviewed by the HSC/HERC.	Advise HSD to add 99091 to the Ancillary List
D48.7	Neoplasm of uncertain behavior of other specified sites • Neoplasm of uncertain behavior or eye • Neoplasm of uncertain behavior of heart • Neoplasm of uncertain behavior of peripheral nerves of orbit	113 CANCER OF EYE AND ORBIT	This code includes neoplasm of uncertain behavior of heart but does not pair with appropriate codes.	Add D48.7 to • Line 372 BENIGN NEOPLASM OF RESPIRATORY AND INTRATHORACIC ORGANS • Line 200 CANCER OF SOFT TISSUE (has malignant neoplasms of the heart)

Genetic Testing Prior to Siponimod Prescribing

Question: Should testing for the CYP2C9*3/*3 genetic variant be paired with multiple sclerosis diagnoses for siponimod prescribing?

Question source: CareOregon

Issue: Siponimod (brand name Mayzent) is a new medication for multiple sclerosis (MS) that has recently been FDA approved, and the FDA requires CYP2C9*3/*3 genetic testing prior to prescribing. If a patient is positive for the CYP2C9*3/*3 genetic variant, the drug is contraindicated. CYP2C9*3/*3 is a variant in cytochrome P450 family 2, subfamily C, polypeptide 9

Testing is billed with CPT 81227 (CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)), which is currently on line 660/GN173. CPT 81227 was placed on line 660 as a new 2012 CPT code. At the time of the 2011 Genetics Advisory Panel review, this code was being used for testing for determining anticoagulant therapy, for which there is no evidence of effectiveness.

From the FDA label for siponimod:
Before initiation of treatment with MAYZENT, test patients to determine CYP2C9 genotype. MAYZENT is contraindicated in patients homozygous for CYP2C9*3 (i.e., CYP2C9*3/*3 genotype), which is approximately 0.4%-0.5% of Caucasians and less in others, because of substantially elevated siponimod plasma levels. MAYZENT dosage adjustment is recommended in patients with CYP2C9*1/*3 or *2/*3 genotype because of an increase in exposure to siponimod.

From CareOregon

> I believe 81227 can be covered under the comorbid rule, since it is medically necessary for patients with MS being considered for Mayzent treatment. However, it may be more expedient to run it past the Genetics Advisory Panel, and if they agree, move 81227 only to the MS line, 252, with possible mention in GN D1.

HERC staff recommendations:

1) Add CPT 81227 (CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)) to line 252 MULTIPLE SCLEROSIS AND OTHER DEMYELINATING DISEASES OF CENTRAL NERVOUS SYSTEM
2) Add CPT 81227 to the GAP agenda for the fall to determine if there are any other evidence-based or regulatory required uses of this test
3) Remove CPT 81227 from line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
4) Modify GN173 as shown below

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

Line 660

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

81225~~-81227~~, 81226, 81230-81231	Cytochrome P450 gene analysis	Insufficient evidence of effectiveness	December, 2011 November, 2017

2019 New ICD-10-CM Codes

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
D75.A	Glucose-6-phosphate dehydrogenase (G6PD) deficiency without anemia	D55 (Anemia due to glucose-6-phosphate dehydrogenase [G6PD] deficiency) is on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	Patients may have normal hematocrit between episodes, but may still require hematology care
D81.30	Adenosine deaminase deficiency, unspecified	D81.3 (Adenosine deaminase [ADA] deficiency) was on lines 71,95,292,313,345,377	Dysfunction lines (71,292,345,377) 95 HEREDITARY IMMUNE DEFICIENCIES Tx Bone marrow transplant 313 DISORDERS INVOLVING THE IMMUNE SYSTEM	All adenosine deaminase deficiency variations can cause developmental delays, growth issues, and some degree of immune deficiency
D81.31	Severe combined immunodeficiency due to adenosine deaminase deficiency		71,95,292,313,345,377	See above
D81.32	Adenosine deaminase 2 deficiency		71,95,292,313,345,377	See above
D81.39	Other adenosine deaminase deficiency		71,95,292,313,345,377	See above
H81.4	Vertigo of central origin	H81.41-H81.49 (Vertigo of central origin, left, right, bilateral, or unspecied ear) are on line 510	510 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM	
I26.93	Single subsegmental pulmonary embolism without acute cor pulmonale	Other PE diagnoses are on line 214	214 ACUTE PULMONARY HEART DISEASE AND PULMONARY EMBOLI	
I26.94	Multiple subsegmental pulmonary emboli without acute cor pulmonale		214 ACUTE PULMONARY HEART DISEASE AND PULMONARY EMBOLI	
I48.11	Longstanding persistent atrial fibrillation	I48.1 (Persistent atrial fibrillation) was on line 347	347 CARDIAC ARRHYTHMIAS	
I48.19	Other persistent atrial fibrillation		347 CARDIAC ARRHYTHMIAS	
I48.20	Chronic atrial fibrillation, unspecified	I48.2 (Chronic atrial fibrillation) was on line 347	347 CARDIAC ARRHYTHMIAS	
I48.21	Permanent atrial fibrillation		347 CARDIAC ARRHYTHMIAS	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
I80.241	Phlebitis and thrombophlebitis of right peroneal vein	Other deep vein phlebitis and thrombophlebitis diagnoses are on line 79	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	Peroneal veins are considered deep veins (not superficial) and therefore should be placed on line 79
I80.242	Phlebitis and thrombophlebitis of left peroneal vein		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	
I80.243	Phlebitis and thrombophlebitis of peroneal vein, bilateral		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	
I80.249	Phlebitis and thrombophlebitis of unspecified peroneal vein		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	
I80.251	Phlebitis and thrombophlebitis of right calf muscular vein		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	See issues
I80.252	Phlebitis and thrombophlebitis of left calf muscular vein		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	See issues
I80.253	Phlebitis and thrombophlebitis of calf muscular vein, bilateral		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	See issues
I80.259	Phlebitis and thrombophlebitis of unspecified calf muscular vein		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	See issues
I82.451	Acute embolism and thrombosis of right peroneal vein	Other acute embolism and thrombosis of deep calf veins are on line 79	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	Peroneal veins are considered deep veins (not superficial) and therefore should be placed on line 79
I82.452	Acute embolism and thrombosis of left peroneal vein		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	
I82.453	Acute embolism and thrombosis of peroneal vein, bilateral		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	
I82.459	Acute embolism and thrombosis of unspecified peroneal vein		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	
I82.461	Acute embolism and thrombosis of right calf muscular vein		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	See issues
I82.462	Acute embolism and thrombosis of left calf muscular vein		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	See issues
I82.463	Acute embolism and thrombosis of calf muscular vein, bilateral		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	See issues

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
I82.469	Acute embolism and thrombosis of unspecified calf muscular vein		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	See issues
I82.551	Chronic embolism and thrombosis of right peroneal vein	Other acute embolism and thrombosis of deep calf veins are on line 79	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	Peroneal veins are considered deep veins (not superficial) and therefore should be placed on line 79
I82.552	Chronic embolism and thrombosis of left peroneal vein	Other acute embolism and thrombosis of deep calf veins are on line 79	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	Peroneal veins are considered deep veins (not superficial) and therefore should be placed on line 79
I82.553	Chronic embolism and thrombosis of peroneal vein, bilateral	Other acute embolism and thrombosis of deep calf veins are on line 79	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	Peroneal veins are considered deep veins (not superficial) and therefore should be placed on line 79
I82.559	Chronic embolism and thrombosis of unspecified peroneal vein	Other acute embolism and thrombosis of deep calf veins are on line 79	79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	Peroneal veins are considered deep veins (not superficial) and therefore should be placed on line 79
I82.561	Chronic embolism and thrombosis of right calf muscular vein		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	See issues
I82.562	Chronic embolism and thrombosis of left calf muscular vein		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	See issues
I82.563	Chronic embolism and thrombosis of calf muscular vein, bilateral		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	See issues
I82.569	Chronic embolism and thrombosis of unspecified calf muscular vein		79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP	See issues
L89.006	Pressure-induced deep tissue damage of unspecified elbow	Other L89 series codes are on line 379	379 CHRONIC ULCER OF SKIN	
L89.016	Pressure-induced deep tissue damage of right elbow		379 CHRONIC ULCER OF SKIN	
L89.026	Pressure-induced deep tissue damage of left elbow		379 CHRONIC ULCER OF SKIN	
L89.106	Pressure-induced deep tissue damage of unspecified part of back		379 CHRONIC ULCER OF SKIN	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
L89.116	Pressure-induced deep tissue damage of right upper back		379 CHRONIC ULCER OF SKIN	
L89.126	Pressure-induced deep tissue damage of left upper back		379 CHRONIC ULCER OF SKIN	
L89.136	Pressure-induced deep tissue damage of right lower back		379 CHRONIC ULCER OF SKIN	
L89.146	Pressure-induced deep tissue damage of left lower back		379 CHRONIC ULCER OF SKIN	
L89.156	Pressure-induced deep tissue damage of sacral region		379 CHRONIC ULCER OF SKIN	
L89.206	Pressure-induced deep tissue damage of unspecified hip		379 CHRONIC ULCER OF SKIN	
L89.216	Pressure-induced deep tissue damage of right hip		379 CHRONIC ULCER OF SKIN	
L89.226	Pressure-induced deep tissue damage of left hip		379 CHRONIC ULCER OF SKIN	
L89.306	Pressure-induced deep tissue damage of unspecified buttock		379 CHRONIC ULCER OF SKIN	
L89.316	Pressure-induced deep tissue damage of right buttock		379 CHRONIC ULCER OF SKIN	
L89.326	Pressure-induced deep tissue damage of left buttock		379 CHRONIC ULCER OF SKIN	
L89.46	Pressure-induced deep tissue damage of contiguous site of back, buttock and hip		379 CHRONIC ULCER OF SKIN	
L89.506	Pressure-induced deep tissue damage of unspecified ankle		379 CHRONIC ULCER OF SKIN	
L89.516	Pressure-induced deep tissue damage of right ankle		379 CHRONIC ULCER OF SKIN	
L89.526	Pressure-induced deep tissue damage of left ankle		379 CHRONIC ULCER OF SKIN	
L89.606	Pressure-induced deep tissue damage of unspecified heel		379 CHRONIC ULCER OF SKIN	
L89.616	Pressure-induced deep tissue damage of right heel		379 CHRONIC ULCER OF SKIN	

2019 New ICD-10-CM Codes

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
L89.626	Pressure-induced deep tissue damage of left heel		379 CHRONIC ULCER OF SKIN	
L89.816	Pressure-induced deep tissue damage of head		379 CHRONIC ULCER OF SKIN	
L89.896	Pressure-induced deep tissue damage of other site		379 CHRONIC ULCER OF SKIN	
L89.96	Pressure-induced deep tissue damage of unspecified site		379 CHRONIC ULCER OF SKIN	
N63.15	Unspecified lump in the right breast, overlapping quadrants	Other breast lump diagnoses are DWF	Diagnostic Workup File (DWF)	
N63.25	Unspecified lump in the left breast, overlapping quadrants		Diagnostic Workup File (DWF)	
N99.85	Post endometrial ablation syndrome		529 CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME, DYSPAREUNIA	See issues
Q66.00	Congenital talipes equinovarus, unspecified foot	Q66.0 (Congenital talipes equinovarus) is on line 359	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.01	Congenital talipes equinovarus, right foot		359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.02	Congenital talipes equinovarus, left foot		359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.10	Congenital talipes calcaneovarus, unspecified foot	Q66.1 (Congenital talipes calcaneovarus) is on line 359	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.11	Congenital talipes calcaneovarus, right foot		359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.12	Congenital talipes calcaneovarus, left foot		359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
Q66.211	Congenital metatarsus primus varus, right foot	Q66.21 (Congenital metatarsus primus varus) is on line 540	540 DEFORMITIES OF FOOT	
Q66.212	Congenital metatarsus primus varus, left foot		540 DEFORMITIES OF FOOT	
Q66.219	Congenital metatarsus primus varus, unspecified foot		540 DEFORMITIES OF FOOT	
Q66.221	Congenital metatarsus adductus, right foot	Q66.22 (Congenital metatarsus adductus) is on line 359	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.222	Congenital metatarsus adductus, left foot		359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.229	Congenital metatarsus adductus, unspecified foot		359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.30	Other congenital varus deformities of feet, unspecified foot	Q66.3 (Other congenital varus deformities of feet) is on line 359	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.31	Other congenital varus deformities of feet, right foot		359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.32	Other congenital varus deformities of feet, left foot		359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.40	Congenital talipes calcaneovalgus, unspecified foot	Q66.4 (Congenital talipes calcaneovalgus) is on line 359	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.41	Congenital talipes calcaneovalgus, right foot		359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.42	Congenital talipes calcaneovalgus, left foot		359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
Q66.70	Congenital pes cavus, unspecified foot	Q66.7 (Congenital pes cavus) is on line 359	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.71	Congenital pes cavus, right foot		359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.72	Congenital pes cavus, left foot		359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.90	Congenital deformity of feet, unspecified, unspecified foot	Q66.9 (Congenital deformity of feet, unspecified) is on line 359	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.91	Congenital deformity of feet, unspecified, right foot		359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q66.92	Congenital deformity of feet, unspecified, left foot		359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
Q79.60	Ehlers-Danlos syndrome, unspecified	Q79.6 (Ehlers-Danlos syndrome) is on line 525	525 DEFORMITIES OF UPPER BODY AND ALL LIMBS	
Q79.61	Classical Ehlers-Danlos syndrome		525 DEFORMITIES OF UPPER BODY AND ALL LIMBS	
Q79.62	Hypermobile Ehlers-Danlos syndrome		525 DEFORMITIES OF UPPER BODY AND ALL LIMBS	
Q79.63	Vascular Ehlers-Danlos syndrome		525 DEFORMITIES OF UPPER BODY AND ALL LIMBS	Considered to be severe Ehlers-Danlos syndrome
Q79.69	Other Ehlers-Danlos syndromes		525 DEFORMITIES OF UPPER BODY AND ALL LIMBS	
Q87.11	Prader-Willi syndrome		Dysfunction lines: 71,292,345,377	see issues
Q87.19	Other congenital malformation syndromes predominantly associated with short stature	Q87.1 (Congenital malformation syndromes predominantly associated with short stature) is on the dysfunction lines	Dysfunction lines: 71,292,345,377	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
R11.15	Cyclical vomiting syndrome unrelated to migraine		526 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS	See issues
R82.81	Pyuria	Similar abnormal urine findings are DWF	Diagnostic Workup File (DWF)	
R82.89	Other abnormal findings on cytological and histological examination of urine	Similar abnormal urine findings are DWF	Diagnostic Workup File (DWF)	
S02.121A	Fracture of orbital roof, right side, initial encounter for closed fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.121B	Fracture of orbital roof, right side, initial encounter for open fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.121D	Fracture of orbital roof, right side, subsequent encounter for fracture with routine healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.121G	Fracture of orbital roof, right side, subsequent encounter for fracture with delayed healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.121K	Fracture of orbital roof, right side, subsequent encounter for fracture with nonunion		441 MALUNION AND NONUNION OF FRACTURE	
S02.121S	Fracture of orbital roof, right side, sequela		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.122A	Fracture of orbital roof, left side, initial encounter for closed fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.122B	Fracture of orbital roof, left side, initial encounter for open fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.122D	Fracture of orbital roof, left side, subsequent encounter for fracture with routine healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.122G	Fracture of orbital roof, left side, subsequent encounter for fracture with delayed healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
S02.122K	Fracture of orbital roof, left side, subsequent encounter for fracture with nonunion		441 MALUNION AND NONUNION OF FRACTURE	
S02.122S	Fracture of orbital roof, left side, sequela		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.129A	Fracture of orbital roof, unspecified side, initial encounter for closed fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.129B	Fracture of orbital roof, unspecified side, initial encounter for open fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.129D	Fracture of orbital roof, unspecified side, subsequent encounter for fracture with routine healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.129G	Fracture of orbital roof, unspecified side, subsequent encounter for fracture with delayed healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.129K	Fracture of orbital roof, unspecified side, subsequent encounter for fracture with nonunion		441 MALUNION AND NONUNION OF FRACTURE	
S02.129S	Fracture of orbital roof, unspecified side, sequela		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.831A	Fracture of medial orbital wall, right side, initial encounter for closed fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.831B	Fracture of medial orbital wall, right side, initial encounter for open fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.831D	Fracture of medial orbital wall, right side, subsequent encounter for fracture with routine healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.831G	Fracture of medial orbital wall, right side, subsequent encounter for fracture with delayed healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
S02.831K	Fracture of medial orbital wall, right side, subsequent encounter for fracture with nonunion		441 MALUNION AND NONUNION OF FRACTURE	
S02.831S	Fracture of medial orbital wall, right side, sequela		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.832A	Fracture of medial orbital wall, left side, initial encounter for closed fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.832B	Fracture of medial orbital wall, left side, initial encounter for open fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.832D	Fracture of medial orbital wall, left side, subsequent encounter for fracture with routine healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.832G	Fracture of medial orbital wall, left side, subsequent encounter for fracture with delayed healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.832K	Fracture of medial orbital wall, left side, subsequent encounter for fracture with nonunion		441 MALUNION AND NONUNION OF FRACTURE	
S02.832S	Fracture of medial orbital wall, left side, sequela		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.839A	Fracture of medial orbital wall, unspecified side, initial encounter for closed fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.839B	Fracture of medial orbital wall, unspecified side, initial encounter for open fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.839D	Fracture of medial orbital wall, unspecified side, subsequent encounter for fracture with routine healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
S02.839G	Fracture of medial orbital wall, unspecified side, subsequent encounter for fracture with delayed healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.839K	Fracture of medial orbital wall, unspecified side, subsequent encounter for fracture with nonunion		441 MALUNION AND NONUNION OF FRACTURE	
S02.839S	Fracture of medial orbital wall, unspecified side, sequela		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.841A	Fracture of lateral orbital wall, right side, initial encounter for closed fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.841B	Fracture of lateral orbital wall, right side, initial encounter for open fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.841D	Fracture of lateral orbital wall, right side, subsequent encounter for fracture with routine healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.841G	Fracture of lateral orbital wall, right side, subsequent encounter for fracture with delayed healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.841K	Fracture of lateral orbital wall, right side, subsequent encounter for fracture with nonunion		441 MALUNION AND NONUNION OF FRACTURE	
S02.841S	Fracture of lateral orbital wall, right side, sequela		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.842A	Fracture of lateral orbital wall, left side, initial encounter for closed fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.842B	Fracture of lateral orbital wall, left side, initial encounter for open fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
S02.842D	Fracture of lateral orbital wall, left side, subsequent encounter for fracture with routine healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.842G	Fracture of lateral orbital wall, left side, subsequent encounter for fracture with delayed healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.842K	Fracture of lateral orbital wall, left side, subsequent encounter for fracture with nonunion		441 MALUNION AND NONUNION OF FRACTURE	
S02.842S	Fracture of lateral orbital wall, left side, sequela		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.849A	Fracture of lateral orbital wall, unspecified side, initial encounter for closed fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.849B	Fracture of lateral orbital wall, unspecified side, initial encounter for open fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.849D	Fracture of lateral orbital wall, unspecified side, subsequent encounter for fracture with routine healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.849G	Fracture of lateral orbital wall, unspecified side, subsequent encounter for fracture with delayed healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.849K	Fracture of lateral orbital wall, unspecified side, subsequent encounter for fracture with nonunion		441 MALUNION AND NONUNION OF FRACTURE	
S02.849S	Fracture of lateral orbital wall, unspecified side, sequela		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.85XA	Fracture of orbit, unspecified, initial encounter for closed fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.85XB	Fracture of orbit, unspecified, initial encounter for open fracture		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
S02.85XD	Fracture of orbit, unspecified, subsequent encounter for fracture with routine healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.85XG	Fracture of orbit, unspecified, subsequent encounter for fracture with delayed healing		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
S02.85XK	Fracture of orbit, unspecified, subsequent encounter for fracture with nonunion		441 MALUNION AND NONUNION OF FRACTURE	
S02.85XS	Fracture of orbit, unspecified, sequela		229 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES	
T50.911A	Poisoning by multiple unspecified drugs, medicaments and biological substances, accidental (unintentional), initial encounter		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS	
T50.911D	Poisoning by multiple unspecified drugs, medicaments and biological substances, accidental (unintentional), subsequent encounter		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS	
T50.911S	Poisoning by multiple unspecified drugs, medicaments and biological substances, accidental (unintentional), sequela		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS	
T50.912A	Poisoning by multiple unspecified drugs, medicaments and biological substances, intentional self-harm, initial encounter		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS	
T50.912D	Poisoning by multiple unspecified drugs, medicaments and biological substances, intentional self-harm, subsequent encounter		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
T50.912S	Poisoning by multiple unspecified drugs, medicaments and biological substances, intentional self-harm, sequela		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS	
T50.913A	Poisoning by multiple unspecified drugs, medicaments and biological substances, assault, initial encounter		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS	
T50.913D	Poisoning by multiple unspecified drugs, medicaments and biological substances, assault, subsequent encounter		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS	
T50.913S	Poisoning by multiple unspecified drugs, medicaments and biological substances, assault, sequela		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS	
T50.914A	Poisoning by multiple unspecified drugs, medicaments and biological substances, undetermined, initial encounter		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS	
T50.914D	Poisoning by multiple unspecified drugs, medicaments and biological substances, undetermined, subsequent encounter		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS	
T50.914S	Poisoning by multiple unspecified drugs, medicaments and biological substances, undetermined, sequela		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS	
T50.915A	Adverse effect of multiple unspecified drugs, medicaments and biological substances, initial encounter	T50.995 (Adverse effect of other drugs, medicaments and biological substances, initial encounter) is on line 103	103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS	
T50.915D	Adverse effect of multiple unspecified drugs, medicaments and biological substances, subsequent encounter		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
T50.915S	Adverse effect of multiple unspecified drugs, medicaments and biological substances, sequela		103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS	
T50.916A	Underdosing of multiple unspecified drugs, medicaments and biological substances, initial encounter	T50.996 (Underdosing of other drugs, medicaments and biological substances, initial encounter) is in the Diagnostic Workup File (DWF)	Diagnostic Workup File (DWF)	
T50.916D	Underdosing of multiple unspecified drugs, medicaments and biological substances, subsequent encounter		Diagnostic Workup File (DWF)	
T50.916S	Underdosing of multiple unspecified drugs, medicaments and biological substances, sequela		Diagnostic Workup File (DWF)	
T67.01XA	Heatstroke and sunstroke, initial encounter	T67.0XX (Heatstroke and sunstroke) is on line 181	181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)	
T67.01XD	Heatstroke and sunstroke, subsequent encounter		181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)	
T67.01XS	Heatstroke and sunstroke, sequela		181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)	
T67.02XA	Exertional heatstroke, initial encounter		181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)	
T67.02XD	Exertional heatstroke, subsequent encounter		181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)	
T67.02XS	Exertional heatstroke, sequela		181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)	
T67.09XA	Other heatstroke and sunstroke, initial encounter		181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
T67.09XD	Other heatstroke and sunstroke, subsequent encounter		181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)	
T67.09XS	Other heatstroke and sunstroke, sequela		181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)	
Y35.009A	Legal intervention involving unspecified firearm discharge, unspecified person injured, initial encounter	Other legal intervention codes are in the Informational Diagnosis File	Informational Diagnosis File	
Y35.009D	Legal intervention involving unspecified firearm discharge, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.009S	Legal intervention involving unspecified firearm discharge, unspecified person injured, sequela		Informational Diagnosis File	
Y35.019A	Legal intervention involving injury by machine gun, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.019D	Legal intervention involving injury by machine gun, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.019S	Legal intervention involving injury by machine gun, unspecified person injured, sequela		Informational Diagnosis File	
Y35.029A	Legal intervention involving injury by handgun, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.029D	Legal intervention involving injury by handgun, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.029S	Legal intervention involving injury by handgun, unspecified person injured, sequela		Informational Diagnosis File	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
Y35.039A	Legal intervention involving injury by rifle pellet, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.039D	Legal intervention involving injury by rifle pellet, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.039S	Legal intervention involving injury by rifle pellet, unspecified person injured, sequela		Informational Diagnosis File	
Y35.049A	Legal intervention involving injury by rubber bullet, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.049D	Legal intervention involving injury by rubber bullet, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.049S	Legal intervention involving injury by rubber bullet, unspecified person injured, sequela		Informational Diagnosis File	
Y35.099A	Legal intervention involving other firearm discharge, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.099D	Legal intervention involving other firearm discharge, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.099S	Legal intervention involving other firearm discharge, unspecified person injured, sequela		Informational Diagnosis File	
Y35.109A	Legal intervention involving unspecified explosives, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.109D	Legal intervention involving unspecified explosives, unspecified person injured, subsequent encounter		Informational Diagnosis File	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
Y35.109S	Legal intervention involving unspecified explosives, unspecified person injured, sequela		Informational Diagnosis File	
Y35.119A	Legal intervention involving injury by dynamite, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.119D	Legal intervention involving injury by dynamite, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.119S	Legal intervention involving injury by dynamite, unspecified person injured, sequela		Informational Diagnosis File	
Y35.129A	Legal intervention involving injury by explosive shell, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.129D	Legal intervention involving injury by explosive shell, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.129S	Legal intervention involving injury by explosive shell, unspecified person injured, sequela		Informational Diagnosis File	
Y35.199A	Legal intervention involving other explosives, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.199D	Legal intervention involving other explosives, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.199S	Legal intervention involving other explosives, unspecified person injured, sequela		Informational Diagnosis File	
Y35.209A	Legal intervention involving unspecified gas, unspecified person injured, initial encounter		Informational Diagnosis File	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
Y35.209D	Legal intervention involving unspecified gas, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.209S	Legal intervention involving unspecified gas, unspecified person injured, sequela		Informational Diagnosis File	
Y35.219A	Legal intervention involving injury by tear gas, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.219D	Legal intervention involving injury by tear gas, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.219S	Legal intervention involving injury by tear gas, unspecified person injured, sequela		Informational Diagnosis File	
Y35.299A	Legal intervention involving other gas, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.299D	Legal intervention involving other gas, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.299S	Legal intervention involving other gas, unspecified person injured, sequela		Informational Diagnosis File	
Y35.309A	Legal intervention involving unspecified blunt objects, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.309D	Legal intervention involving unspecified blunt objects, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.309S	Legal intervention involving unspecified blunt objects, unspecified person injured, sequela		Informational Diagnosis File	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
Y35.319A	Legal intervention involving baton, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.319D	Legal intervention involving baton, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.319S	Legal intervention involving baton, unspecified person injured, sequela		Informational Diagnosis File	
Y35.399A	Legal intervention involving other blunt objects, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.399D	Legal intervention involving other blunt objects, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.399S	Legal intervention involving other blunt objects, unspecified person injured, sequela		Informational Diagnosis File	
Y35.409A	Legal intervention involving unspecified sharp objects, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.409D	Legal intervention involving unspecified sharp objects, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.409S	Legal intervention involving unspecified sharp objects, unspecified person injured, sequela		Informational Diagnosis File	
Y35.419A	Legal intervention involving bayonet, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.419D	Legal intervention involving bayonet, unspecified person injured, subsequent encounter		Informational Diagnosis File	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
Y35.419S	Legal intervention involving bayonet, unspecified person injured, sequela		Informational Diagnosis File	
Y35.499A	Legal intervention involving other sharp objects, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.499D	Legal intervention involving other sharp objects, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.499S	Legal intervention involving other sharp objects, unspecified person injured, sequela		Informational Diagnosis File	
Y35.819A	Legal intervention involving manhandling, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.819D	Legal intervention involving manhandling, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.819S	Legal intervention involving manhandling, unspecified person injured, sequela		Informational Diagnosis File	
Y35.831A	Legal intervention involving a conducted energy device, law enforcement official injured, initial encounter		Informational Diagnosis File	
Y35.831D	Legal intervention involving a conducted energy device, law enforcement official injured, subsequent encounter		Informational Diagnosis File	
Y35.831S	Legal intervention involving a conducted energy device, law enforcement official injured, sequela		Informational Diagnosis File	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
Y35.832A	Legal intervention involving a conducted energy device, bystander injured, initial encounter		Informational Diagnosis File	
Y35.832D	Legal intervention involving a conducted energy device, bystander injured, subsequent encounter		Informational Diagnosis File	
Y35.832S	Legal intervention involving a conducted energy device, bystander injured, sequela		Informational Diagnosis File	
Y35.833A	Legal intervention involving a conducted energy device, suspect injured, initial encounter		Informational Diagnosis File	
Y35.833D	Legal intervention involving a conducted energy device, suspect injured, subsequent encounter		Informational Diagnosis File	
Y35.833S	Legal intervention involving a conducted energy device, suspect injured, sequela		Informational Diagnosis File	
Y35.839A	Legal intervention involving a conducted energy device, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.839D	Legal intervention involving a conducted energy device, unspecified person injured, subsequent encounter		Informational Diagnosis File	
Y35.839S	Legal intervention involving a conducted energy device, unspecified person injured, sequela		Informational Diagnosis File	
Y35.99XA	Legal intervention, means unspecified, unspecified person injured, initial encounter		Informational Diagnosis File	
Y35.99XD	Legal intervention, means unspecified, unspecified person injured, subsequent encounter		Informational Diagnosis File	

ICD10 Code	Description	Similar Code(s)	Recommended Placement	Notes
Y35.99XS	Legal intervention, means unspecified, unspecified person injured, sequela		Informational Diagnosis File	
Z01.020	Encounter for examination of eyes and vision following failed vision screening without abnormal findings	Similar code Z01.110 (Encounter for hearing examination following failed hearing screening) is on line 3	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	
Z01.021	Encounter for examination of eyes and vision following failed vision screening with abnormal findings		3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	
Z11.7	Encounter for testing for latent tuberculosis infection	Similar code Z11.1 (Encounter for screening for respiratory tuberculosis) is on line 3	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	
Z22.7	Latent tuberculosis		50 PULMONARY TUBERCULOSIS	See issues
Z71.84	Encounter for health counseling related to travel		Excluded file (Travel Vaccines Etc.)	OHP is unable to pay for travel related medical care
Z86.002	Personal history of in-situ neoplasm of other and unspecified genital organs	Other Z86.00 codes are in the Informational Diagnosis File	Informational Diagnosis File	
Z86.003	Personal history of in-situ neoplasm of oral cavity, esophagus and stomach		314 CANCER OF ESOPHAGUS; BARRETT'S ESOPHAGUS WITH DYSPLASIA	See issues
Z86.004	Personal history of in-situ neoplasm of other and unspecified digestive organs		166 ANAL, RECTAL AND COLONIC POLYP	See issues
Z86.005	Personal history of in-situ neoplasm of middle ear and respiratory system		Informational Diagnosis File	
Z86.006	Personal history of melanoma in-situ		Informational Diagnosis File	
Z86.007	Personal history of in-situ neoplasm of skin		Informational Diagnosis File	
Z86.15	Personal history of latent tuberculosis infection		Informational Diagnosis File	
Z96.82	Presence of neurostimulator		Informational Diagnosis File	

2019 ICD-10 Code Review Issues

1) Embolism of calf veins
    a. Issue: Phlebitis, thrombophlebitis, and embolisms of the deep veins (eg. popliteal, tibial) are on line 79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP, whereas embolisms of superficial veins are on line 514 PHLEBITIS AND THROMBOPHLEBITIS, SUPERFICIAL. Peroneal veins are considered deep veins and therefore the new ICD-10 codes related to peroneal veins should be on line 79. Calf muscular veins are not generally considered deep veins, but are also not superficial veins. Controversy exists regarding whether calf muscular vein thrombosis requires treatment
    b. New ICD-10 codes
        i. I80.241-I80.249 (Phlebitis and thrombophlebitis of peroneal vein)
        ii. I80.251-I80.259 (Phlebitis and thrombophlebitis of calf muscular vein)
        iii. I82.451-I82.459 (Acute embolism and thrombosis of peroneal vein)
        iv. I82.461-I82.469 (Acute embolism and thrombosis of calf muscular vein)
        v. I82.551-I82.559 (Chronic embolism and thrombosis of peroneal vein)
        vi. I82.561-I82.569 (Chronic embolism and thrombosis of calf muscular vein)
    c. Evidence
        i. **De Martino 2012**, Systematic review and meta-analysis of treatment of deep calf venous thrombosis
            1. 2 RCTs and 6 cohort studies (454 patients)
                a. Adults with isolated calf vein deep venous thrombosis (DVT).
                b. The methodologic quality of most studies was poor.
            2. Pulmonary embolism (PE; odds ratio, 0.12; 95% confidence interval, 0.02-0.77; P = .03) and thrombus propagation (odds ratio, 0.29; 95% confidence interval, 0.14-0.62; P = .04) were significantly less frequent in those who received anticoagulation.
            3. Conclusions: Our review suggests that anticoagulation therapy for calf vein DVT may decrease the incidence of PE and thrombus propagation.
        ii. **Kearon 2016**, CHEST guideline for treatment of DVT
            1. isolated distal DVT
                a. two management options: (1) treat patients with anticoagulant therapy or (2) do not treat patients with anticoagulant therapy unless extension of their DVT is detected on a follow-up US examination (eg, after 1 and 2 weeks, or sooner if there is concern; there is no widely accepted protocol for surveillance US testing)
                b. Because about 15% of untreated isolated distal DVT are expected to subsequently extend into the popliteal vein and may cause PE, it is not acceptable to neither anticoagulate nor do surveillance to detect thrombus extension
    d. HERC staff summary: It is difficult to differentiate calf muscle veins from deep veins of the calf in the medical literature. It appears that calf muscle veins are generally included with peroneal veins in studies. While controversy exists about the need to treat calf vein thromboses, particularly the muscular calf veins, it appears that at a minimum follow up ultrasound is required and therefore these diagnoses should be on a covered line

e. HERC staff recommendation:
    i. Place all new I80/I82 ICD-10 codes on line 79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP

2) Post endometrial ablation syndrome
    a. New ICD-10 Code: N99.85 Post endometrial ablation syndrome
    b. Definition: There appears to be no clear definition in the medical literature for "post endometrial ablation syndrome" and MEDLINE does not include any literature with that wording as a key word/phrase. **Sharp (2012)** outlines complications of endometrial ablation including pelvic pain and dysmenorrhea, failure to control menses, infection, pregnancy complications, and obstructed menses. Treatment generally involves hysterectomy, although specific treatment might include antibiotics or repeat endometrial ablation.
    c. Similar diagnoses
        i. N94.6 Dysmenorrhea: 555 DYSMENORRHEA
        ii. R10.2 Pelvic pain: 529 CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME, DYSPAREUNIA
    d. Expert input: Dr. Michael Adler recommends prioritizing post endometrial ablation syndrome with other pelvic pain syndrome type diagnoses
    e. HERC staff recommendation
        i. Place ICD-10 N99.85 (Post endometrial ablation syndrome) on line 529 CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME, DYSPAREUNIA
            1. Unclear what this diagnosis refers to, but appears to generally include pelvic pain

3) Prader Willi Syndrome
    a. New ICD-10 code: Q87.11 Prader-Willi syndrome
    b. Definition: Prader-Willi syndrome is a complex genetic condition that affects many parts of the body. Symptoms include hypotonia, poor growth, hyperphagia and obesity. People with Prader-Willi syndrome typically have mild to moderate intellectual impairment and learning disabilities. Behavioral problems are common. Puberty is delayed or incomplete.
    c. HERC staff recommendation:
        i. Place Q87.11 on the dysfunction lines (71,292,345,377) to allow for supportive therapies

4) Cyclical vomiting syndrome unrelated to migraine
    a. New ICD-10 code: R11.15 Cyclical vomiting syndrome unrelated to migraine
    b. Definition: Cyclic vomiting syndrome is a disorder that causes recurrent episodes of nausea, vomiting, and lethargy. This condition is diagnosed most often in young children, but it can affect people of any age. The episodes of nausea, vomiting, and lethargy last anywhere from an hour to 10 days. An affected person may vomit several times per hour, potentially leading to a dangerous loss of fluids (dehydration). Additional symptoms can include abdominal pain, diarrhea, headache, fever, and an increased sensitivity to light (photophobia) or to sound (phonophobia). Episodes of nausea, vomiting, and lethargy can occur regularly or apparently at random, or can be triggered by a variety of factors. If the condition is not treated, episodes usually occur four to 12 times per year. Between attacks, vomiting is absent, and nausea is either

absent or much reduced. However, many affected people experience other symptoms during and between episodes, including pain, lethargy, digestive disorders such as gastroesophageal reflux and irritable bowel syndrome, and fainting spells (syncope). Cyclic vomiting syndrome is often considered to be a variant of migraines, which are severe headaches often associated with pain, nausea, vomiting, and extreme sensitivity to light and sound. Cyclic vomiting syndrome is likely the same as or closely related to a condition called abdominal migraine, which is characterized by attacks of stomach pain and cramping.

c. Similar ICD-10 code: G43.D Abdominal migraine, which is on line 526 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS
d. HERC staff recommendation:
    i. Place R11.15 on line 526 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS

5) Latent TB
    a. New ICD-10 code: Z22.7 Latent tuberculosis
    b. Definition: Persons with latent TB infection do not feel sick and do not have any symptoms. They are infected with *M. tuberculosis*, but do not have TB disease. The only sign of TB infection is a positive reaction to the tuberculin skin test or TB blood test. Persons with latent TB infection are not infectious and cannot spread TB infection to others. Treatment of latent TB infection is indicated if the patient meets criteria outlined by the CDC.
    c. In November, 2018, the HERC placed ICD-10 R76.1 (positive reaction to TB test) on line 50. Previously, this code series had been on the Diagnostic Workup File, which did not allow treatment for the positive test. Positive skin or blood tests for TB without active TB on chest xray is the definition of latent TB.
    d. Current Prioritized List status:
        i. There are 2 current TB lines:
            1. 50 PULMONARY TUBERCULOSIS
            2. 152 NON-PULMONARY TUBERCULOSIS
    e. HERC staff recommendation:
        i. Place Z22.7 on line 50 PULMONARY TUBERCULOSIS to be consistent with November 2018 placement of codes potentially associated with latent TB.

6) Personal history of in-situ neoplasm of gastrointestinal organs
    a. New ICD-10 Codes:
        i. Z86.003 Personal history of in-situ neoplasm of oral cavity, esophagus and stomach
        ii. Z86.004 Personal history of in-situ neoplasm of other and unspecified digestive organs
    b. Patients with a history of an in-situ neoplasm of the esophagus need regular EGDs for surveillance. A similar diagnosis would be K22.711 (Barrett's esophagus with high grade dysplasia), which is on line 314 CANCER OF ESOPHAGUS; BARRETT'S ESOPHAGUS WITH DYSPLASIA. Similarly, a stomach neoplasm diagnosis may require regular EGDs as a follow up.
    c. Patients with a history of a colon in-situ neoplasm would need surveillance with colonoscopies. A similar diagnosis would be K63.5 (Polyp of colon) which is on line 166 ANAL, RECTAL AND COLONIC POLYPS.

d. HERC staff recommendations
    i. Place Z86.003 on line 314 CANCER OF ESOPHAGUS; BARRETT'S ESOPHAGUS WITH DYSPLASIA
    ii. Place Z86.004 on line 166 ANAL, RECTAL AND COLONIC POLYP

Certification for Lymphedema Providers

Question: How should the lymphedema therapy guideline be best modified to allow coverage if therapy is done by non-LANA certified therapists?

Question sources: several CCOs and providers; coverage guidance nomination process

Issue: This topic was discussed at the May, 2019 VBBS meeting. The initial concern of the CCOs was that there is a shortage of LANA-certified therapists in some areas of the state. At the May meeting, the VBBS was in favor of adding coverage for lymphedema therapy provided by non-LANA certified therapists, but had concerns with the proposed guideline wording changes proposed by HERC staff. Staff was directed to revise the guideline further and bring back for approval. Staff has reviewed the recommended new guideline changes with the CCO medical directors, who agree with the staff recommended changes.

Subsequently, the LANA executive director, Ms. Katina Kirby, and president, Dr. Paula Stewart, contacted HERC staff with concerns regarding the proposed changes. Specifically, they felt that usual NALEA was too limited (it includes only 4 schools) and did not ensure quality.

From Ms. Kirby:

> NALEA is too limited – only 4 schools comprise NALEA. This still would not achieve the availability of specialists to the patients. NALEA has no guidelines or policy/procedure for schools to join and has to date not included any of lymphedema program. By saying LANA eligible graduates from programs meeting the LANA educational eligibility requirement (which does include the NALEA schools but is not limited to just 4 programs) will be authorized to treat.

The LANA staff suggested changing the guideline to include

> "CLT-LANA eligible (graduates from a minimum 135-hour lymphedema program that meet the LANA eligibility requirements). http://www.clt-lana.org"

Per LANA, eligible training programs

> Provide proof of successful completion of qualified instructional course in Complete Decongestive Therapy (CDT) course work (consisting of 1/3 theoretical instruction and 2/3 practical lab work and documentation of 135-classroom hours) from no more than four consecutive or cumulative courses from one training program. Practical lab work is defined as real-time instruction with an instructor present. An instructional video that a student watches during home study would NOT be counted as part of the expected 2/3 practical lab work. Proof is accepted in the form of a computer certificate or letter from the school director.

Per LANA staff, their suggested edit would include Vodder trained therapists, but not likely Chickley (they have had no applications for certification from Chickley trained therapists).

Current guideline

GUIDELINE NOTE 43, LYMPHEDEMA

Line 421

Lymphedema treatments are included on this line when medically appropriate. These services are to be provided by a licensed practitioner who is certified by one of the accepted lymphedema training certifying organizations or a graduate of one of the National Lymphedema Network accepted training courses within the past two years. The only accepted certifying organization at this time is LANA (Lymphology Association of North America; http://www.clt-lana.org). Treatments for lymphedema are not subject to the visit number restrictions found in Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES.

It is the intent of the HERC that compression dressings/garments and other medical equipment needed for the treatment of lymphedema be covered even in the absence of ulcers or other complications.

HERC staff recommendation:

1) Modify GN 43 to remove the limitation to only LANA certified providers
    a. The version for entry #2 proposed by LANA is in purple

GUIDELINE NOTE 43, LYMPHEDEMA

Line 421

Lymphedema treatments are included on this line when medically appropriate. These services are to be provided by a licensed practitioner who is:

1) Certified by Lymphology Association of North America (LANA, http://www.clt-lana.org), OR
2) A graduate of one of the National Lymphedema Network or North American Lymphedema Education Association (NALEA) accepted training courses
2) CLT-LANA eligible (graduates from a minimum 135-hour lymphedema program that meet the LANA eligibility requirements). http://www.clt-lana.org

Services should be provided by a LANA certified therapist if available.
~~certified by one of the accepted lymphedema training certifying organizations or a graduate of one of the National Lymphedema Network accepted training courses within the past two years. The only accepted certifying organization at this time is LANA (Lymphology Association of North America; http://www.clt-lana.org).~~ Treatments for lymphedema are not subject to the visit number restrictions found in Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES.

It is the intent of the HERC that compression dressings/garments and other medical equipment needed for the treatment of lymphedema be covered even in the absence of ulcers or other complications.

Varicocele Repair in Pediatric Patients

Question: Should coverage for varicocele repair in certain pediatric populations be moved to a higher priority line on the Prioritized List?

Question source: Casey A Seideman MD, OHSU Pediatric Urology

Issue: Varicoceles are currently on a low priority line below the funding line. Dr. Seideman has requested consideration for coverage for varicoceles in children which meet certain criteria.

A varicocele is an enlargement of the veins within the scrotum. The prevalence of varicoceles is as high as 15% in children and adolescents. The main effect of varicocele is its potential role in male infertility. In about 20% of adolescents with varicocele, fertility problems will arise. Management options include monitoring, radiographic intervention, or surgical varicocelectomy. Current guidelines recommend testicular volume loss or growth lag as the main indication for intervention to preserve or improve fertility. Other indications include pain, co-existing testicular anomalies, and abnormal semen analysis.

From Dr. Seideman:

> Most of the time, varicoceles in kids are asymptomatic – and do not require surgical intervention. Sometimes, however, they can cause significant pain/discomfort and impact daily living, or they can stunt testicular growth. In these rare instances, I would say that a varicocelectomy is the gold standard of treatment.

Varicoceles in adult men are only recommended for treatment if they are causing infertility issues.

Current Prioritized List status
ICD10 I86.1 (Scrotal varices) is on line 545 SUBLINGUAL, SCROTAL, AND PELVIC VARICES.

Similar diagnoses:
ICD10 N43.3 (Hydrocele, unspecified) is on line 542 HYDROCELE
ICD10 N43.4 (Spermatocele of epididymis) in on line 542 HYDROCELE
ICD10 N50.0 (Atrophy of testis) is on line 467 GONADAL DYSFUNCTION, MENOPAUSAL MANAGEMENT (no surgical CPT codes pair)
ICD10 N50.81 (testicular pain) is on the Diagnostic Work Up File

Fertility surgery/issues cannot be covered as part of a Medicaid program by federal rules.

Evidence:

1) **Locke 2017**, systematic review and meta-analysis of RCTS of treatment for varicoceles in children and adolescents
    a. N=9 studies (N=1266 patients) total included
        i. N=5 studies (N=385 patients) included in quantitative analysis
    b. In the nine studies included, some of the authors reported indications for treatment as pain, discrepancy in testicular volume >20% from the contralateral side and varicocele grade II or higher
    a. Meta-analysis based on available outcomes data demonstrated an improvement in testicular volume (mean difference 3.18 mL, 95% CI 1.94-4.42) and in sperm count (mean difference 25.54 x 10^6/mL, 95% CI 12.84-38.25) in patients who underwent radiological or surgical treatment compared with conservative management.
    b. Surgical outcomes and adverse events are not reported consistently.
    a. Conclusions: Based on current available randomized controlled trials, there is low to moderate level of evidence that radiological or surgical treatment of adolescent varicocele is associated with improved testicular size/growth and sperm concentration. The ultimate effects on fertility and paternity rates are not known.

Expert guidelines

1) **American Urological Association 2001** (archived): Report on varicocele and infertility
    a. Adolescents who have a varicocele and objective evidence of reduced ipsilateral testicular size should be offered varicocele repair. Adolescents who have a varicocele but normal ipsilateral testicular size should be offered follow-up monitoring with annual objective measurements of testicular size and/or semen analyses.
1) **Tekgul 2015** European Society for Pediatric Urology guidelines
    a. There is no evidence that treatment of varicocele at pediatric age will offer a better andrological outcome than an operation performed later.
    b. The recommended indication criteria for varicocelectomy in children and adolescents are:
        i. varicocele associated with a small testis;
        ii. additional testicular condition affecting fertility;
        iii. bilateral palpable varicocele;
        iv. pathological sperm quality (in older adolescents);
        v. symptomatic varicocele (pain).

    Level of evidence: 2; Grade of Recommendation: B

HERC staff summary

Repair of varicoceles in children and adolescents is recommended by expert opinion when there is pain and/or a reduction in testicular volume by 20% compared to the contralateral side. Repair of varicocele has limited evidence of improving fertility; no reports on improvement in gonadal function were found.

HERC staff recommendation:

1) Consider moving varicoceles in children and adolescents to a covered line on the Prioritized List with a guideline
    a. Add ICD-10 I86.1 (Scrotal varices) to line 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
    b. Add the following treatment CPT codes to line 327
        i. CPT 36470 (Injection of sclerosant; single incompetent vein (other than telangiectasia))
        ii. CPT 37241-37242 (Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (eg, congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles))
        iii. CPT 55530-55550 (Excision of varicocele or ligation of spermatic veins for varicocele)
    c. Add a new guideline as shown below to lines 327 and 545 SUBLINGUAL, SCROTAL, AND PELVIC VARICES

GUIDELINE NOTE XXX REPAIR OF VARICOCELES IN CHILDREN AND ADOLESCENTS

Lines 327,545

Varicocele repair is only included on line 327 for children and adolescents (up through age 18) with:

1) Pain affecting activities of daily living from the varicocele; OR
2) Objective evidence of reduced ipsilateral testicular size of 20% of more compared to the contralateral testicle; OR
3) Varicocele in a patient with a solitary testicle.

All other varicocele repair is included on line 545.

Treatments for Urinary Incontinence

Question: Which procedures should be paired with urinary incontinence on the Prioritized List?

Question source: HSD claims reconsideration

Issue: Multiple procedure codes that do not pair with urinary incontinence have been identified by HSD claims reconsideration. There has not been a comprehensive review of treatments covered for urinary incontinence in many years.

Stress incontinence (N39.3), mixed incontinence (N39.46) and intrinsic sphincter deficiency (ISD) (N36.42) are on line 453 URINARY INCONTINENCE and pair with a variety of treatments. There is a guideline note applied to line 453 outlining when surgical treatments are covered.

Treatments for urinary incontinence include pelvic muscle exercises (Kegel exercise), behavioral therapies such as bladder training and/or biofeedback, pharmacotherapies (e.g., anti-cholinergic agents, musculotropic relaxants, calcium channel blockers, tricyclic anti-depressants, or a combination of anti-cholinergic, anti-spasmodic medications and tricyclic anti-depressants), and a variety of surgical procedures including intra-urethral injection of collagen, and implantation of an artificial urinary sphincter. Surgical procedures can also include bladder suspension and sling procedures.

Additionally, sacral nerve stimulation for treatment of urinary incontinence was suggested for review by the coverage guidance process. HERC approved the review of this procedure by VBBS at their May, 2019 meeting.

Treatments for Urinary Incontinence

Procedure codes identified in claims reconsideration as not pairing with urinary incontinence:

CPT code	Code description	Current Placement	HERC staff recommendation
51700	Bladder irrigation, simple, lavage and/or instillation	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES, 215,271,275, 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION 329,352	Do not add to line 453 No mention of bladder irrigation found in NICE or Aetna coverage documents
51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck	87 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM 327 432 HYPOSPADIAS AND EPISPADIAS	See separate review
53440	Sling operation for correction of male urinary incontinence (eg, fascia or synthetic)	71,87,327	See separate review
53445	Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff	71,87,327	See separate review
97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities	60+ lines	Do not add to line 453 Multiple appropriate PT codes already are on line 453

Sacral Nerve Stimulation

Question: What, if any, conditions should sacral nerve stimulation be paired with on the Prioritized List?

Question source: Healthshare CCO; HTAS; HERC staff

Issue: Sacral nerve stimulation for non-obstructive urinary retention was nominated as an HTAS topic in 2016 but has not yet been reviewed by HTAS. The CPT codes for this treatment are listed as "Never Reviewed" in the HERC database and do not currently appear on the Prioritized List. A CCO recently requested guidance on what conditions this treatment should be covered for.

Sacral nerve stimulation (also known as sacral neuromodulation therapy) is a reversible treatment that uses a small device to send electrical impulses to the sacral nerves. These electrical impulses alter muscles and organs (the bladder, sphincter, and pelvic floor muscles) that contribute to bladder control. The electrical stimulation can often successfully eliminate or reduce certain bladder-control problems in some people. This treatment is used for non-obstructive urinary retention, overactive bladder, and urinary incontinence. It has also been used to treat fecal incontinence.

Currently, urinary incontinence, overactive bladder, and non-obstructive urinary retention are on a covered line paired with a variety of therapies. These therapies include surgical treatments like bladder sling procedures, as well as Botox injections, pelvic physical therapy, various oral medications, and DME such as catheters. Fecal incontinence is on a dysfunction line for pairing with DME such as adult sanitary garments, and on an uncovered line for surgical and other therapies according to Guideline Note 129.

Current Prioritized List status

CPT Code	Code Description	Current Placement
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed	Never Reviewed
64581	Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)	Never Reviewed
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling	Never Reviewed
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver	285/422 COMPLICATIONS OF A PROCEDURE ALWAYS/USUALLY REQUIRING TREATMENT
HCPCS		
A4290	Sacral nerve stimulation test lead, each	Never reviewed
C1767	Generator, neurostimulator (implantable), non-rechargeable	174,250,292,346,361,440,527,660
C1778	Lead, neurostimulator (implantable)	174,250,292,346,361,440,527,660
C1787	Patient programmer, neurostimulator	Never reviewed
C1897	Lead, neurostimulator test kit (implantable)	174,250,292,346,361,440,527,660
L8679	Implantable neurostimulator, pulse generator, any type	Never reviewed
L8680	Implantable neurostimulator electrode, each	Never reviewed
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only	Never reviewed
L8682	Implantable neurostimulator radiofrequency receiver	Never reviewed
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver	Never reviewed
L8684	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement	Never reviewed
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension	Never reviewed
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension	Never reviewed
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension	Never reviewed
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension	Never reviewed

L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only	Never reviewed
ICD-10		
R15.9	Full incontinence of feces	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 526 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS
N32.81	Overactive bladder	327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
N39.3-N39.9	Urinary incontinence	453 URINARY INCONTINENCE
R32	Unspecified urinary incontinence	Diagnostic Workup File
R33.8	Other retention of urine	327; DWF
R33.9	Retention of urine, unspecified	Diagnostic Workup File

GUIDELINE NOTE 129, FECAL INCONTINENCE

Lines 71,526

ICD-10-CM R15.9 (Full incontinence of feces) is included on Line 71 only for supportive equipment (e.g. diapers, gloves). Surgical treatment for fecal incontinence is included on Line 526 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS

Evidence

1) **NICE 2015** Sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention
    a. Overall recommendation: Current evidence on the safety and efficacy of sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention is adequate to support the use of this procedure
    b. First line therapies are medications (men) and urethral dilation and self-catheterization (men and women)
    c. Sacral nerve stimulation involves an evaluation phase to help the patient and clinician decide if long-term therapy will be beneficial
    d. Efficacy:
        i. A randomized controlled trial of 51 patients treated by sacral nerve stimulation or standard medical treatment
            1. the mean catheter volume per catheterization decreased from 339 ml to 49 ml at 6-month follow-up in the treatment group and from 350 ml to 319 ml in the control group ($p<0.0001$ comparing the mean differences).
            2. the mean total voided volume per day increased from 722 ml to 1808 ml at 6-month follow-up in the treatment group and decreased from 560 ml to 488 ml in the control group ($p<0.0001$ comparing the mean differences).
            3. the mean number of catheterizations per day decreased from 5.7 to 1.4 at 6-month follow-up in the treatment group and from 4.0 to 3.9 in the control group ($p<0.0001$) comparing the mean differences). At 18-month follow-up 58% (14/24) of patients treated by sacral nerve stimulation did not need catheterization.
        ii. A case series of 60 patients reported that 72% (43/60) of patients were voiding spontaneously and 50% (30/60) of patients no longer needed to use catheterization after a mean follow-up of 4 years. A case series of 40 patients reported that the mean number of catheterizations per day decreased from 4.3 to 1.0 after a mean follow-up of 41 months ($p<0.001$) and 55% (11/20) of patients with complete retention were able to stop catheterization completely.
    e. Safety
        i. The neurostimulator device was removed in 14% (4/28) of patients in a case series of 40 patients: 2 because of infection, 1 because of pain and 1 because of the need for MRI. In the same study, neurostimulator revision was necessary in 21% (6/28) of patients because of battery expiry or device malfunction in 4 patients and infection in 2 patients.
        ii. In a systematic review of 14 articles (1239 patients)
            1. Infection was reported in 4% of patients
            2. Lead migration was reported in 5% of patients
            3. Pain at the implant site, pain at the lead site and new pain (unspecified) were reported in 10% (128/1239), 2% and 4% of patients respectively
            4. Sensation of electric shock was reported in 2% of patients
        iii. In a case series of 60 patients
            1. Lead migration was reported in 28% (17/60) of patients
            2. Pain at the implant site was reported in 32% (19/60) of patients

3. Leg pain, pelvic pain and urethral pain were reported in 30% (18/60), 3% (2/60) and 3% (2/60) of patients respectively

2) **NICE 2019** Urinary Incontinence in Women
    a. Transcutaneous sacral nerve stimulation
        i. Do not offer transcutaneous sacral nerve stimulation to treat overactive (OAB) in women
    b. Percutaneous sacral nerve stimulation
        i. Offer percutaneous sacral nerve stimulation to women after review if:
            1. their OAB has not responded to conservative management including medicines, and
            2. their symptoms have not responded to botulinum toxin type A or
            3. they are not prepared to accept the risks of needing catheterisation associated with botulinum toxin type A.
        i. Discuss the long-term implications of percutaneous sacral nerve stimulation with women including:
            a. the need for test stimulation and probability of the test's success
            b. the risk of failure
            c. the long-term commitment
            d. the need for surgical revision
            e. the adverse effects.
3) **NICE 2004** Sacral nerve stimulation for fecal incontinence
    a. Overall recommendation:
        i. Current evidence on the safety and efficacy of sacral nerve stimulation for fecal incontinence appears adequate to support the use of this procedure
    b. Efficacy
        i. This procedure was subject to a systematic review commissioned by the Institute. The systematic review included six case series studies reporting on 266 patients in total. In patients who had permanent implants, complete continence was achieved in 41–75% (19/46–12/16) of patients, whereas 75–100% (3/4–16/16) of patients experienced a decrease of 50% or more in the number of incontinence episodes. There was also evidence to suggest an improvement in the ability to defer defecation after permanent implantation. Patients also reported improvements in both disease-specific and general quality-of-life scores after the procedure.
    c. Safety
        i. Complications were reported both during the test peripheral nerve evaluation phase and after implantation. Evidence from the systematic review indicated that of the 266 patients receiving test evaluation, 4% (10/266) experienced an adverse event. Fifty-six per cent (149/266) went on to receive permanent implantation. Of the patients who had permanent implants, 13% (19/149) reported adverse events. These included three patients who developed infections requiring device removal, seven patients who had lead migration requiring either relocation (five cases) or removal of the device, and six patient who experienced pain after implantation.
4) **AHRQ 2009** Treatment of Overactive Bladder in Women
    a. N= 1 RCT (98 patients) comparing sacral neuromodulation to medical therapy.
        i. This study, which randomized after successful test stimulation, found a reduction in daily urge incontinence episodes from 9.7 to 2.6 in the sacral

neuromodulation group, compared to an increase of 9.3 to 11.3 in the medical management group at 6 months ($p<0.01$) for patients with refractory OAB.124 At 18 months, 76 percent of participants receiving sacral neuromodulation reported that they were completely dry or had experienced a reduction in symptoms of 50 percent or greater. Note that the comparison is not ideal, as subjects continuing to receive medical therapy had already failed medical management.

ii. Reported an 82 percent decrease in pad use from 6.2 to 1.1 pads daily, six months following initiation of sacral neuromodulation

b. N=6 case series
   i. Decreases in mean incontinence episodes per day of 51 percent to 80 percent and from a median of five down to zero incontinence episodes a day. Length of follow-up in these studies ranged for six months to five years.
   ii. Three case series evaluating sacral neuromodulation also found significant decreases in pad use ranging from 49 to 84 percent fewer mean pads and a 75 percent decrease in median pad use.
c. Reduction in urinary frequency of between 31 and 45 percent is seen consistently across studies of sacral neuromodulation, regardless of study design
d. One cohort study and two case series found that sacral neuromodulation increased the mean voided volume between 1.7 to 1.9 fold, an increase of 78 mL to 108 mL per void
e. Peripheral neuromodulation and electromagnetic stimulation were clinically ineffective in changing voiding frequency

1) **NICE 2004** Sacral nerve stimulation for urge incontinence and urgency-frequency
   a. Overall recommendation
      i. Current evidence on the safety and efficacy of sacral nerve stimulation for urge incontinence and urgency-frequency appears adequate to support the use of this procedure
   b. Efficacy
      i. This procedure was subject to a systematic review commissioned by the Institute in November 2003. Evidence from two randomized controlled trials (RCTs), including a total of 50 patients with urge incontinence, showed that complete continence (completely dry with no incontinent episodes) or improvement of more than 50% in incontinence symptoms was observed in 50% and 80% of patients, respectively, following the procedure. This compared with 5% of patients in the control groups, who were receiving conservative treatments while waiting for an implant. In the one RCT that reported on patients with urgency-frequency, an improvement of more than 50% in incontinence symptoms was observed in 56% (14/25) of patients, compared with 4% (1/25) in the control group.
   a. Safety
      a. The results of the systematic review showed that, overall, the re-operation rate for patients with implants was 33% (283/860). The most common reasons for surgical revision were to replace or reposition implants due to pain or infection at the implant site, or to adjust and modify the lead system to correct breakage or migration.
      b. Pain at the site of the pulse generator or at the site of stimulation was reported in 24% (162/663) of patients, sometimes requiring replacement and repositioning of the pulse generator. Other complications included lead-related

problems such as migration (16%), wound problems (7%), adverse effects on bowel function (6%), and infection (5%). No cases of long-lasting neurological complications were identified.

Other payer policies

1) **Noridian 2019** LCD on Sacral Nerve Stimulation for Urinary and Fecal Incontinence
    1. Sacral nerve stimulation is covered for the treatment of urinary urge incontinence, urgency-frequency syndrome, and urinary retention. Sacral nerve stimulation involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in appropriate candidates. Both the test and the permanent implantation are covered. The NCD describes the following limitations for coverage to all three conditions:
        1) Patient must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and be an appropriate surgical candidate such that implantation with anesthesia can occur.
        2) Patients with stress incontinence, urinary obstruction, and specific neurologic diseases (e.g., diabetes with peripheral nerve involvement) which are associated with secondary manifestations of the above three indications are excluded.
        3) Patient must have had a successful test stimulation in order to support subsequent implantation. Before a patient is eligible for permanent implantation, he/she must demonstrate a 50% or greater improvement through test stimulation. Improvement is measured through voiding diaries. Patient must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated.
    b. Fecal Incontinence: Noridian will cover sacral nerve modulation/stimulation for fecal incontinence when all of the following criteria are met:
        a. Chronic fecal incontinence with greater than two incontinent episodes on average per week and duration of incontinence greater than six months or for more than twelve months after vaginal childbirth; AND
        b. Documented failure or intolerance to conventional therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment); AND
        c. A successful percutaneous test stimulation, defined as at least 50% sustained (more than one week) improvement in symptoms; AND
        d. Condition is not related to anorectal malformation (e.g., congenital anorectal malformation; defects of the external anal sphincter over 60 degrees; visible sequelae of pelvic radiation; active anal abscesses and fistulae) and/or chronic inflammatory bowel disease; AND
        e. Incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.
    c. Sacral nerve modulation/stimulation is considered experimental, investigational and unproven for the treatment of chronic constipation or chronic pelvic pain**.**
2) **Aetna 2018** Urinary Incontinence
    a. Aetna considers implantation of the InterStim (Medtronic Inc., Minneapolis, MN), a device for unilateral stimulation of the sacral nerve, medically necessary for the

treatment of urge UI or symptoms of urge-frequency when all of the following criteria are met:

i. The member has experienced urge UI or symptoms of urge-frequency for at least 12 months and the condition has resulted in significant disability (the frequency and/or severity of symptoms are limiting the member's ability to participate in daily activities); *and*
ii. Pharmacotherapies (i.e., at least 2 different anti-cholinergic drugs or an anti-cholinergic and a beta-3 adrenergic receptor agonist (mirabregon)) as well as behavioral treatments (e.g., pelvic floor exercise, biofeedback, timed voids, and fluid management) have failed; *and*
iii. Test stimulation provides at least 50 % decrease in symptoms.

b. Aetna also considers implantation of the InterStim medically necessary for the treatment of non-obstructive urinary retention when all of the following criteria are met:

i. The member has experienced urinary retention for at least 12 months and the condition has resulted in significant disability (the frequency and/or severity of symptoms are limiting the member's ability to participate in daily activities); *and*
ii. Pharmacotherapies (e.g., alpha blockers and cholinergics, and antibiotics for urinary tract infections) as well as intermittent catheterization have failed or are not well-tolerated; *and*
iii. A test stimulation of the device has provided at least 50 % decrease in residual urine volume.

c. *Exclusions*: InterStim therapy has no proven value for individuals with mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture; persons with stress incontinence; and individuals with neurologic disease origins, such as multiple sclerosis or diabetes with peripheral nerve involvement. InterStim has not been shown to be effective for urinary retention due to these causes.

3) **CIGNA 2018** Sacral Nerve and Tibial Nerve Stimulation for Urinary Voiding Dysfunction, Fecal Incontinence and Constipation

a. Urinary Voiding Dysfunction

i. A percutaneous screening trial of sacral nerve stimulation (SNS) with an external stimulator is considered medically necessary for the treatment of any of the following urinary voiding dysfunctions when there is failure, intolerance or contraindication to conservative medical management:
    1. urinary urge incontinence
    2. nonobstructive urinary retention
    3. urinary urgency/frequency syndrome
ii. Permanent SNS implantation for the treatment of urinary voiding dysfunction is considered medically necessary when BOTH of the following criteria are met:
    1. the individual has met the criteria for a percutaneous screening trial of SNS
    2. the individual experienced a beneficial clinical response to a percutaneous screening trial of SNS as evidenced by at least a 50% improvement in reported symptoms

b. Fecal Incontinence

i. A percutaneous screening trial of SNS with an external stimulator for fecal incontinence is considered medically necessary when ALL of the following criteria are met:
    1. failure, intolerance, or contraindication to conservative medical management
    2. sphincter surgery is either not indicated or is contraindicated
    3. absence of a significant anorectal malformation or chronic inflammatory bowel disease involving the anus
    4. fecal incontinence is not secondary to another neurological condition such as peripheral neuropathy or complete spinal cord injury
ii. Permanent SNS implantation for fecal incontinence is considered medically necessary when BOTH of the following criteria are met:
    1. the individual has met the criteria for a percutaneous screening trial of SNS
    2. the individual experienced a beneficial clinical response to a percutaneous screening trial of SNS as evidenced by at least a 50% improvement in reported symptoms
iii. SNS for the treatment of any other indication, including constipation is considered experimental, investigational or unproven.

HERC staff summary

Based on a limited number of small studies, a trusted source (NICE) recommends the use of sacral nerve stimulation for treatment of urinary incontinence, non-obstructive urinary retention, and overactive bladder, as well as fecal incontinence. AHRQ, in a review that is over 10 years old, did not find sufficient evidence to reach a conclusion on the use of sacral nerve stimulation for urinary incontinence. However, the limited number of studies included in the AHRQ review were all positive. All major insurers reviewed cover sacral nerve stimulation for urinary and fecal incontinence when patients meet certain criteria.

HERC staff recommendations

1) Add Sacral nerve stimulation to lines 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION, 453 URINARY INCONTINENCE and 526 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS
    1. CPT 64561 Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
    2. CPT 64581 Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
    3. CPT 64590 (Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling)
    4. HCPCS A4290, C1767, C1778, C1787, C1897, L8679-L8689 (Implantable pulse generator, implantable electrodes, patient programmer, transmitter)
2) Modify GN129 as shown below

GUIDELINE NOTE 129, FECAL INCONTINENCE

Lines 71,526

ICD-10-CM R15.9 (Full incontinence of feces) is included on Line 71 only for supportive equipment (e.g. diapers, gloves). Surgical treatment for fecal incontinence is included on Line 526 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS.

Sacral nerve stimulation is included on line 526 only for fecal incontinence and only when all of the following criteria are met:

1) Documented failure or intolerance to conventional therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment); AND
2) A successful percutaneous test stimulation, defined as at least 50% sustained (more than one week) improvement in symptoms; AND
3) Condition is not related to anorectal malformation and/or chronic inflammatory bowel disease; AND
4) Incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.

3) Adopt a new guideline note for lines 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION and 453 URINARY INCONTINENCE as shown below:

GUIDELINE NOTE XXX SACRAL NERVE STIMULATION FOR URINARY CONDITIONS

Lines 327, 453

Sacral nerve stimulation is included on these lines only for urinary incontinence, non-obstructive urinary retention, and overactive bladder AND only when all of the following criteria are met:

1) The patient has had symptoms for at least 12 months and the condition has resulted in significant disability (the frequency and/or severity of symptoms are limiting the member's ability to participate in daily activities); AND
2) Documented failure or intolerance to pharmacotherapies and behavioral treatments (e.g., pelvic floor exercise, biofeedback, timed voids, and fluid management) and, for non-obstructive urinary retention, intermittent catheterization; AND

3) The patient must be an appropriate surgical candidate such that implantation with anesthesia can occur; AND
4) The patient does not have stress incontinence, urinary obstruction, and specific neurologic diseases (e.g., diabetes with peripheral nerve involvement, spinal cord injury, or multiple sclerosis); AND
5) Patient must have had a successful test stimulation, defined as a 50% or greater improvement in symptoms.

4) Consider reprioritization of surgical treatment of fecal incontinence as part of the 2022 Biennial Review

Sling Procedure for Treatment of Male Urinary Incontinence

Question: Should the sling procedure be paired with male urinary incontinence?

Question source: HSD claims reconsideration

Issue: The male sling procedure helps men with urinary incontinence due to sphincter weakness or insufficiency caused by prior pelvic surgery including TURP (transurthethral resection of the prostate) and radical prostatectomy. In the male sling procedure, synthetic mesh-like tape is positioned around part of the urethral bulb, slightly compressing the urethra and moving it into a new position. Complications of this type of procedure are rare but may occur. They include bleeding and infection (of the mesh or the bone area or public bone), erosion, inability to urinate, or recurrent leakage.

Currently, the male sling procedure (CPT 53440 Sling operation for correction of male urinary incontinence (eg, fascia or synthetic)) does not pair with urinary incontinence. However, the more generic CPT codes generally used for female sling procedures (e.g. CPT 51990 and 51992, 57288) are paired with urinary incontinence on line 453 URINARY INCONTINENCE. There is currently a guideline associated with line 453 which outlines when surgical procedures are covered for treatment of urinary incontinence.

GUIDELINE NOTE 47, URINARY INCONTINENCE

Line 453

Surgery for genuine stress urinary incontinence may be indicated when all of the following are documented (A-G):

A) Patient history of (1, 2, and 3):
   1) Involuntary loss of urine with exertion
   2) Identification and treatment of transient causes of urinary incontinence, if present (e.g., delirium, infection, pharmaceutical causes, psychological causes, excessive urine production, restricted mobility, and stool impaction)
   3) Involuntary loss of urine on examination during stress (provocative test with direct visualization of urine loss) and low or absent post void residual
B) Patient's voiding habits
C) Physical or laboratory examination evidence of either (1 or 2):
   1) Urethral hypermobility
   2) Intrinsic sphincter deficiency
D) Diagnostic workup to rule out urgency incontinence
E) Negative preoperative pregnancy test result unless patient is postmenopausal or has been previously sterilized
F) Nonmalignant cervical cytology, if cervix is present
G) Patient required to have 3 months of alternative therapy (e.g., pessaries or physical therapy, including bladder training, pelvic floor exercises and/or biofeedback, as available). If limited coverage of physical therapy is available, patients should be taught pelvic floor exercises by their treating provider, physical therapist or trained staff, and have documented consistent practice of these techniques over the 3 month period.

Current Prioritized List status

CPT code	Code description	Current Lines
51990	Laparoscopy, surgical; urethral suspension for stress incontinence	453 URINARY INCONTINENCE
51992	Laparoscopy, surgical; sling operation for stress incontinence (eg, fascia or synthetic)	453
53440	Sling operation for correction of male urinary incontinence (eg, fascia or synthetic)	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 87 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
53442	Removal or revision of sling for male urinary incontinence (eg, fascia or synthetic)	71,87,327 422 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
57287	Removal or revision of sling for stress incontinence (eg, fascia or synthetic)	208 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 327,453 464 UTERINE PROLAPSE; CYSTOCELE
57288	Sling operation for stress incontinence (eg, fascia or synthetic)	453, 464

Evidence

1) **Welk 2011**, review of male slings for post-prostatectomy urinary incontinence (PPI)
    a. Three principal slings are described in the literature.
        i. The bone-anchored sling has success rates of 40 – 88%, with some series having a mean follow-up of 36 – 48 months. It is associated with a mesh infection rate of 2 – 12%, which usually requires sling explantation.
        ii. The retrourethral transobturator sling has a success rate of 76 – 91% among three large case series with follow-ups of 12 – 27 months. There is a low reported explantation rate.
        iii. The adjustable retropubic sling has a success rate of 72 – 79% with follow-ups of 26 – 45 months. Erosion (3 – 13%) and infection (3 – 11%) can lead to explantation.
    b. Conclusion: Most male slings have a similar reported efficacy. Most case series define success as either dry or improved. True cure rates are lower. Mid- and long-term data are now available that indicate the male sling is a viable option for PPI. The use of male slings in severe urinary incontinence, radiated patients, and non-radical prostatectomy patients is still unclear. Further study is needed to try and define criteria for the use of male slings, and to directly compare different procedures.

Other payers:
All private payers surveyed cover sling operations for male urinary incontinence, generally after failure of conservative management (e.g., pelvic floor muscle training, electrical stimulation, and biofeedback).

HERC staff summary:
Male urethral slings are considered standard of care for moderate to severe urinary incontinence after procedures such as TURP and radical prostatectomy. There is little evidence evaluating outcomes. However, similar procedures for female urinary incontinence are covered with an appropriate guideline on the urinary incontinence line.

HERC staff recommendations:

1) Add CPT 53440 (Sling operation for correction of male urinary incontinence (eg, fascia or synthetic)) ad 53442 (Removal or revision of sling for male urinary incontinence (eg, fascia or synthetic)) to line 453 URINARY INCONTINENCE
2) Remove CPT 53440 and 53442 from lines 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES, 87 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM, and 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
    a. Not associated with GN 47
    b. Similar sling procedures for female surgeries are not included on these lines
3) No changes required to GN 47 URINARY INCONTINENCE

Artificial Urinary Sphincters

Question: Should artificial urinary sphincters (AUS) be paired with urinary incontinence?

Question source: HSD claims reconsideration

Issue: HSD has received several claims for the procedure codes for insertion of artificial urinary sphincters paired with diagnosis codes for urinary incontinence. The majority of CPT codes (CPT 53445-53449) for artificial urinary sphincters are not paired with urinary incontinence; however, the CPT codes for removal and removal/replacement of AUS are paired with urinary incontinence. On review of past minutes, no previous review or discussion of artificial urinary sphincters was found.

An artificial urinary sphincter (AUS) is composed of a pressure regulating balloon placed in the pre-vesical space using an abdominal suprapubic incision; an inflatable cuff is placed around the urethra using a perineal incision; and a control pump is placed in the scrotum via the abdominal incision. The intervention is expensive and requires invasive surgery and experienced surgeons, but is generally considered the gold standard for treatment of severe or persistent incontinence in men. AUS is most commonly placed for postprostatectomy stress urinary incontinence. There is some utilization for female urinary stress incontinence.

Current Prioritized List status

CPT code	Code description	Current Placement
53445	Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 87 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
53446	Removal of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff	87,327, 422 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT 453 URINARY INCONTINENCE
53447	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session	71,87,327
53448	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff through an infected field at the same operative session including irrigation and debridement of infected tissue	87,327,422,453

53449	Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff	71,87,327
HCPCS code		
C1815	Prosthesis, urinary sphincter (implantable)	71,87,327
ICD-10 Code		
N36.42	Intrinsic sphincter deficiency (ISD)	453 URINARY INCONTINENCE

Utilization:

2 OHP patients received artificial urinary sphincters in 2018, both for urinary stress incontinence (currently non-paired diagnosis)

Evidence

1) **Silva 2014,** Cochrane review of surgery for stress urinary incontinence due to presumed sphincter deficiency after prostate surgery
    1) N=1 study (45 patients) (Imamoglu 2005)
        i. 45 men with urinary incontinence lasting 6 months to 1 year after radical prostatectomy
        ii. RCT of artificial urethral sphincter (AUS) implantation (AMS 800) vs Macroplastique injection
        iii. Follow-up ranged from 6 to 120 months.
    2) In the trial as a whole, the men treated with AUS were more likely to be dry (18/20, 82%) than those who had the injectable treatment (11/23, 46%) (odds ratio (OR) 5.67, 95% confidence interval (CI) 1.28 to 25.10). However, this effect was only statistically significant for the men with more severe ('total') incontinence (OR 8.89, 95% CI 1.40 to 56.57) and the CIs were wide.
    3) There were more severe complications in the group undergoing AUS, and the costs were higher. AUS implantation was complicated in 5/22 (23%) men: the implant had to be removed from one man because of infection and in one man due to the erosion of the cuff, in one man the pump was changed due to mechanical failure, in one man there was migration to the intraperitoneal region, and one man experienced scrotal erosion. In the injectable group, 3/23 (13%) men had a complication: one man treated with Macroplastique injection had to be catheterized because of urinary retention and two men developed urinary tract infections.
    4) Authors' conclusions: The evidence available at present was of very low quality because we identified only one small randomized clinical trial. Although the result was favorable for the implantation of AUS in the group with severe incontinence, this result should be considered with caution due to the small sample size and uncertain methodological quality of the study found.
2) **Van der Aa 2012,** systematic review of artificial urinary sphincter in male non-neurogenic incontinence

1) N=12 studies (623 patients) [included Imamoglu 2005 as in Silva 2014]
    i. Only three studies were prospective.
2) Continence, evaluated only by patient-reported pad use and various questionnaires, was achieved in 61–100% of cases (no pad or one pad per day). Dry rates (no pad) were only available in seven studies and varied from 4% to 86%.
3) A pooled analysis showed that infection or erosion occurred in 8.5% of cases (3.3–27.8%), mechanical failure in 6.2% of cases (2.0–13.8%), and urethral atrophy in 7.9% (1.9–28.6%). Reoperation rate was 26.0% (14.8–44.8%).
4) Patient satisfaction was evaluated in four studies with four different tools and seems to improve after AUS implantation.
5) Conclusions: Quality of evidence supporting the use of AUS in non-neurogenic male patients with SUI is low, based on heterogeneous data, low-quality studies, and mostly out-of-date efficacy outcome criteria. AUS outcomes need to be revisited to be compared with new surgical alternatives, all of which should be prospectively evaluated according to current evidence-based medicine standards.

3) **Lipp 2014**, Cochrane review of artificial devices for urinary incontinence in women
    1) N=8 trials (787 women)
    2) Results
        i. No trials listed using artificial urinary sphincters

<u>Expert guidelines</u>

1) **Lucas 2015**, European Urology Association guideline on urinary incontinence
    i. AUS in women
        1. The major advantage of AUS over other anti-incontinence procedures is the perceived ability to be able to void normally. However, voiding dysfunction is a known side effect, with a lack of data making it difficult to assess its importance. Because of significant differences in design between devices and in selection criteria between case series, results obtained with specific devices cannot be extrapolated generally to the use of adjustable devices.
        2. A previous review of mechanical devices concluded that there was insufficient evidence to support the use of AUS in women
    ii. AUS in men
        1. AUS is the standard treatment for moderate-to-severe male SUI. Most data available on the efficacy and adverse effects of AUS implantation are from older retrospective cohort studies with RCTs not performed due to the lack of a comparator. Men considering insertion of an AUS should understand that if the ability of an individual to operate the pump is uncertain, it may not be appropriate to implant an AUS. There are several recognized complications of AUS implantation, e.g. mechanical dysfunction, urethral constriction by fibrous tissue, erosion and infection.
        2. Evidence
            a. there are two systematic reviews presenting limited evidence, of generally poor quality, except for one RCT comparing with bulking agents. A continence rate of about 80% can be

expected, while this may be lower in men who have undergone pelvic radiotherapy.

Other policies

1) NICE 2019

ii. Do not offer women an artificial urinary sphincter to manage stress urinary incontinence unless previous surgery has failed.

2) Aetna 2019

iii. Aetna considers the implantation of an artificial urinary sphincter (AUS) medically necessary for the treatment of urinary incontinence (UI) due to intrinsic urethral sphincter deficiency (IUSD) for members with any of the following indications:

1. Children with intractable UI due to IUSD who are refractory to behavioral or pharmacological therapies and are unsuitable candidates for other types of surgical procedures for correction of UI; *or*
2. Members who are 6 or more months post-prostatectomy who have had no improvement in the severity of UI despite trials of behavioral and pharmacological therapies; *or*
3. Members with epispadias-exstrophy in whom bladder neck reconstruction has failed; *or*
4. Women with intractable UI who have failed behavioral, pharmacological, and other surgical treatments.

3) MODA 2019

i. Artificial Urinary Sphincters (HCS-0067A) are covered for the treatment of urinary incontinence due to intrinsic urethral sphincter deficiency with 1 or more of the following:

1. Patient is 6 or more months post-prostatectomy and has not had improvement in the severity of urinary incontinence despite trying pharmacological therapy and behavior modification
2. Patient has epispadias-exstrophy and has not had success with bladder neck reconstruction surgery
3. Patient is a woman with intractable urinary incontinence who has failed behavioral modification, pharmacological therapy, and other surgical treatments
4. Patient is a child with intractable urinary incontinence due to intrinsic urethral sphincter deficiency and has been refractory to behavioral modification or pharmacological therapy and is an unsuitable candidate for other surgical procedures for the correction of the urinary incontinence. Request for indications other than those listed above, is considered experimental and investigational because its effectiveness has not been established.

Artificial Urinary Sphincters

HERC staff summary

Artificial urinary sphincters (AUS) are considered standard of care in men with moderate to severe urinary incontinence following radical prostatectomy; however, the evidence to support this technology is limited and considered of very low quality. AUS for men with such moderate to severe urinary incontinence is recommended by expert groups and is covered by private payers. AUS for urinary incontinence in women has little or no evidence to support its use, but is recommended by trusted sources and covered by private payers for women with intractable urinary incontinence who have failed previous surgery, behavioral and pharmacologic therapy.

Currently, initial placement of AUS is not paired with urinary incontinence on the Prioritized List. However, if the patient already has an AUS, removal as well as removal and replacement are covered. AUS currently also appears on several lines with no appropriate diagnoses, as AUS is only used for urinary incontinence caused by intrinsic sphincter deficiency.

HERC staff recommendations:

1) Remove the CPT codes for insertion/removal/reinsertion of artificial urinary sphincters (CPT 53445-53449; HCPCS C1815) from lines 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES, 87 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM, and 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
    a. Lack of appropriate diagnoses on these lines; the only appropriate diagnosis to pair is ICD-10 N36.42 Intrinsic sphincter deficiency (ISD)
2) Add CPT codes for insertion of AUS to line 453 URINARY INCONTINENCE
    a. CPT 53445 Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff
    b. CPT 53447 Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session
    c. CPT 53449 Repair of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff
    d. HCPCS C1815 Prosthesis, urinary sphincter (implantable)
3) Keep removal and removal/replacement CPT codes for AUS (CPT 53446, 53448) on line 453 URINARY INCONTINENCE and on line 422 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
4) Add a new guideline to line 453 as shown below
    a. Requirements based on standard commercial insurance criteria

GUIDELINE NOTE XXX ARTIFICIAL URINARY SPHINCTERS

Line 452

Artificial urinary sphincters are included on this line only for patients with intrinsic sphincter deficiency with any of the following indications:

1) Children with intractable urinary incontinence due to intrinsic sphincter deficiency who are refractory to behavioral or pharmacological therapies and are unsuitable candidates for other types of surgical procedures for correction of urinary incontinence; *or*

2) Patients who are 6 or more months post-prostatectomy who have had no improvement in the severity of urinary incontinence despite trials of behavioral and pharmacological therapies; *or*
3) Members with epispadias-exstrophy in whom bladder neck reconstruction has failed; *or*
4) Women with intractable urinary incontinence who have failed behavioral, pharmacological, and other surgical treatments.

Periurethral Injection of Bulking Agents for Urinary Incontinence

Question: Should periurethral injection of bulking agents be paired with urinary incontinence?

Question source: HSD claims reconsideration

Issue: Intramural urethral bulking aims to augment the urethral wall and increase the urethral closure force. Various types of bulking agents are injected into the submucosa of the proximal urethra just distal to the bladder neck. The injections are usually administered under local anesthesia, either transurethrally or paraurethrally. It is used as a treatment for urinary incontinence.

Currently, CPT 51715 (Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck) is found on lines 87 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM, 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION and 432 HYPOSPADIAS AND EPISPADIAS.

The code was originally added as a biennial review change in 1995 with no prior review of this procedure found in old minutes.

Evidence

1) **Kirchin 2012**, Cochrane review of periurethral bulking agents for women with urinary incontinence
    a. N=14 trials (2004 women)
        i. Trials were small and generally of moderate quality.
    b. One trial of 45 women that compared injection therapy with conservative treatment showed early benefit for the injectable with respect to continence grade (risk ratio (RR) 0.7, 95% confidence interval (CI) 0.52 to 0.94) and quality of life (RR 0.54, 95%CI 0.16 to 0.92).
    c. Another, comparing injection of autologous fat with placebo terminated early because of safety concerns.
    d. Two trials that compared injection with surgical management found significantly better objective cure in the surgical group (RR 4.77, 95% CI 1.96 to 11.64; and RR 1.69, 95% CI 1.02 to 2.79), although the latter trial data did not reach statistical significance if an intention-to-treat analysis was used.
    e. One trial of 30 women showed a weak (but not clinically significant) advantage for patient satisfaction (data not suitable for analysis in Revman) after mid-urethral injection in comparison to bladder neck injection but with no demonstrable difference in continence levels.
    f. Authors' conclusions: The available evidence base remains insufficient to guide practice. In addition, the finding that placebo saline injection was followed by a similar symptomatic improvement to bulking agent injection raises questions about the mechanism of any beneficial effects. One small trial comparing silicone particles with pelvic floor muscle training was suggestive of benefit at three months but it is not known if this was sustained, and the treatment was associated with high levels of postoperative retention and dysuria. Greater symptomatic improvement was observed with surgical treatments, though the advantages need to be set against likely higher risks.

2) **NICE 2005** Intramural urethral bulking procedures for stress urinary incontinence in women
    a. Efficacy
        i. A small randomised controlled trial reported that 53% (34/64) of patients treated by urethral bulking with collagen had no incontinence at 12 months, compared with 72% (39/54) treated with conventional open surgery.
        ii. One case series of patients treated with collagen reported that, after 12 months, 42% (38/90) had either no incontinence or an improvement in symptoms, as measured objectively using cystometry and abdominal leak point pressure.
        iii. One case series of patients treated with silicone particles reported that 68% (69/102) had either no incontinence or marked improvement after a mean follow-up of 3 months. This proportion decreased to 48% (40/84) after a mean follow-up of 18 months.
    b. Safety
        i. Five case series reported safety data on a total of 389 patients. The most commonly reported adverse events were urinary tract infection, affecting 1% (1/102) to 12% (11/90) of patients, and urinary retention, affecting 0% (0/40) to 11% (10/90) of patients. Other reported complications included abscess at the injection site, urgency of micturition and prolonged pain.
        ii. The Specialist Advisors stated that migration of the bulking agent, voiding difficulties, urinary tract infection and allergic reaction are potential adverse events. Haemorrhage was listed as a rare potential adverse event.

<u>Trusted sources coverage recommendation</u>

1) **NICE 2019** Urinary incontinence and pelvic organ prolapse in women: management
    a. Consider intramural bulking agents to manage stress urinary incontinence if alternative surgical procedures are not suitable for or acceptable to the woman. Explain to the woman that:
        i. these are permanent injectable materials
        ii. repeat injections may be needed to achieve effectiveness
        iii. limited evidence suggests that they are less effective than the surgical procedures listed in recommendation 1.5.2 and the effects wear off over time
        iv. there is limited evidence on long-term effectiveness and adverse events

<u>Expert guidelines</u>

1) **American Urology Association 2017**: SURGICAL TREATMENT OF FEMALE STRESS URINARY INCONTINENCE
    a. In patients considering surgery for stress urinary incontinence, physicians may offer the following options: (Strong Recommendation; Evidence Level: Grade A)
        i. Bulking agents
            1. "The Panel believes that bulking agents are viable treatments for SUI; however, little long-term data exists for them."
            2. Still, the role for bulking agents may best be considered in patients who wish to avoid more invasive surgical management or who are concerned with the lengthier recovery time after surgery or who experience

insufficient improvement following a previous anti-incontinence procedure.

b. In patients with stress urinary incontinence and a fixed, immobile urethra (often referred to as 'intrinsic sphincter deficiency') who wish to undergo treatment, physicians should offer pubovaginal slings, retropubic midurethral slings, or urethral bulking agents. (Expert Opinion)

2) **Syan 2016**, summary of guidelines for treatment of urinary incontinence
   a. Bulking agents are periurethral injections that allow for short term improvement in SUI symptoms. The European Association of Urology (EAU) determined that repeat injections are often required for therapeutic effect (level of evidence 2a); however, the benefit is low adverse risks compared with open surgery. The Canadian Urology Association (CUA) advises bulking agents for indications such as older age, patients opting for less invasive surgery, and patients with high anaesthetic risk. They give a Grade B recommendation to offer this treatment, although both CUA and NICE recommend that patients should be counselled on the likelihood of requiring repeat injections, that the efficacy is inferior to conventional surgical techniques, and that the efficacy decreases over time.

Other payers:

1) MODA 2019
   a. Periurethral Injections of bulking agents will be covered to plan limitations when all of the following criteria is met:
      i. The bulking agent is cleared by the FDA for urinary incontinence (e.g., Coaptite [calcium hydroxylapatite], Contigen [glutaraldehyde crossed-linked collagen], Durasphere [carbon-coated spheres/beads], Macroplastique [polydimethylsiloxane], Uryx [ethylene vinyl alcohol copolymer])
      ii. Patient has urinary incontinence resulting from intrinsic sphincter deficiency that is refractory to 12 months conservative management (e.g. Kegel exercises, biofeedback, electrical stimulation, and/or pharmacotherapies); or
      iii. The member has stress incontinence for six months and ALL of the following:
         1. No other causes of stress incontinence (urinary tract infection, etc.)
         2. Activities of daily living are limited by the stress incontinence
      iv. Request for injection of periurethral bulking agents for UI is considered experimental and investigational for neurogenic bladder and all other indications
      v. Request is for 5 injection procedures only.
   b. Request for continuation of treatment will be covered for 1 or more of the following:
      i. Periurethral Injections of Bulking Agents will be covered when…the following criteria are met:
         1. Incontinence improves after 3 treatments with bulking agents
      ii. NOTE**:** If incontinence does not improve after 3 treatments with bulking agents, treatment is considered ineffective and further treatment with bulking agents is not considered medically necessary.

2) **Aetna 2019**
   a. Periurethral Injections of Bulking Agents: Aetna considers periurethral injections of bulking agents that are cleared by the Food and Drug Administration (FDA) for urinary incontinence (UI) (e.g., Coaptite [calcium hydroxylapatite], Contigen [glutaraldehyde

crossed-linked collagen], Durasphere [carbon-coated spheres/beads], Macroplastique [polydimethylsiloxane], Uryx [ethylene vinyl alcohol copolymer]) medically necessary for the management of members with UI resulting from intrinsic sphincter deficiency that is refractory to conservative management (e.g., Kegel exercises, biofeedback, electrical stimulation, and/or pharmacotherapies).

Members whose incontinence does not improve after 3 treatments with bulking agents are considered treatment failures and are not likely to respond to this therapy. In such cases, further treatment with bulking agents is not considered medically necessary.

Aetna considers injection of periurethral bulking agents for UI experimental and investigational for neurogenic bladder and all other indications.

Periurethral injections of bulking agents have no proven value in any of the following circumstances:

i. Members undergoing or planning to undergo desensitization injections to meat products; *or*
ii. Members with an acute condition involving cystitis, urethritis, or infection; *or*
iii. Members with severe allergies manifested by a history of anaphylaxis, or history or presence of multiple severe allergies; *or*
iv. Previous pelvic radiation therapy; *or*
v. Unstable or noncompliant bladder.

Claims history

Review of claims data found one claim for CPT 51715 for 1 diagnosis that currently pairs with that code on line 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION; however, this diagnosis does not appear appropriate for periurethral bulking agents (ICD-10 N35.81 Other urethral stricture). Other diagnoses paired with CPT 51715 were on line 453 URINARY INCONTINENCE, line 464 UTERINE PROLAPSE; CYSTOCELE or line 529 CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME, DYSPAREUNIA.

HERC staff summary: There is very little evidence available regarding periurethral injection of bulking agents for treatment of urinary incontinence. The low-quality evidence that is available indicates that these agents have little long term effectiveness, but may provide some short term benefits. There are adverse events associated with these injections. Other treatments for urinary incontinence that are currently covered on the Prioritized List are more effective than bulking agent therapy. However, bulking agents are recommended by expert groups and covered by other payers, due to the short term improvement in symptoms and the preference of some patients to avoid more invasive procedures.

Periurethral bulking agents are currently paired on the Prioritized List with a variety of diagnoses that are not indicated for this procedure.

HERC staff recommendations:

1) Remove CPT 51715 (Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck) from lines 87 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM, 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION, 432 HYPOSPADIAS AND EPISPADIAS.
    a. No appropriate diagnoses on these lines for pairing

2) Add limited coverage of periurethral bulking agents based on expert opinion for those patients who are not surgical candidates or who choose not to have invasive surgery
    a. Add CPT 51715 to 453 URINARY INCONTINENCE
    b. Modify GN47 as shown below

GUIDELINE NOTE 47, URINARY INCONTINENCE

Line 453

Surgery for genuine stress urinary incontinence may be indicated when all of the following are documented (A-G):

A) Patient history of (1, 2, and 3):
    1) Involuntary loss of urine with exertion
    2) Identification and treatment of transient causes of urinary incontinence, if present (e.g., delirium, infection, pharmaceutical causes, psychological causes, excessive urine production, restricted mobility, and stool impaction)
    3) Involuntary loss of urine on examination during stress (provocative test with direct visualization of urine loss) and low or absent post void residual

B) Patient's voiding habits

C) Physical or laboratory examination evidence of either (1 or 2):
    1) Urethral hypermobility

2) Intrinsic sphincter deficiency

D) Diagnostic workup to rule out urgency incontinence

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

F) Nonmalignant cervical cytology, if cervix is present

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

H) Periurthral bulking agent injection is only covered for patients who otherwise meet the criteria for surgery for urinary incontinence above but who:

   i. Are not candidates for major surgery due to comorbidities OR

   ii. Choose not to have major surgery and are aware of the limited benefits of bulking agent injections and the need for repeat procedures.

Note: Patients whose incontinence does not improve after 3 treatments with bulking agents are considered treatment failures and no longer candidates for this procedure

Lower Extremity Chronic Venous Disease

Question: Should coverage of lower extremity chronic venous disease (e.g. varicose veins) on the Prioritized List be updated?

Question source: HERC Staff

Issue: This topic had been identified for an EbGS Coverage Guidance. However, it was felt more appropriate to go through VbBS for consideration of Prioritized List changes rather than requiring a full Coverage Guidance due to the availability of a recent high quality AHRQ evidence review of this topic.

Lower extremity chronic venous disease (LECVD) is a heterogeneous term that encompasses a variety of conditions. Patients with LECVD can be asymptomatic or symptomatic, and they can exhibit a myriad of signs including varicose veins, telangiectasias, LE edema, skin changes, and/or ulceration. The etiology of LECVD includes venous dilation, venous reflux, (venous) valvular incompetence, mechanical compression (e.g., May-Thurner syndrome), and post-thrombotic syndrome. While the majority of patients with LECVD are asymptomatic, serious complications can occur, including LE amputation, acute and chronic VTE, chronic thromboembolic pulmonary hypertension, and mortality. A serious and common issue with LECVD is the formation of venous leg ulceration. Uncomplicated LECVD can result in reduced quality of life, pain, and social isolation.

Currently, varicose veins that cause swelling or pain are including on line 637 VARICOSE VEINS OF LOWER EXTREMITIES WITHOUT ULCER OR OTHER MAJOR COMPLICATION, with various treatments pairing on that line. A similar condition to varicose veins, post-thrombotic syndrome, is included on line 517 POSTTHROMBOTIC SYNDROME. If a varicose vein is associated with an ulcer, treatment is paired on line 379 CHRONIC ULCER OF SKIN. If the varicose vein is causing inflammation (phlebitis), then the diagnosis is included on line 514 PHLEBITIS AND THROMBOPHLEBITIS, SUPERFICIAL.

The treatment of LECVD varies tremendously and can be divided into noninvasive and invasive therapies. Noninvasive approaches include therapies that improve venous circulation and reduce LE edema (e.g., compression devices, medical therapy [e.g., diuretics], and exercise), therapies that prevent thromboembolic complications (e.g., anticoagulation), and therapies that specifically address skin changes and ulceration (e.g., wound care). When these more conservative measures fail, invasive therapies are often recommended and include endovascular intervention (e.g., ablation, angioplasty) and/or surgical management (e.g., venous ligation, venous excision).

The providers who nominated this topic requested coverage for varicose veins and similar conditions that caused pain that interfered with ability to work, walk, etc., recurrent swelling despite conservative therapy such as compression garments, bleeding from a varicosity, or recurrent phlebitis.

The CCO medical directors felt strongly that pain should not be a criterion for coverage, as it is not a criterion for coverage of uncomplicated hernias or similar conditions.

Recurrent phlebitis involves a redness or warmth along the vein, and pain in the area. It is usually treated conservatively. In rare cases, it can progress to cellulitis or DVT.

VBBS/HERC history

May 2015

Coverage of various treatment options for varicose veins was broadened to include many of the minimally invasive modalities. There was some discussion that there was no evidence to support broadening the complications that would allow coverage of varicose veins. The current coverage of varicose veins only being treated if they caused ulceration or infection was felt to encompass the major complications that require treatment of the varicosities. The addition of additional types of treatments based on good efficacy and lower cost was thought to be an excellent idea.

September 24, 2004

Varicose veins of lower extremities with edema, pain and swelling were moved from a covered line to an uncovered line. Coverage for severe venous stasis dermatitis without an ulcer to prevent ulceration was added to the cellulitis line.

Current Prioritized List status--procedures

CPT Code	Code Description	Line(s)
36465-36466	Injection of non-compounded foam sclerosant … (eg, great saphenous vein, accessory saphenous vein)	379 CHRONIC ULCER OF SKIN 514 PHLEBITIS AND THROMBOPHLEBITIS, SUPERFICIAL 517 POSTTHROMBOTIC SYNDROME 637 VARICOSE VEINS OF LOWER EXTREMITIES WITHOUT ULCER OR OTHER MAJOR COMPLICATION
36470-36471	Injection of sclerosant; single incompetent vein (other than telangiectasia)	379,514,517,545 SUBLINGUAL, SCROTAL, AND PELVIC VARICES, 637
36473-36479	Endovenous ablation therapy of incompetent vein, extremity, percutaneous (mechanochemical, radiofrequency, laser) (first or subsequent vein)	379,514,517,637
36482-36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate)	660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
37700 37718 37722 37735 37760-37766 37780 37785	Vein ligation (various veins of lower extremity)	379,514,517,637 Limited number on line 79 PHLEBITIS AND THROMBOPHLEBITIS, DEEP

Current Prioritized List status: diagnoses

ICD-10 code	Code description	Current line(s)
I83.0	Varicose veins of unspecified lower extremity with ulcer	379 CHRONIC ULCER OF SKIN
I83.1	Varicose veins of lower extremity with inflammation	514 PHLEBITIS AND THROMBOPHLEBITIS, SUPERFICIAL
I83.2	Varicose veins of unspecified lower extremity with both ulcer and inflammation	379
I83.81	Varicose veins of lower extremity with pain	637 VARICOSE VEINS OF LOWER EXTREMITIES WITHOUT ULCER OR OTHER MAJOR COMPLICATION
I83.89	Varicose veins of lower extremities with other complications	637
I86.8	Varicose veins of other specified sites	Undefined Diagnosis File
I83.9	Asymptomatic varicose veins of lower	637

	extremity	
I87.00	Postthrombotic syndrome without complications of lower extremity	517 POSTTHROMBOTIC SYNDROME 637
I87.01	Postthrombotic syndrome with ulcer of lower extremity	379
I87.02	Postthrombotic syndrome with inflammation of lower extremity	514,517
I87.03	Postthrombotic syndrome with ulcer and inflammation of lower extremity	379
I87.09	Postthrombotic syndrome with other complications of lower extremity	517,637
I87.2	Venous insufficiency (chronic) (peripheral)	637
I87.8	Other specified disorders of veins	637
I87.9	Disorder of vein, unspecified	637

Evidence Summary

AHRQ, 2017 Treatment Strategies for Patients with Lower Extremity Chronic Venous Disease (LECVD); Technology Assessment Report

1) Systematic review
2) Treatment of lower extremity chronic venous insufficiency/incompetence/reflux
    a) N=93 studies on treatment effectiveness (87 RCTs, 6 observational)
    b) Modalities: exercise training, medical therapy, weight reduction, mechanical compression therapy, surgical intervention, and endovenous intervention
    c) Effectiveness
        i. Among patients undergoing endovenous interventions, radiofrequency ablation (RFA), endovenous laser ablation (EVLA), and sclerotherapy, improvement demonstrated in quality-of-life scores and standardized symptom scores.
        ii. When compared with patients treated with placebo, those treated with foam sclerotherapy had statistically significant improvement in standardized symptom scores, occlusion rates, and quality of life.
        iii. There was no difference in effectiveness between sclerotherapy and surgery (SOE=low).
        iv. Meta-analysis of any surgery vs compression therapy on wound healing: the summary effect of these studies was a non-statistically significant OR of 1.24 (95% CI, 0.83 to 1.84) favoring surgery
        v. Reported harms of surgical interventions included infection, bleeding, skin burns and thromboembolism
        vi. KQ3a: The comparative effectiveness of exercise, medical therapy, mechanical compression therapy, and invasive procedures on health outcomes
            - insufficient strength of evidence limits ability to make any conclusions regarding effectiveness of any of the studied interventions
3) Treatment of lower extremity chronic venous obstruction/thrombosis
    a) N= 8 studies (3 randomized controlled trials, 5 observational)
        i. Modalities: exercise training, medical therapy, weight reduction, mechanical compression therapy, surgical intervention, and endovenous intervention
    b) In patients with post-thrombotic syndrome, exercise training plus patient education and monthly phone follow-up resulted in improved quality of life but not improved symptom severity when compared with patient education and monthly phone follow-up. In patients with both May-Thurner Syndrome and superficial venous reflux who were treated with EVLA (with or without stent placement), there were fewer recurrent ulcerations, improvement in reflux severity and symptoms, and improvement in quality of life in long-term follow-up.
4) **Conclusions.** The available evidence for treatment of patients with LECVD is limited by heterogeneous studies that compared multiple treatment options, measured varied outcomes, and assessed disparate outcome timepoints. When compared with patients' baseline measures, endovenous interventions (e.g. EVLA, sclerotherapy, and RFA) and surgical ligation demonstrated improvement in quality-of-life scores and Venous Clinical Severity Score at various timepoints after treatment; however, there were no

statistically significant differences in outcomes between treatment groups (e.g. endovenous vs. endovenous; endovenous vs. surgical). Several advances in care in endovenous interventional therapy have not yet been rigorously tested, and there are very few studies on conservative measures (e.g., lifestyle modification, compression therapy, exercise training) in the literature published since 2000. Additionally, the potential additive effects of many of these therapies are unknown. The presence of significant clinical heterogeneity of these results makes conclusions for clinical outcomes uncertain and provides an impetus for further research to improve the care of patients with LECVD.

Other payer policies

1) **Noridian (CMS) 2017**
    - **a.** Indications for surgical treatment (CPT codes: 37700, 37718, 37722, 37735, 37760, 37761, 37765, 37766, 37780, 37785) and sclerotherapy (CPT codes: 36470, 36471) [similar guidance for endovascular therapies]:
        - **i.** A 3-month trial of conservative therapy such as exercise, periodic leg elevation, weight loss, compressive therapy, and avoidance of prolonged immobility where appropriate, has failed, AND
        - **ii.** The patient is symptomatic and has one, or more, of the following:
            1. **Pain or burning in the extremity severe enough to impair mobility**
            2. **Recurrent episodes of superficial phlebitis**
            3. **Non-healing skin ulceration**
            4. **Bleeding from a varicosity**
            5. **Stasis dermatitis**
            6. **Refractory dependent edema**
2) **Aetna 2018**
    - a. Aetna considers the following procedures medically necessary for treatment of varicose veins when the following criteria are met: great saphenous vein or small saphenous vein ligation / division / stripping, radiofrequency endovenous occlusion (VNUS procedure), and endovenous laser ablation of the saphenous vein (ELAS) (also known as endovenous laser treatment (EVLT)).
    - b. Incompetence at the saphenofemoral junction or saphenopopliteal junction is documented by recent (performed within the past 6 months) Doppler or duplex ultrasound scanning, and all of the following criteria are met:
        - i. Ultrasound documented junctional reflux duration of 500 milliseconds (ms) or greater in the saphenofemoral or saphenopopliteal vein to be treated; *and*
        - ii. Vein size is 4.5 mm or greater in diameter measured by ultrasound below the saphenofemoral or saphenopopliteal junction (not valve diameter at junction); *and*
        - iii. Saphenous varicosities result in *any* of the following:
            1. Intractable ulceration secondary to venous stasis; *or*
            2. More than 1 episode of minor hemorrhage from a ruptured superficial varicosity; or a single significant hemorrhage from a

ruptured superficial varicosity, especially if transfusion of blood is required; *or*

3. Saphenous varicosities result in *either* of the following, and symptoms persist despite a 3-month trial of conservative management (including analgesics and prescription gradient support compression stockings):
    a. Recurrent superficial thrombophlebitis; *or*
    b. Severe and persistent pain and swelling interfering with activities of daily living and requiring chronic analgesic medication.

Disposition of submitted literature

1) Morrison 2018: comparison of different treatment techniques, no conservative therapy control
2) Eberhardt 2014: non-systematic review
3) Ragu 2016: retrospective cohort study, higher level evidence available
4) Lee 2015: cohort study, higher level evidence available
5) Pannier 2015: non-systematic review
6) Puleo 2013: cohort study, higher level evidence available

HERC staff summary:

Currently, chronic lower extremity venous insufficiency is only on a covered line on the Prioritized List if there is associated ulceration. There is insufficient evidence to determine if treatment of chronic lower extremity venous disease with surgery or minimally invasive treatments results in improved outcomes (pain, quality of life, symptom scores) compared to placebo or usual (non-surgical) care. Most major insurers cover therapies for varicose veins when there are complications such as ulceration or bleeding. However, most major insurers also cover therapy for complications which are "below the line" such as recurrent superficial thrombophlebitis, severe and persistent pain interfering with activities of daily living, and stasis dermatitis. It does not appear that the prior intent of the HSC/HERC to cover varicose veins with cellulitis is currently possible with the pairings on the Prioritized List. Based on discussions with the CCO medical directors, recurrent thrombophlebitis would be a more accurate description than cellulitis for the condition intended for coverage.

HERC staff recommendations:

1) Add coverage of chronic lower extremity venous disease for patients with recurrent thrombophlebitis, consistent with prior HSC/HERC intent to cover with "cellulitis"
    a. Add varicose veins with other complications to line 379 CHRONIC ULCER OF SKIN and keep on line 517 POSTTHROMBOTIC SYNDROME/637 VARICOSE VEINS OF LOWER EXTREMITIES WITHOUT ULCER OR OTHER MAJOR COMPLICATION
        i. ICD10 I83.89 (Varicose veins of lower extremities with other complications)
        ii. ICD10 I87.09 (Postthrombotic syndrome with other complications of lower extremity)
    b. Adopt a new guideline note to line 379 as shown below
2) Clarify when ulceration is an indication for varicose vein treatment in the new guideline
3) Modify the line title of line 379 to CHRONIC ULCER OF SKIN; VARICOSE VEINS WITH MAJOR COMPLICATIONS

GUIDELINE NOTE XXX, TREATMENT OF CHRONIC LOWER EXTREMITY VENOUS DISEASE

Lines 379,517,637

Treatment of chronic lower extremity venous disease is only included on line 379 when

1) The patient has had an adequate 3-month trial of conservative therapy and failed; AND
2) The patient has one of the following:
    a. Non-healing skin ulceration in the area of the varicose vein(s), OR
    b. Recurrent episodes of superficial thrombophlebitis.

Otherwise, these diagnoses are included on lines 517 or 637.

Lead Screening and Lead Investigation

Question: How can the Prioritized List best be modified to assist in statewide public health efforts to improve lead screening and investigations?

Question source: Public Health Division, HSD

Issue: Oregon has a very low rate of serum lead testing for Medicaid children, despite a federal mandate to screen all Medicaid children prior to age 2 with serum testing (not just risk questionnaires). If a child's blood lead level is elevated over 5 µg/dL, the local public health office can go out to the home and look for sources of lead contamination and assist the family in reducing future lead exposures, as recommended by the CDC. These home investigations are also being done at very low rates. The public health division is working to increase lead screening rates and the number of home lead investigations. It has come to light that there are certain non-pairings on the Prioritized List that need correction to allow these statewide public health initiatives to move forward.

From the Oregon Public Health Division:

> The goal of lead screening is to identify children who have been exposed to lead, provide appropriate interventions and reduce the risk of exposure…The single most important factor in managing childhood lead poisoning is identifying and reducing the child's exposure to lead.
>
> Blood lead testing is the only acceptable laboratory test for screening and confirming lead poisoning. Venipuncture is preferred for specimen collection, but capillary testing is acceptable if care is taken to properly clean and prepare the finger…All capillary BLLs of 5 µg/dL or higher must be followed with a confirmatory venous test.

Very high lead levels (>45 µg/dL) are treated with chelation therapy. Lead levels above 5ug/dL require investigation into possible sources of lead exposure, abatement of the exposure source if possible, education of the family, and monitoring lead serum levels.

Currently, chelation HCPCS and CPT codes will pair with lead poisoning (ICD10 T56.0X). However, home visits for lead abatement (HCPCS T1029 Comprehensive environmental lead investigation, not including laboratory analysis, per dwelling) does not pair with elevated lead level diagnoses or with lead poisoning.

The AAP recommends using ICD-10 Z13.88 (Encounter for screening for disorder due to exposure to contaminants) for lead screening; however, Z77.011 (Contact with and (suspected) exposure to lead) is frequently used in practice. Providers can also pair lead screening with a well child check diagnosis code.

Lead screening is occasionally used in the work up of dementia in older adults.

Current Prioritized List status

ICD-10 Code	**Code description**	**Current placement**
R78.71	Abnormal lead level in blood	Diagnostic Workup File (DWF)
T56.0X	Toxic effect of lead and its compounds	103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
Z00.12	Encounter for routine child health examination	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
Z13.88	Encounter for screening for disorder due to exposure to contaminants	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
Z77.011	Contact with and (suspected) exposure to lead	Diagnostic Workup File (DWF)
CPT code		
83655	Lead (serum level)	Diagnostic Procedures File
96365 - 96368	Intravenous infusion, for therapy (used for chelation)	Ancillary Procedures File
HCPCS code		
S9355	Home infusion therapy, chelation therapy	103,151,158,194,295,339
T1029	Comprehensive environmental lead investigation, not including laboratory analysis, per dwelling	Never Reviewed HSD has in Ancillary File

HERC staff recommendations:

1) Add ICD-10 R78.71 (Abnormal lead level in blood) to lines 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS and 103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
    a. Advise HSD to remove ICD-10 R78.71 from the Diagnostic Workup File
2) Add HCPCS T1029 (Comprehensive environmental lead investigation, not including laboratory analysis, per dwelling) to lines 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS, and 103 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS
    a. Advise HSD to remove HCPCS T1029 from the Ancillary File

Vestibular Rehabilitation

Question: Should coverage of vestibular rehabilitation be modified on the Prioritized List?

Question source: Physical therapists at Providence

Issue: As part of the HERC Coverage Guidance topic nomination process, HERC staff received multiple nominations from Providence physical therapists about coverage of vestibular rehabilitation for vestibular disorders.

The submitters identified a number of codes that are repeatedly denied for coverage by OHP and are requesting reconsidering of coverage of vestibular rehabilitation for OHP patients.

Codes raised by stakeholders

Code	Code Description	Current Prioritized List Placement
R29.6	Repeated falls	Diagnostic Workup File (DWF)
Z91.81	History of falling	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
W19.XXD	Unspecified fall, subsequent encounter	Informational Diagnosis File
H81.X	Benign paroxysmal vertigo, vestibular neuronitis	510 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM
H81.9X	Unspecified disorder of vestibular function	510 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM
H83.0X	Labrynthitis	572 ACUTE NON-SUPPURATIVE LABYRINTHITIS
G43.109	Migraine with aura, not intractable, without status migrainosus	409 MIGRAINE HEADACHES
95992	Canalith repositioning procedure(s) (eg, Epley maneuver, Semont maneuver), per day	510 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop	31,46,57,68,71,72,74,81 and 56 other lines (not

	strength and endurance, range of motion and flexibility	including 510)
97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities	31,46,57,68,71,72,81,91 and 51 other lines (not including 510)
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes	31,46,57,68,71,72,81,91 and 52 other lines (not including 510)

Other relevant codes currently placed on Prioritized List

Code	Code Description	Current Prioritized List Placement
92531	Spontaneous nystagmus, including gaze	292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 416 MENIERE'S DISEASE 510 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM
92532	Positional nystagmus test	292,416,510
92533	Caloric vestibular test, each irrigation (binaural, bithermal stimulation constitutes 4 tests)	292,416,510
92534	Optokinetic nystagmus test	292,416,510
92537	Caloric vestibular test with recording, bilateral; bithermal (ie, one warm and one cool irrigation in each ear for a total of four irrigations)	292,416,510
92538	Caloric vestibular test with recording, bilateral; monothermal (ie, one irrigation in each ear for a total of two irrigations)	292,416,510
92540	Basic vestibular evaluation, includes spontaneous nystagmus test with eccentric gaze fixation nystagmus, with recording, positional nystagmus test, minimum of 4 positions, with recording, optokinetic nystagmus test, bidirectional foveal and peripheral stimulation, with recording, and oscillating tracking test, with recording	292,416,510

Code	Code Description	Current Prioritized List Placement
92541	Spontaneous nystagmus test, including gaze and fixation nystagmus, with recording	292,416,510
92542	Positional nystagmus test, minimum of 4 positions, with recording	292,416,510
92544	Optokinetic nystagmus test, bidirectional, foveal or peripheral stimulation, with recording	292,416,510
92545	Oscillating tracking test, with recording	292,416,510
92546	Sinusoidal vertical axis rotational testing	292,416,510
92547	Use of vertical electrodes (List separately in addition to code for primary procedure)	292,416,510
92548	Computerized dynamic posturography	292,416,510
S9476	Vestibular rehabilitation program, non-physician provider, per diem	Never Reviewed

Evidence Summary

USPSTF, 2018

https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/falls-prevention-in-older-adults-interventions1

Population	Recommendation	Grade (What's This?)
Adults 65 years or older	The USPSTF recommends exercise interventions to prevent falls in community-dwelling adults 65 years or older who are at increased risk for falls.	B
Adults 65 years or older	The USPSTF recommends that clinicians selectively offer multifactorial interventions to prevent falls to community-dwelling adults 65 years or older who are at increased risk for falls. Existing evidence indicates that the overall net benefit of routinely offering multifactorial interventions to prevent falls is small. When determining whether this service is appropriate for an individual, patients and clinicians should consider the balance of benefits and harms based on the circumstances of prior falls, presence of comorbid medical conditions, and the patient's values and preferences.	C

Kundakci, 2018

- Systematic review of vestibular rehabilitation for chronic dizziness in adults
- 4 trials included
- Comparison to usual medical care (3 studies) or placebo eye exercise (1 study).
    - Hall
        - 3 times a day vestibular exercises, comparison placebo eye exercises. Both groups received a balance and gait home exercise program.
        - There were no significant differences between the intervention and comparison group with the exception of Dynamic Gait Index (4 other scales had no difference). The intervention group showed a significant decrease in fall risk. While 90% of the intervention group showed an improvement in fall risk, in the comparison group it was 50%.
    - Yardley
        - Booklet based vestibular rehabilitation (VR) only and booklet based VR with telephone support. Daily exercises at home for up to twelve weeks. Telephone support, up to three brief sessions from a vestibular therapist.
        - At 12 weeks, the treatment and comparison groups did not show any significant difference on the vertigo symptom scale. After one year follow-up there was a significant improvement in the intervention groups compared to the comparison group.
    - Yardley
        - 30–40 minute Vestibular Compensation Exercises after assessment at baseline and 6-week follow-up. Eight sets of standard head and body movements performed twice daily. Comparison standard medical care.
        - The intervention group improved on all measures (Vertigo symptom scale, Hospital Anxiety and Depression Scale, Vertigo Handicap Questionnaire, Provocative movements, and Sharpened Romberg Tests), while the comparison group demonstrated no improvement.
    - Yardley
        - Nurse-delivered VR exercises. Patients were seen individually for 30 to 40 minutes to take them the booklet and additional support, after first session advice by telephone at one and three weeks. Comparison of usual medical care.
        - There was a greater improvement on all primary outcome measures (series of subjective scales) in the treatment group compared to the usual medical care.

- **Author Conclusions:** This review suggests that exercise-based vestibular rehabilitation shows benefits for adult patients with chronic dizziness with

regard to improvement in the vertigo symptom scale, fall risk, balance and emotional status.

McDonnell, 2015
https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD005397.pub4/full

- Cochrane systematic review of vestibular rehabilitation for unilateral peripheral vestibular dysfunction
- 39 studies involving 2441 participants with unilateral peripheral vestibular disorders
- Individual and pooled analyses of the primary outcome, frequency of dizziness, showed a statistically significant effect in favour of vestibular rehabilitation over control or no intervention (odds ratio (OR) 2.67, 95% confidence interval (CI) 1.85 to 3.86; four studies, 565 participants).
- Secondary outcomes measures related to levels of activity or participation measured, for example, with the Dizziness Handicap Inventory, which also showed a strong trend towards significant differences between the groups (standardised mean difference (SMD) -0.83, 95% CI -1.02 to -0.64). The exception to this was when movement-based vestibular rehabilitation was compared to physical manoeuvres for benign paroxysmal positional vertigo (BPPV), where the latter was shown to be superior in cure rate in the short term (OR 0.19, 95% CI 0.07 to 0.49). There were no reported adverse effects.
- Author conclusions: There is moderate to strong evidence that vestibular rehabilitation is a safe, effective management for unilateral peripheral vestibular dysfunction, based on a number of high-quality randomised controlled trials. There is moderate evidence that vestibular rehabilitation resolves symptoms and improves functioning in the medium term. However, there is evidence that for the specific diagnostic group of BPPV, physical (repositioning) manoeuvres are more effective in the short-term than exercise-based vestibular rehabilitation; although a combination of the two is effective for longer-term functional recovery. There is insufficient evidence to discriminate between differing forms of vestibular rehabilitation.

Others policies
Aetna, 2019
http://www.aetna.com/cpb/medical/data/200_299/0238.html

Aetna considers vestibular rehabilitation for chronic vertigo medically necessary when all of the following criteria are met:

1. Symptoms (e.g., vertigo and imbalance) have existed for more than 6 months; *and*

2. The member has confirmed diagnosis of a vestibular disorder or has undergone ablative vestibular surgery; *and*
3. The member has failed medical management (e.g., use of vestibular suppressant medications to reduce symptoms).

Aetna considers vestibular rehabilitation experimental and investigational for all other indications because its effectiveness for indications other than the one listed above has not been established.

Note: Up to 12 visits (generally given 2 times a week for 6 weeks) are considered medically necessary initially. Up to 12 additional visits are considered medically necessary if, upon medical review, there is evidence of clinically significant improvement. If there is no evidence of improvement after 12 visits, additional visits are not considered medically necessary.

Excerpt from evidence summary

The literature indicates that the following groups of patients are generally not good candidates for vestibular rehabilitation:

- Patients with an unstable lesion, usually indicative of a progressive degenerative process (e.g., autoimmune inner ear disease);
- Patients with endolymphatic hydrops, Meniere's disease, or perilymphatic fistula;
- Patients with vertiginous symptoms from a demyelinating disease, epilepsy, or migraine.

HERC Staff Summary

Most of the concerns about non-pairing relate to the prioritization of vertiginous syndromes on Line 510, below the funding line. There is evidence of the efficacy of vestibular rehabilitation for a variety of vertiginous conditions.

The Prioritized List needs updating to enable intended coverage for fall prevention in alignment with the USPSTF recommendation. Currently "history of falling" is on Line 3, but there are no exercise therapy interventions that pair on this line.

Recommendations:

1. Add the following codes to Line 510 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM

97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
97112	Therapeutic procedure, 1 or more areas, each 15 minutes;

	neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes

2. Add Z91.81 *History of falling* to Line 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
    a. Delete from Line 3
    b. Rationale: Pairing on the dysfunction line rather than Line 3 seems most appropriate as PT/OT codes are here already. Placing all the PT codes on line 3 could result in unintended consequences.
3. Modify guideline note 106 as follows:

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Lines 3,619

Included on Line 3 are the following preventive services:

A) US Preventive Services Task Force (USPSTF) "A" and "B" Recommendations in effect and issued prior to January 1, 2017.
    1) http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/
        a. Treatment of falls prevention with exercise interventions is included on Line 292.
    2) USPSTF "D" recommendations are not included on this line or any other line of the Prioritized List.

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

C) Health Resources and Services Administration (HRSA) Women's Preventive Services-Required Health Plan Coverage Guidelines as retrieved from http://www.hrsa.gov/womensguidelines/ on 1/1/2017.

D) Immunizations as recommended by the Advisory Committee on Immunization Practices (ACIP): http://www.cdc.gov/vaccines/schedules/hcp/index.html or approved for the Oregon Immunization Program: https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Documents/DMAPvactable.pdf

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

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

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

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

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

4. Add S9476 *Vestibular rehabilitation program, non-physician provider, per diem* to Line 510 VERTIGINOUS SYNDROMES AND OTHER DISORDERS OF VESTIBULAR SYSTEM

5. If vertigo is the cause of recurrent falls, then the comorbidity rule could be used to allow coverage of vestibular rehabilitation for vertigo-associated "history of falling" on Line 292.

Prolotherapy

Question: Should noncoverage of prolotherapy be clarified on the Prioritized List?

Question source: Indian Health Service is seeking clarification of HERC intended coverage.

Issue: There is no specific CPT code for prolotherapy. HERC has current coverage recommendations for back pain and for knee arthritis to not cover prolotherapy and platelet-rich plasma injections, respectively.

There is a new HCPCS code specific to prolotherapy which has not been reviewed by HERC.

Clinical Background:
From United, 2019

Prolotherapy is an injection-based complementary and alternative medical therapy for chronic musculoskeletal pain. Its core principle is that a relatively small volume of an irritant or sclerosing solution is injected at sites on painful ligament and tendon insertions, and in adjacent joint space over the course of several treatment sessions. It has been assessed as a treatment for a wide variety of painful chronic musculoskeletal conditions which are refractory to "standard of care" therapies. The three most commonly used prolotherapy solutions are hypertonic dextrose, phenol-glycerine-glucose, and morrhuate sodium.

Code	Code Description	Prioritized List Placement
M0076	Prolotherapy	Never Reviewed
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed	Temporary code
0481T	Injection(s), autologous white blood cell concentrate (autologous protein solution), any site, including image guidance, harvesting and preparation, when performed	Temporary code

Evidence summary

Prior HERC reviews:
HERC Coverage Guidance, Newer interventions for osteoarthritis of the knee, 2019.

- Platelet-rich plasma is not recommended for coverage (*weak recommendation*) for osteoarthritis of the knee
- Guideline Note 104 excludes platelet-rich plasma for osteoarthritis of the knee

HERC Coverage Guidance, Low back pain: minimally invasive and non-corticosteroid percutaneous interventions, 2018

- Prolotherapy is not included on back lines due to lack of evidence of effectiveness for the treatment of conditions on these lines, including cervical, thoracic, lumbar, and sacral conditions in Guideline Note 37 SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS

Other Payers
United Healthcare, 2019
https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/prolotherapy-musculoskeletal-indications.pdf

Evidence review for
- Knee arthritis
- Fingers
- Lateral epicondylosis
- Rotator cuff tendinopathies
- Groin pain
- Temporal mandibular joint hypermobility
- Lower limb tendinopathies
- Low back pain
- Chronic pain

Coverage Rationale - Prolotherapy is unproven and not medically necessary due to insufficient evidence of efficacy.

Aetna, 2019
http://www.aetna.com/cpb/medical/data/200_299/0207.html
Aetna considers prolotherapy (also known as proliferant therapy, proliferation therapy, joint sclerotherapy, or reconstructive ligament therapy) experimental and investigational for all indications, including the following (not an all-inclusive list), because there is inadequate evidence of its effectiveness:

- Achilles tendinosis
- Back pain
- Coccynodynia
- Epicondylitis
- Hand osteoarthritis
- Iliotibial band syndrome
- Ischio-femoral impingement
- Knee ligament instability
- Knee osteoarthritis
- Metatarso-phalangeal joint instability
- Myofascial pain
- Neuropathic pain
- Osgood-Schlatter disease
- Osteomyelitis pubis
- Plantar fasciopathy
- Rotator cuff disease
- Sacroiliac joint pain / instability

- Shoulder pain
- Temporomandibular joint syndrome/Temporomandibular joint hypermobility
- Tendinopathies.

Aetna considers neural prolotherapy (low dose dextrose) experimental and investigational for neurogenic inflammatory pain and all other indications.

Aetna considers prolozone therapy experimental and investigational for any diagnosis because there is no peer-reviewed published clinical literature regarding its effectiveness.

Aetna considers Sarapin, an herbal extract that has been used as a sclerosant in prolotherapy, experimental and investigational for all indications because there is inadequate evidence of its effectiveness.

Cigna, 2019 https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/CMM-204_Prolotherapy.pdf

Prolotherapy performed for the treatment of musculoskeletal pain and/or instability (e.g., laxity, weakness) is considered **experimental, investigational or unproven**.

Premera Blue Cross, 2019
https://www.premera.com/medicalpolicies/2.01.26.pdf
Prolotherapy is considered investigational as a treatment of musculoskeletal pain.

HERC Staff Summary
Prolotherapy has been previously reviewed for some indications and not found to have sufficient evidence to warrant inclusion on the Prioritized List. Major commercial payers consider prolotherapy experimental for all indications. There is a lack of clarity about general coverage intent on the Prioritized List.

HERC Staff Recommendations:
1) Place M0076 *Prolotherapy* on Line 660
2) Add to guideline note 173

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

M0076	Prolotherapy	Insufficient evidence of effectiveness	August, 2019

3) Modify Guideline Note 37 to remove prolotherapy, since it will be on 660
GUIDELINE NOTE 37, SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS

Lines 346,527

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

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

   Foraminal or central spinal stenosis causing only radiating pain (e.g. radiculopathic pain) is included only on Line 527.

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

For all other indications, spine surgery is included on Line 527.

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

- ~~prolotherapy~~
- local injections (including ozone therapy injections)
- botulinum toxin injection

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

Corticosteroid injections for low back pain with or without radiculopathy are only included on Line 527.

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

4) Make no change to Guideline Note 104. It specifically considers platelet rich plasma and not broader prolotherapy. Terminology around this may be changing as well.

GUIDELINE NOTE 104, NEWER INTERVENTIONS FOR OSTEOARTHRITIS OF THE KNEE

Lines 430,461

The following treatments are not included on this line for osteoarthritis of the knee:

· Whole body vibration
· Glucosamine/chondroitin (alone, or in combination)
· Platelet rich plasma
· Viscosupplementation
· Transcutaneous electrical stimulation (TENS)

CPT 20610 and 20611 are included on these lines only for interventions other than viscosupplementation for osteoarthritis of the knee.

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

Opportunistic Salpingectomy Guideline Clarification

Question: Should the opportunistic salpingectomy guideline and code placement be modified?

Question source: HSD Medicaid unit, RHEA staff

Issue: There is still ongoing confusion about the intent of the opportunistic salpingectomy guideline and concern about a need to modify the current pairing of salpingectomy codes. Due to coding and billing practices, opportunistic salpingectomy needs to be available on lines with the co-occurring gynecological surgeries. There is a request to clarify the definition of opportunistic salpingectomy.

Prioritized List Status

Code	Code Description	Current Prioritized List Placement
Z40.03	Encounter for prophylactic removal of fallopian tube(s)	6 REPRODUCTIVE SERVICES 191 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER
58700	Salpingectomy, complete or partial, unilateral or bilateral (separate procedure)	6,37,51,61,428,529,578
58260	Vaginal hysterectomy, for uterus 250 g or less;	1,25,37,51,133,209,239,286 and 7 other lines.
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)	1,25,51,209,312,395,403,420 and 2 other lines.
58290	Vaginal hysterectomy, for uterus greater than 250 g;	1,25,51,209,286,312,395,403 and 4 other lines.
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	1,25,51,209,312,395,403,420 and 2 other lines.
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)	6,37,51,61,191,239,286,312 and 6 other lines.

GUIDELINE NOTE 176, OPPORTUNISTIC SALPINGECTOMY

Line 6

Opportunistic salpingectomy during gynecologic procedures is included on Line 6, when it does not involve an increased payment (i.e., using a form of reference-based pricing) or require a change in the setting in which the procedure would be performed (e.g. necessitate a hospital setting instead of an ambulatory surgical center.)

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.

Opportunistic Salpingectomy Guideline Clarification

Gynecology lines

Line	Condition	Treatment	HERC Staff Recommendation
1	PREGNANCY	MATERNITY CARE	Add opportunistic salpingectomy
6	REPRODUCTIVE SERVICES	CONTRACEPTION MANAGEMENT; STERILIZATION	Add opportunistic salpingectomy
25	DYSPLASIA OF CERVIX AND CERVICAL CARCINOMA IN SITU, CERVICAL CONDYLOMA	MEDICAL AND SURGICAL TREATMENT	Add opportunistic salpingectomy
35	TERMINATION OF PREGNANCY	INDUCED ABORTION	Do not add
37	ECTOPIC PREGNANCY; HYDATIDIFORM MOLE; CHORIOCARCINOMA	MEDICAL AND SURGICAL TREATMENT	Add opportunistic salpingectomy
51	ACUTE PELVIC INFLAMMATORY DISEASE	MEDICAL AND SURGICAL TREATMENT	Add opportunistic salpingectomy
52	GONOCOCCAL INFECTIONS AND OTHER SEXUALLY TRANSMITTED DISEASES OF THE ORAL, ANAL AND GENITOURINARY TRACT	MEDICAL THERAPY	Do not add
61	TORSION OF OVARY	OOPHORECTOMY, OVARIAN CYSTECTOMY	Add opportunistic salpingectomy
63	SPONTANEOUS ABORTION; MISSED ABORTION	MEDICAL AND SURGICAL TREATMENT	Add opportunistic salpingectomy
133	CANCER OF CERVIX	MEDICAL AND SURGICAL TREATMENT, WHICH INCLUDES CHEMOTHERAPY AND RADIATION THERAPY	Add opportunistic salpingectomy
239	CANCER OF OVARY	MEDICAL AND SURGICAL TREATMENT, WHICH INCLUDES CHEMOTHERAPY AND RADIATION THERAPY	Add opportunistic salpingectomy
285	COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	MEDICAL AND SURGICAL TREATMENT	Do not add
286	CANCER OF VAGINA, VULVA, AND OTHER FEMALE GENITAL ORGANS	MEDICAL AND SURGICAL TREATMENT, WHICH INCLUDES CHEMOTHERAPY AND RADIATION THERAPY	Add opportunistic salpingectomy
298	FISTULA INVOLVING FEMALE GENITAL TRACT	CLOSURE OF FISTULA	Add opportunistic salpingectomy
353	STRUCTURAL CAUSES OF AMENORRHEA	SURGICAL TREATMENT	Add opportunistic salpingectomy
395	ENDOMETRIOSIS AND ADENOMYOSIS	MEDICAL AND SURGICAL TREATMENT	Add opportunistic salpingectomy

403	UTERINE LEIOMYOMA AND POLYPS	SURGICAL TREATMENT	Add opportunistic salpingectomy
420	MENSTRUAL BLEEDING DISORDERS	MEDICAL AND SURGICAL TREATMENT	Add opportunistic salpingectomy
427	VAGINITIS AND CERVICITIS	MEDICAL THERAPY	Do not add
428	NONINFLAMMATORY DISORDERS AND BENIGN NEOPLASMS OF OVARY, FALLOPIAN TUBES AND UTERUS; OVARIAN CYSTS; GONADAL DYSGENISIS	MEDICAL AND SURGICAL TREATMENT	Add opportunistic salpingectomy
434	PRECANCEROUS VULVAR CONDITIONS	MEDICAL THERAPY	Do not add
437	FOREIGN BODY IN UTERUS, VULVA AND VAGINA	MEDICAL AND SURGICAL TREATMENT	Do not add
453	URINARY INCONTINENCE	MEDICAL AND SURGICAL TREATMENT	Add opportunistic salpingectomy
464	UTERINE PROLAPSE; CYSTOCELE	MEDICAL AND SURGICAL TREATMENT	Add opportunistic salpingectomy
467	GONADAL DYSFUNCTION, MENOPAUSAL MANAGEMENT	OOPHORECTOMY, ORCHIECTOMY, HORMONAL REPLACEMENT FOR PURPOSES OTHER THAN INFERTILITY	Add opportunistic salpingectomy
478	BREAST CYSTS AND OTHER DISORDERS OF THE BREAST	MEDICAL AND SURGICAL TREATMENT	Do not add
479	CYSTS OF BARTHOLIN'S GLAND AND VULVA	INCISION AND DRAINAGE, MEDICAL THERAPY	Do not add
521	SEXUAL DYSFUNCTION	PSYCHOTHERAPY, MEDICAL AND SURGICAL TREATMENT	Do not add
529	CHRONIC PELVIC INFLAMMATORY DISEASE, PELVIC PAIN SYNDROME, DYSPAREUNIA	MEDICAL AND SURGICAL TREATMENT	Add opportunistic salpingectomy
555	DYSMENORRHEA	MEDICAL AND SURGICAL TREATMENT	Add opportunistic salpingectomy
561	BENIGN NEOPLASM AND CONDITIONS OF EXTERNAL FEMALE GENITAL ORGANS	EXCISION	Do not add
569	OTHER COMPLICATIONS OF A PROCEDURE	MEDICAL AND SURGICAL TREATMENT	Do not add
578	CONGENITAL ANOMALIES OF FEMALE GENITAL ORGANS EXCLUDING VAGINA	SURGICAL TREATMENT	Add opportunistic salpingectomy
627	BENIGN CERVICAL CONDITIONS	MEDICAL THERAPY	Do not add

634	GALACTORRHEA, MASTODYNIA, ATROPHY, BENIGN NEOPLASMS AND UNSPECIFIED DISORDERS OF THE BREAST	MEDICAL AND SURGICAL TREATMENT	Do not add
656	GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	EVALUATION	Do not add

HERC Staff Recommendations:

1) Add the following ICD-10-CM and CPT codes to multiple surgical OB/GYN lines (1, 25, 37, 51, 61, 63, 133, 239, 286, 298, 353, 395, 403, 420, 428, 453, 464, 467, 529, 555, 578):
    a. Z40.03 Encounter for prophylactic removal of fallopian tube(s)
    b. 58700 Salpingectomy, complete or partial, unilateral or bilateral (separate procedure)
2) Make no change to 58661 Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
3) Add CPT code 58262 (Vaginal hysterectomy, for uterus 250 g or less with removal of tubes(s), and/or ovary(s)) to surgical OB/GYN lines 37, 133, 239, 286 and 555, where it does not appear, but which do include 58260 (Vaginal hysterectomy, for uterus 250 g or less)
4) Add CPT code 58291 (Vaginal hysterectomy, for uterus greater than 250 g with removal of tube(s) and/or ovary(s)) to surgical OB/GYN lines 286 and 420, where it does not appear, but which do include 58290 (Vaginal hysterectomy, for uterus greater than 250 g)
5) Modify Guideline Note 176 as follows:

GUIDELINE NOTE 176, OPPORTUNISTIC SALPINGECTOMY

Lines 1, 6, 25, 37, 51, 61, 63, 133, 239, 286, 298, 353, 395, 403, 420, 428, 453, 464, 467, 529, 555, 578

~~Opportunistic salpingectomy during gynecologic procedures is included on Line 6, when it does not involve an increased payment (i.e., using a form of reference-based pricing) or require a change in the setting in which the procedure would be performed (e.g. necessitate a hospital setting instead of an ambulatory surgical center.)~~

Opportunistic salpingectomy is defined as the prophylactic removal of the fallopian tubes for the primary prevention of ovarian cancer when a woman is undergoing pelvic surgery for another indication, or instead of a bilateral tubal ligation (BTL) for the purpose of sterilization. It is included on these lines when used for these purposes, however, no additional payment is intended beyond the cost of the indicated pelvic surgery (e.g. using reference-based pricing) or the cost of the BTL and as long as the addition of the opportunistic salpingectomy does not result in a change in setting (for example requiring a hospital setting versus ambulatory surgery center).

Opportunistic salpingectomy should be paired with Z40.03 *Encounter for prophylactic removal of fallopian tube(s) or Z30.2 Encounter for sterilization.*

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.

Surgical Treatment for Chronic Pancreatitis Including Pancreatectomy with Autologous Islet Cell Transplant

Questions:

1) Is there any intention to cover islet cell transplant for type 1 diabetes on the Prioritized List?
2) Should partial and total pancreatectomy without autologous islet cell transplant be added to the surgical line for chronic pancreatitis?
3) Should total pancreatectomy with autologous islet cell transplant be added to the surgical line for chronic pancreatitis?

Question sources: California Medicaid; HERC staff

Issue:

Chronic pancreatitis is long-term inflammation of the pancreas characterized by an irreversible, permanent and progressive destruction of the pancreatic tissue. Chronic pancreatitis may be either hereditary, with a genetic cause often presenting in childhood or young adulthood, or acquired, which usually presents in adulthood. Alcohol is the most frequent cause of acquired chronic pancreatitis. Chronic pancreatitis is a disabling condition with a number of symptoms, of which the most debilitating is severe abdominal pain. Long-term pancreatitis may also interfere with insulin production and lead to diabetes. Current treatment is mainly symptom control, including opioid therapy. Some patients may benefit from surgical procedures; these may include drainage procedures in patients where there is dilatation of the main pancreatic duct and/or segmental resection of the pancreas where appropriate. Patients may also benefit from nerve block type procedures. The primary goal of surgery is to remove the cause of the symptoms by removing the pancreas (total pancreatectomy), with an aim to control pain resistant to other therapies; islet auto transplantation (a procedure where the patient's own islet cells are isolated and infused into their liver) is intended to prevent or lessen the very brittle diabetes mellitus which is an inevitable result of total pancreatectomy. Patients will also need lifelong oral replacement therapy of the digestive enzymes produced by the pancreas.

Islet cell transplant has been proposed as a treatment of type 1 diabetes. In this case, the transplanted cells can come from a cadaveric donor (allogenic). Such a transplant requires lifelong immunosuppression and is considered experimental by the FDA.

California Medicaid is looking at coverage of islet cell transplants and contacted Oregon to clarify coverage for OHP. Pancreatic islet cell transplant from cadaveric donors for treatment of type 1 diabetes has not been reviewed in detail in many years and has previously been considered experimental. There is currently one ambiguous code that could include pancreatic islet transplantation that is in the funded region and creates a lack of clarity as to HERC coverage intent. Pancreatectomy with autologous islet cell transplant has never been reviewed.

Currently, there are two lines for chronic pancreatitis, 251 CHRONIC PANCREATITIS/MEDICAL THERAPY and 596 CHRONIC PANCREATITIS/SURGICAL TREATMENT. Line 596 does not have the CPT codes for pancreatectomy, however. Searches through old minutes could not find any reference to why pancreatectomy was not included on the surgical treatment line. If the patient has a pancreatic pseudocyst, which is a complication of acute and chronic pancreatitis, then the patient could be treated with a partial or total pancreatectomy on line 363 CYST AND PSEUDOCYST OF PANCREAS.

Surgical Treatment for Chronic Pancreatitis Including Pancreatectomy with Autologous Islet Cell Transplant

Current Prioritized List Status:

Code	Code Description	Current Prioritized List Status
48150-48154	Subtotal pancreatectomy	47 DEEP ABSCESSES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS 316 CANCER OF PANCREAS 363 CYST AND PSEUDOCYST OF PANCREAS 433 CANCER OF GALLBLADDER AND OTHER BILIARY
48155	Pancreatectomy, total	27 TYPE 2 DIABETES MELLITUS 156 ACROMEGALY AND GIGANTISM 316 342 OTHER AND UNSPECIFIED ANTERIOR PITUITARY HYPERFUNCTION, BENIGN NEOPLASM OF THYROID GLAND AND OTHER ENDOCRINE GLANDS 433
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells	84 DIABETES MELLITUS WITH END STAGE RENAL DISEASE Tx SIMULTANEOUS PANCREAS/KIDNEY (SPK) TRANSPLANT, PANCREAS AFTER KIDNEY (PAK) TRANSPLANT
G0341	Percutaneous islet cell transplant, includes portal vein catheterization and infusion	Never Reviewed
G0342	Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion	Never Reviewed
G0343	Laparotomy for islet cell transplant, includes portal vein catheterization and infusion	Never Reviewed
S2102	Islet cell tissue transplant from pancreas; allogeneic	Excluded File

Transplant services OARs
https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=84704

Surgical Treatment for Chronic Pancreatitis Including Pancreatectomy with Autologous Islet Cell Transplant

Evidence for pancreatic surgery for chronic pancreatitis

1) **Ahmed 2015**, Cochrane review of endoscopic vs surgical intervention for painful obstructive chronic pancreatitis
    a. N=2 trials of endoscopic vs surgical intervention (N=111 patients, 55 endoscopic and 56 surgical)
        i. Compared with the endoscopic group, the surgical group had a higher proportion of participants with pain relief, both at middle/long-term follow-up (two to five years: risk ratio (RR) 1.62, 95% confidence interval (CI) 1.22 to 2.15) and long-term follow-up (≥ five years, RR 1.56, 95% CI 1.18 to 2.05). Surgical intervention resulted in improved quality of life and improved preservation of exocrine pancreatic function at middle/long-term follow-up (two to five years), but not at long-term follow-up (≥ 5 years). No differences were found in terms of major post-interventional complications or mortality, although the number of participants did not allow for this to be reliably evaluated.
    b. N=1 trial (N=32 patients, 17 surgical and 15 conservative) of surgical intervention vs conservative therapy.
    c. The trial showed that surgical intervention resulted in a higher percentage of participants with pain relief and better preservation of pancreatic function. The trial had methodological limitations, and the number of participants was relatively small.
    d. Authors' conclusions: For patients with obstructive chronic pancreatitis and dilated pancreatic duct, this review shows that surgery is superior to endoscopy in terms of pain relief. Morbidity and mortality seem not to differ between the two intervention modalities, but the small trials identified do not provide sufficient power to detect the small differences expected in this outcome. Regarding the comparison of surgical intervention versus conservative treatment, this review has shown that surgical intervention in an early stage of chronic pancreatitis is a promising approach in terms of pain relief and pancreatic function. Other trials need to confirm these results because of the methodological limitations and limited number of participants assessed in the present evidence.
2) **Yang 2014**, systematic review of early surgery for chronic pancreatitis
    a. N=11 studies
        i. Seven studies examined pain, three studies examined pancreatic function, and three studies examined rates of re-intervention.
    b. Meta-analysis of the three studies with comparative raw data regarding complete pain relief showed that early surgery compared to late surgery was associated with an increased likelihood of complete postoperative pain relief (RR=1.67, 95 % CI 1.09–2.56, p=0.02). Early surgery was also associated with reduced risk of pancreatic insufficiency and low re-intervention rates.
    c. Conclusions: Data from this study supports considering early surgery for pain management in patients with chronic pancreatitis, with the potential of a reduced risk of pancreatic insufficiency and the need for further intervention. Further prospective randomized studies are warranted comparing early surgery against conservative step-up approaches.
3) **Hartmann 2016**, review of surgery for chronic pancreatitis

   a. In general, several randomized controlled trials provide strong evidence that surgical therapy for painful obstructive chronic pancreatitis leads to significantly better long-term results than endoscopic interventions and that early surgical intervention is associated with improved postoperative pain relief, reduced risk of pancreatic insufficiency and decreased re-intervention rates in comparison with conservative 'step-up approaches.'

4) **Branganza 2011**, review of chronic pancreatitis
   a. Pancreatectomy is the last step in their algorithm for treatment
   b. Duodenum-preserving head resection combined, when appropriate, with lateral pancreaticojejunostomy, has been a major advance: only 8.7% of patients continued to have pancreatic pain at a median of 5-7 years follow-up, whereas 93% of patients had pancreatic pain preoperatively.

<u>Evidence for total pancreatectomy with islet cell autotransplantation for chronic pancreatitis</u>

1) **NHS 2018:** evidence review of total pancreatectomy and islet cell autotransplantation (TP IAT) for chronic pancreatitis
   a. N=15 studies
      i. three systematic reviews (Wu et al 2015, Bramis et al 2012, Dong et al 2011)
      ii. four uncontrolled studies of TP IAT (Fazlalizadeh et al 2016, Morgan et al 2015, Chinnakotla et al 2014a, Wilson et al 2014)
      iii. one comparative study (Bhayani et al 2014)
      iv. five uncontrolled studies conducted in paediatric patients only (Bellin et al 2017, Chinnakotla et al 2014b, Wilson et al 2013, Bellin et al 2011, Bellin et al 2008).
      v. There was one cost study of TP IAT based on a small comparative study.
   b. *Question 1: What is the clinical effectiveness and cost effectiveness of TP IAT in the management of uncontrolled pain caused by small duct chronic pancreatitis and resistant to other forms of treatment in patients of all ages?*
      i. One systematic review (Bramis et al 2012) included two studies which report post-operative reduction of 116mg and 55mg daily respectively in the use of morphine. One case series reported narcotic independence rate of 55% at one year and 73% at five years (Wilson 2014).
      ii. Two systematic reviews which carried out meta-analyses reported pooled insulin independence rates of 27% (95% CI: 21-33%) and 28.4% (95% CI: 15.7-46.0) at one year and 21% (95% CI: 16-27%) and 19.7% (95% CI: 5.1-52.6%) at two years respectively (Dong et al 2011, Wu et al 2015).
   c. *Question 4: Evidence for improvement of QoL*
      i. One study reported significant improvements in PhysQoL relative to baseline at one, two, and three years' post-surgery of 7.1, 5.8, and

7.8 and in PsychQoL relative to baseline at one year, two years, and three years' post-surgery of 3.9, 4.9, and 6.6 ($p < 0.001$ for all) (Morgan et al 2015). Another study reported MCS and PCS scale scores statistically improved over time ($p<0.001$).

ii. In one study, 92% of patients reported overall improvement in their health at one year and 85% at 5 years follow-up (Wilson et al 2014).

d. Conclusion: NHS England has concluded that there is sufficient evidence to support the routine commissioning of this treatment for the indication. Therefore, total pancreatectomy (for the indication of chronic pancreatitis) cannot be offered to patients if the option of islet auto transplant is not available (except in patients who already have no functioning islet cells).

e. Guideline:

i. TP IAT will be reserved for patients with acquired intractable chronic pancreatitis who:

1. have intractable abdominal pain despite regular opiate analgesia
2. are receiving care guided by a pain control team
3. have not responded to more conservative surgery including endoscopic pancreatic decompression or in whom such surgery is not clinically indicated
4. have not responded to nerve block procedures or in whom these interventions are not clinically indicated
5. are assessed by the multidisciplinary team as suffering from pain of an organic nature and are thought likely to achieve significant pain reduction from TP IAT

ii. Exclusions

1. TP IAT will not be performed:

a. in patients with C-peptide negative diabetes, type 1 diabetes, known pancreatic cancer and any other condition that would prevent isolation of islet cells for auto transplant. These patients maybe suitable for pancreatectomy alone.
b. where the risk associated with major surgery (pancreatectomy) is high
c. where islet cell transplant risks are high including portal vein thrombosis, and significant parenchymal liver disease (e.g. cirrhosis of the liver)
d. in patients considered by the MDT assessment to be unable to adhere to the complex medical management required following TP IAT

2) **Bramis 2012**, systematic review of total pancreatectomy and islet autotransplantation for chronic pancreatitis
    a. N=5 studies (n=296 patients)
        i. 4 case series, 1 retrospective cohort
    b. 2 studies reported post-operative morphine usage and found a reduction of 55mg and 116 mg in mean morphine dosage compared to pre-operative dosage
    c. The insulin independence rate ranged from 46 percent of patients at a mean follow-up of 5 years to 10 percent at 8 years.
    d. The impact on quality of life was poorly reported.
    e. Conclusion: This systematic review showed that TP/IAT had favorable outcomes with regard to pain reduction. Concurrent IAT enabled a significant proportion of patients to remain independent of insulin supplementation.
2) **Dong 2011**, systematic review and meta-analysis of islet autotransplantation after pancreatectomy for minimizing diabetes
    a. N=15 studies, (n=384 patients)—included 3 of the studies in Bramis 2012 above
        i. all single center case series
        ii. The overall quality of the included studies was suboptimal
    b. The rate of insulin independence at last follow-up was reported in all included studies except one. The pooled rate was 4.62 per 100 person-years (95% CI: 1.53–7.72; I2 = 97%).
    c. Insulin independence at 1 year was 27% (95% CI: 21– 33%) in 221 patients from five studies, and at 2 years 21% (95% CI: 16–27%) in 201 patients from three studies.
    d. The 30-day mortality was 5% (95% CI: 2–10%, I2 = 0%), whereas the mortality rate at last follow-up was 1.38 per 100 person-years (95% CI: 0.66–2.11; I2 = 0%). The cumulative mortality at 1 year (reported by ten studies including 321 patients) was 4.9% (95% CI: 2.6–7.3%) and at 2 years (reported by five studies including 254 patients), it was 6.2% (95% CI: 3.3–9.2%).
    e. Conclusions: islet cell autotransplantation postpancreatectomy offers some patients a chance for insulin independence. Better data reporting is essential to establish the risks and benefits of IAT after pancreatic surgery.

<u>Other payer policies</u>:

1) Aetna (2019) and Cigna (2019) and BCBS (2019) and Wellmark (2019) cover autologous islet cell transplantation for patients undergoing total or near total pancreatectomy, but consider allogenic (cadaveric) transplant for type 1 diabetes to be experimental
2) No insurer surveyed had a policy about partial or total pancreatectomy without islet cell autotransplantation for chronic pancreatitis; presumably all were covering this intervention

Surgical Treatment for Chronic Pancreatitis Including Pancreatectomy with Autologous Islet Cell Transplant

HERC staff summary

Allogenic (cadaveric) islet cell transplantation for treatment of type 1 diabetes is considered experimental by the FDA and all private insurers queried; it is appropriately on the Excluded File.

Partial pancreatectomy appears, based on limited data, to result in significant pain relief and improved quality of life for patients with chronic pancreatitis, particularly that caused by chronic duct obstruction. Partial or total pancreatectomy is the end step in standard treatment algorithms for chronic pancreatitis. Meta-analyses indicate that surgery has better pain reduction outcomes than the endoscopic procedures which are currently included on the medical chronic pancreatitis line.

The effectiveness of autologous islet cell transplantation after total or near total pancreatectomy for chronic pancreatitis on the reduction for the need for insulin is difficult to determine based on the current evidence base, which consists of nearly all poor-quality case series. The limited evidence base finds that only a minority (approximately 20%) of patients will avoid insulin 1 to 2 years after islet cell autologous transplantation. However, NHS/NICE, one of our trusted sources, has reviewed the evidence and found it sufficient to recommend coverage. All major insurers appear to cover this procedure.

HERC staff recommendations:

1) Add allogenic islet cell transplantation HCPCS S2012 (Islet cell tissue transplant from pancreas; allogeneic) to line 660/GN173
    a. Makes more visible the current placement on the Excluded File
    b. Not FDA approved; cannot be covered by Medicaid

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
S2012	Islet cell tissue transplant from pancreas; allogeneic	Insufficient evidence of effectiveness	August 2019

2) Add partial and total pancreatectomy CPT codes to line 596 CHRONIC PANCREATITIS Treatment: SURGICAL TREATMENT
    a. CPT 48150-48154 (Subtotal pancreatectomy)
    b. CPT 48155 (Pancreatectomy, total)

3) Add autologous islet cell transplantation after total pancreatectomy to line 596 CHRONIC PANCREATITIS Treatment: SURGICAL TREATMENT
    a. Add CPT 48160 and HCPCS G0341-G0343 to line 596
        i. 48160 Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells
        ii. G0341 Percutaneous islet cell transplant, includes portal vein catheterization and infusion
        iii. G0342 Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion
        iv. G0343 Laparotomy for islet cell transplant, includes portal vein catheterization and infusion
    b. Remove CPT 48160 from line 84 DIABETES MELLITUS WITH END STAGE RENAL DISEASE Tx SIMULTANEOUS PANCREAS/KIDNEY (SPK) TRANSPLANT, PANCREAS AFTER KIDNEY (PAK) TRANSPLANT
        i. Not a treatment for diabetes mellitus
    c. Add a new guideline to line 596
        i. Based on NHS/NICE guideline

GUIDELINE NOTE XXX, TOTAL PANCREATECTOMY WITH ISLET CELL AUTOTRANSPLANT

Line 596

Total pancreatectomy with islet cell autotransplant (TP IAT) is only included on this line when the patient meets all of the following criteria:

1) Has acquired intractable chronic pancreatitis
2) Has intractable abdominal pain despite optimal medical therapy
3) Has not responded to more conservative surgery including endoscopic pancreatic decompression or in whom such surgery is not clinically indicated
4) Has not responded to nerve block procedures or in whom these interventions are not clinically indicated
5) Has been assessed by the multidisciplinary team and determined to have pain of an organic nature and are thought likely to achieve significant pain reduction from TP IAT
6) Is an appropriate candidate for major surgery
7) Is able to adhere to the complex medical management required following TP IAT
8) Does not have type 1 diabetes, known pancreatic cancer or any other condition that would prevent isolation of islet cells for autotransplant
9) Does not have a high risk of islet cell transplant including portal vein thrombosis, and significant parenchymal liver disease (e.g. cirrhosis of the liver)

Breast Reconstruction with Acellular Matrix

Question: Should acellular matrix be added to the breast cancer line for post-mastectomy breast reconstruction?

Question sources: multiple CCOs, multiple providers

Issue: Acellular dermal matrix (ADM) is an implant material used in breast reconstruction after mastectomy. ADMs are soft tissue matrix grafts created by a process that results in decellularization but leaves the extracellular matrix intact. This matrix provides a scaffold upon and within which the patient's own cells can repopulate and revascularize the implanted tissue. Several products are currently on the market/FDA approved.

Acellular matrix for breast reconstruction was reviewed as a new CPT code in 2011. At that time, this type of implant for reconstruction was found to have a 12% risk of complications and HERC decided not to cover this procedure due to increased risk versus usual reconstruction techniques. This lack of coverage was affirmed in March, 2015.

This material is also listed by the manufacturer as being used in tympanoplasty, parotidectomy, facial soft tissue defects, fascial sling, lower eyelid reconstruction, nasal reconstruction, nasal septal perforation, cleft palate repair, oral resurfacing, vestibuloplasty, radial forearm freeflap repair, abdominal wall repair, and for burn therapy. Major insurers only appear to be covering for breast reconstruction after mastectomy.

Multiple CCOs have contacted HERC staff for clarification and re-evaluation of the policy of non-coverage for ADM. The surgeons in many of their communities are insisting that use of ADM is standard of care for post-mastectomy breast reconstruction.

The most recent American Society of Plastic Surgeons (2015) data estimate that acellular dermal matrices were used in 65 percent of nonautologous breast reconstructions in the United States (Lennox 2017).

From CareOregon

> Based on conversations…with Juliana Hansen at OHSU and Bruce Weber at Good Samaritan, these tissue expanders are the current standard of care, and are needed to complete breast reconstruction in 50-90% of cases, depending on the surgeon.
>
> It appears that the older plastic surgeons are the only ones trained to do recon breast surgery [without] using the matrix and as they are retiring only the younger plastic surgeons are available for the surgeries but they are not trained to do the reconstruction without using matrix. So this has become a problem with nobody trained to do the surgery the older way (without using matrix).
>
> …the decision to use this material is often made intraoperatively, if the patient lacks sufficient tissue of her own to achieve an optimal reconstruction result. I don't think a formal review of the literature is needed in this case, as apparently the benefits sufficiently exceed the risks that it has become standard practice, particularly among more recently trained plastic surgeons.

From Samaritan Health:

> One of our in-network plastic surgeons is questioning the placement of CPT 15777 (acellular dermal matrix) on line 660 stating that to his knowledge there are no other effective therapies for breast reconstruction and that the use of acellular dermal matrix is the current standard of care in non-autologous breast reconstruction used in over 80% of implant-based breast reconstructions in the US. He is asking me to advise him how to proceed surgically to treat his patients.

Plastic surgeons contacted as part of this review felt that cellular dermal matrix was generally standard of care and felt that the complications rate was similar to other techniques. Specific feedback from surgeons:

From Dr. Mark Jewell:

> Your records review is very outdated regarding the safety profile of ADM. ADM is a necessary part of contemporary breast reconstruction and unless OHP will pay for it in primary and secondary cases, I will not accept OHP covered patients.
>
> One additional topic is the use of ADM to address capsular contracture in breast reconstruction. ADM seems to be effective in treating capsular contracture versus ordinary capsulectomy procedures. I would argue that by not offering coverage for ADM during the initial breast reconstruction procedure, OHP is subjecting its covered to an increased risk of capsular contracture and reoperation along with risk of unsuccessful revisionary surgery.

From Dr. Dann Leonard

> I too have a large breast cancer reconstruction practice and use ADM regularly. The use of a dual plane pocket with supplement using ADM inferiorly, is now standard of care, and Medicaid patients are receiving inferior treatment under the current rules. I am sure that none of us want to give the poor of our state a lesser set of medical care standards.

Current code status

15777 (Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (eg, breast, trunk)) is 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:

Procedure Code	Intervention Description	Rationale	Last Review
15777	Acellular dermal matrix for soft tissue reinforcement (eg, breast, trunk)	Greater harms than other effective therapies	March, 2015

Evidence

Systematic reviews

1) **Hallberg 2018**, systematic review and meta-analysis of use of ADM for immediate breast reconstruction
    a. N=51 studies (28 non-randomized controlled studies and 23 case series)
        i. Inclusion criteria were all randomised and non-randomised controlled trials, and case series comprising > 200 patients reconstructed with AlloDermVR or > 20 with any other ADM or matrices/meshes
        ii. CEbP rated this review as fair to good quality
    a. The certainty of evidence for overall complication rate and implant loss is low
        iii. Overall complication rate (17 cohort studies and 18 case series)
            1. All the cohort studies had severe study limitations and a meta-analysis demonstrated high heterogeneity.
            2. The pooled relative risk ratio for the ten studies using biological matrix (ADM) compared with no matrix, including 6122 breasts, was 1.31 with a 95% confidence interval (CI) of 0.94–1.81.
            3. In summary, the use of matrices in breast reconstruction may result in little or no difference in the rate of complications compared without the use of matrices in women operated on for breast cancer. The certainty of evidence is low.
        iv. Implant loss (16 cohort studies, 21 case series), all with severe study limitations.
            1. A meta-analysis of studies that used biological matrix (ADM) demonstrated a high heterogeneity. The pooled relative risk ratio was 1.02 with a 95% CI of 0.65–1.58, including 16,830 breasts.
            2. A meta-analysis of studies that used synthetic meshes did not reveal a significant difference between the study groups either.
            3. Four studies, with severe limitations, reported implant loss per patient. The pooled relative risk ratio was 1.33 with a 95% confidence interval of 0.73–2.43, including 1307 patients.
            4. The case series reported implant loss at frequencies varying from 0% to 17%.
            5. In summary, it is uncertain whether there is little or no difference in the incidence of implant loss after breast reconstruction with matrix compared with no matrix in women with surgery for breast cancer. The certainty of evidence is very low.
    a. The certainty of evidence for delay of adjuvant treatment, implant loss, infection, capsular contraction and aesthetic outcome is very low
        a. Infection (21 cohort studies, 20 case series)
            i. All the cohort studies had severe study limitations.
            ii. A meta-analysis of studies that used biological matrix (ADM), including 8144 breasts, demonstrated an increased risk of infection with a relative risk ratio of 1.61 and a 95% CI of 1.20–2.15.

iii. The pooled relative risk ratio was 1.30 with a 95% confidence interval of 1.14–1.48 for the four studies using biological matrix (ADM) compared with no matrix.
iv. It is uncertain whether the use of matrices in breast reconstruction increases the risk of infection. The certainty of evidence is very low.

b. Capsular contraction (5 cohort studies, 5 case series)
i. All the cohort studies had severe study limitations and a meta-analysis demonstrated moderate heterogeneity.
ii. The pooled relative risk ratio using biological matrix (ADM) compared with no matrix, including 1645 breasts was 0.55 with a 95% confidence interval of 0.38–1.69.
iii. The case series reported capsular contraction at various frequencies; 0.4–13%.
iv. It is uncertain whether there is little or no difference in the incidence of capsular contraction after breast reconstruction with matrix compared with no matrix in women operated for breast cancer. The certainty of evidence is very low.

c. Aesthetic outcome (3 studies)
i. A total of 328 breasts were reconstructed with matrix, and 307 breasts were reconstructed without matrix. Evaluators who were unaware of the surgical method scored the aesthetic results. Three studies reported different results with regard to the overall aesthetic outcome, in one of them a statistically significant improved aesthetic score could be seen, while the opposite was reported in the other. The third study only reported five different sub-scores, with no consistent results in favor of either of the two methods. None of the studies used validated scales. It is uncertain whether there is little or no difference in aesthetic outcome following the use of matrix in patients with surgery for breast cancer. The certainty of evidence is very low.

b. In conclusion, there is a lack of high-quality studies that compare the use of matrix with no matrix in immediate breast reconstruction. Specifically, there are no data on risk of recurrence of cancer, delay of adjuvant treatment and health related quality of life (HRQoL). In addition, there is a risk of bias in many studies. It is often unclear what complications have been included and how they have been diagnosed, and how and when capsular contracture and aesthetic outcome have been evaluated. Controlled trials that further analyze the impact of radiotherapy, type of matrix and type of procedure (one or two stages) are necessary.

2) **Smith 2018**, meta-analysis of risks of human acellular dermal matrix (HADM) for breast reconstruction
a. Update of Kim 2012
b. N=13 studies
c. Complication rates were higher in HADM patients compared to submuscular reconstruction: total complications, 17.7% versus 6.1%; seroma, 8.3% versus 5.4%; infection, 7.2% versus 5.9%; and flap necrosis, 14.7% versus 7.1%. Meta-analysis revealed a statistically significant increased risk of total complications in patients who underwent reconstruction with HADM when compared with their submuscular reconstruction cohort (p = 0.03; relative risk (RR) = 1.46; confidence interval (CI): 1.04–2.04). Patients who underwent reconstruction with HADM demonstrated a significantly

increased risk of flap necrosis ($p < 0.01$; RR = 2.39; CI: 1.8–3.16) and infection ($p = 0.02$; RR = 1.5; CI: 1.07–2.09) when compared with those who underwent submuscular reconstruction. There was no significant difference in seroma, hematoma, or implant explantation between these two groups.

d. *Conclusions:* This study suggests an increased risk of overall complications, specifically infection and flap necrosis, in patients who underwent tissue expander/implant breast reconstruction with HADM when compared with those who underwent submuscular placement.

3) **Lee 2016**, meta-analysis of ADM for implant-based breast reconstruction
   a. N=23 studies (6199 patients)
      i. 1 RCT
      ii. 2 prospective cohort studies
      iii. Majority were retrospective cohort studies (range 32-628 patients)
      iv. 3 studies included in Hallberg above
   b. Increased risks: The use of ADM significantly elevated the risks of infection, seroma, and mastectomy flap necrosis, but did not affect the risks of implant loss, unplanned reoperation, and total complications.
      i. Infection: risk ratio 1.42 [1.02,1.99]
      ii. Seroma: risk ratio 1.41 [1.12, 1.78]
      iii. Mastectomy flap necrosis: risk ratio 1.44 [1.11, 1.87]
   c. No difference in risk:
      i. Unplanned return to OR: risk ratio 1.09 [0.63, 1.90]
      ii. Implant loss: risk ratio 1.00 [0.68, 1.48]
      iii. Total complications: risk ratio 1.08 [0.87, 1.34]
   d. Reduced risks: The risks of capsular contracture and implant malposition were significantly reduced by the application of ADM. The ADM allows for significantly greater intraoperative expansion and reduced frequency of injection to complete expansion.
      i. Capsular contracture: risk ratio 0.26 [0.15, 0.47]
      ii. Implant malrotation: risk ratio 0.21 [0.07, 0.59]
      iii. Injection frequency: risk ratio -1.56 [2.77, 0.35]
      iv. Time to complete expansion: risk ratio -17.73 [-40.36, 4.91]
   e. Conclusions. According to this meta-analysis, the increasing risks for serious complication and overall morbidity related to ADM use might not be remarkable, while its benefits for preventing late complications and improving expander dynamics might be appreciable. Although future well-controlled studies would be required, the implant-based breast reconstruction using ADM may be reliable and advantageous.

4) **Potter 2015**, systematic review of ADM for implant-based breast reconstruction
   f. N=69 articles (8 systematic reviews, 1 RCT, 40 comparative studies and 20 case series)
      i. All at high risk of bias
      ii. ADM was most commonly used for immediate (40) two-stage implant-based breast reconstruction (IBBR; 36) using human ADM (47), with few studies evaluating ADM-assisted single-stage procedures (10). Heterogeneity between study design and, especially, outcome measurement precluded meaningful data synthesis.
      iii. Conclusion: Current evidence for the value of ADMs in IBBR is limited. Use in practice should therefore be considered experimental, and evaluation within registries or well designed and conducted studies, ideally RCTs, is recommended to prevent widespread adoption of a potentially inferior intervention.

5) **Krisnan 2013**, cost-effectiveness evaluation for acellular dermal matrix for immediate breast reconstruction
    a. The overall complication rates were 30% and 34.5% with and without ADM. The decision model revealed a baseline cost increase of $361.96 when acellular dermal matrix is used. The increase in Quality-Adjusted Life Years (QALYs) is 1.37 in the population with acellular dermal matrix. This yields a cost-effective incremental cost-utility ratio (ICUR) of $264.20/QALY. Univariate sensitivity analysis confirmed that using acellular dermal matrix is cost-effective even when using retail costs for unilateral and bilateral reconstructions.
6) **Maxwell 2014**, systematic review of ADM for breast revision surgery
    a. N=7 studies (570 patients/736 breasts)
        i. All case series
    b. The recurrence rate for capsular contracture was 1.1 percent to 4.3 percent over an average follow-up period of 17 months to 3.1 years. By comparison, the 3-year cumulative incidence of capsular contracture in the Mentor Core study was 19 percent in the revision augmentation cohort.

RCTs not included in above systematic reviews

1) **Lohmander 2019**, RCT of acullular breast matrix
    a. N=135 women (64 with ADM, 65 without ADM)
    b. Four patients (6%) in each group had reconstructive failure with implant loss, but IBBR with ADM exhibited a trend of more overall complications and reoperations (difference 0.16, 95% CI, -0.01 to 0.32, P = 0.070), and with higher risk of wound healing problems (P = 0.013).
    c. Conclusions: With 6-months follow-up for all participants, immediate IBBR with ADM carried a risk of implant loss equal to conventional IBBR without ADM, but was associated with more adverse outcomes requiring surgical intervention. Further investigation of risk factors and patient selection in a long-term follow-up is warranted.
1) **Dikmans 2017**, RCT of one stage vs two stage breast reconstruction
    a. N=142 women (59 one stage implant-based breast reconstruction (IBBR) with ADM; 62 with two stage reconstruction without ADM)
    b. One-stage IBBR with ADM was associated with significantly higher risk per breast of surgical complications (crude odds ratio 3·81, 95% CI 2.67–5.43, p<0·001), reoperation (3.38, 2.10–5.45, p<0·001), and removal of implant, ADM, or both (8.80, 8.24–9.40, p<0·001) than two-stage IBBR. Severe (grade 3) adverse events occurred in 26 (29%) of 91 breasts in the one-stage IBBR with ADM group and in five (5%) of 92 in the two-stage IBBR group. The frequency of mild to moderate adverse events was similar in the two groups.
    c. Interpretation: Immediate one-stage IBBR with ADM was associated with adverse events and should be considered very carefully. Understanding of selection of patients, risk factors, and surgical and postsurgical procedures needs to be improved.

<u>Submitted literature</u>:

1) **Basu 2012,** non-systematic review of ADM for prevention of capsular contracture in breast reconstruction
    a. Note: lead author is a consultant for Lifecell Corp.

   b. N=15 articles (886 women/1,381 breasts)
      i. 1 prospective cohort, 13 retrospective cohort, 1 case series
   c. Rate of capsular contracture: 0-4%
   d. 1 study compared ADM against non-ADM reconstruction
      i. N=123 patients (208 breasts) with immediate two-stage construction with AlloDerm
      ii. N=80 patients (129 breasts) no ADM reconstruction
      iii. Capsular contracture was observed in eight out of 208 breasts in the acellular dermal matrix group (3.8 percent) and 25 out of 129 breasts in the nonmatrix group (19.4 percent).
   e. although the level of evidence remains III or lower and the studies are limited by duration of follow-up or by small sample size (low power), we did find that all the clinical studies revealed capsular contracture rates ranging between 0 percent and 4 percent.
   f. While the evidence for capsular contracture is suggestive, especially in postmastectomy breast reconstruction, the level of evidence should improve through better controlled studies with higher power, longer follow-up, and attention to the use of acellular dermal matrix and capsular contracture rates in revisionary breast surgery.
2) **Jansen 2011**, systematic review of AlloDerm for breast reconstruction
   a. N=14 studies (3 prospective cohort, 11 retrospective cohort)
      i. N=417 patients (623 breasts)
      ii. No comparison groups
   b. Complication rates were as follows: infection, 0 to 11 percent; hematoma, 0 to 6.7 percent; seroma, 0 to 9 percent; partial flap necrosis, 0 to 25 percent; implant exposure with removal, 0 to 14 percent; implant exposure with salvage, 0 to 4 percent; capsular contracture, 0 to 8 percent; and rippling, 0 to 6 percent.
   c. **Conclusions:** Complications using AlloDerm are comparable to those of non- AlloDerm alloplastic reconstructions. AlloDerm appears to confer a low rate of capsular contracture.

Disposition of other submitted literature:
1) Spear 2011: case series of 52 patients; higher level evidence available
2) Moyer 2014: case series of 9 patients; higher level evidence available

Future research:
1) Potter 2016
   a. Pragmatic RCT to evaluate the relative risks and benefits of ADMs in breast reconstruction
   b. Protocol published 2016, unclear when any results will be published

Expert society recommendations:
1) American Society of Plastic Surgeons 2013
   a. Recommendation: Evidence on acellular dermal matrix (ADM) in post-mastectomy expander/implant breast reconstruction is varied and conflicting. Surgeons should evaluate each clinical case individually and objectively determine the use of ADM.
   b. Level III Evidence; Recommendation Grade: C.

2) **Association of Breast Surgery and the British Association of Plastic, Reconstructive and Aesthetic Surgeons 2013**
    a. Recommends use only in a selected population

Other payer policies:
Most major insurers cover acellular dermal matrix for breast reconstruction, but only specific products.

HERC staff summary

Overall, the evidence regarding acellular dermal matrix (ADM) for breast reconstruction mainly relies on small cohort and case series studies and the level of evidence is judged to be low to very low for various outcomes. Three RCTs were identified examining ADM for primary reconstruction vs conventional reconstruction, which found increased risk of adverse events and reoperation and implant loss with ADM.

The systematic reviews for acellular dermal matrix use in breast reconstruction with implants or tissue expanders after mastectomy finds conflicting conclusions regarding complication rates and benefits. One systematic review and meta-analysis found significantly higher complication rates (infection, seroma, flap necrosis) with ADM compared to other reconstruction techniques not using ADM, while another systematic review and meta-analysis found no significant difference in complication rates. This difference might be explained by the inclusion of different types of complications or different definitions of a complication. Similarly, a reduction in rate of capsular contracture is seen in one systematic review and meta-analysis, but not in another. However, patient satisfaction is the same with both techniques. There is also increased rates of reoperation with ADM, which may counteract any improvement in capsular contracture. In general, the literature indicates limited, if any, benefit with use of ADMs but risk of increased complications. The major plastic surgery specialty society in the US expresses caution on use of ADMs due to varied and conflicting evidence.

The evidence on the use of ADM for revision of breast reconstruction consists solely of case series.

Many CCOs are indicating that they cannot contract with surgeons who do not use ADM. All major insurers cover ADM for breast reconstruction, although they limit the brands they include in coverage.

CEbP secondary review

Conclusions:

1. Of the recently published systematic reviews, the review by Hallberg and colleagues appears to be the most comprehensive (k=51). There is generally poor overlap of included studies among the recent systematic reviews published on this topic. It is likely that many of the studies included in other reviews did not meet criteria for inclusion in the Hallberg review because they did not report on a sufficient number of reconstructions. Center staff assessed the methodologic quality of the Hallberg review as good.
2. An additional systematic review focused on harms and adverse events reported in comparative cohort studies of ADM-assisted reconstruction and submuscular reconstructions found that ADM-assisted procedures were associated with a greater risk of complications including flap necrosis and infection.
3. Two randomized controlled open-label trials (reported in 3 manuscripts) were published between 2017 and 2019.
    a. The BRIOS study, which compared 1-stage implant-based breast reconstruction with ADM to 2-stage implant-based breast reconstruction, found that 1-stage procedures with ADM did not improve patient reported quality of life or aesthetic outcomes and were associated with a higher rate of adverse events.

b. A second trial reporting 6-month safety outcomes between IBBR with ADM and IBBR without ADM found that while implant loss was similar between the two groups, the rate of adverse events was greater in the group treated with IBBR with ADM.

HERC staff recommendation:

1) Do not add coverage for acellular dermal matrix for breast reconstruction
    a. Evidence to date is varied and conflicting regarding complication rates, as well as conflicting findings on benefits such as reduced contracture rates compared to other breast reconstruction techniques
2) Move acellular dermal matrix form line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS to line 500 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS
    a. Unclear if any difference in benefits or harms compared to other techniques
    b. Modify GN172 as shown below
    c. Modify GN173 as shown below

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

Line 500

The following interventions are prioritized on Line 500 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS:

Procedure Code	Intervention Description	Rationale	Last Review
15777	Acellular dermal matrix for soft tissue reinforcement (eg, breast, trunk)	Unclear benefits versus other effective therapies; increased risk of adverse events	May 2019

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
~~15777~~	~~Acellular dermal matrix for soft tissue reinforcement (eg, breast, trunk)~~	~~Greater harms than other effective therapies~~	~~March 2019~~

Section 4.0
Community Health Workers for Patients with Chronic Disease

Community Health Workers for Patients with Chronic Disease

Draft Multisector Intervention Report for HERC Consideration

August 8, 2019

Oregon Health Authority

OREGON HEALTH & SCIENCE UNIVERSITY

Center For Evidence-based Policy

Background

The American Public Health Association definition of a community health worker (CHW):

"a frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served. This trusting relationship enables the worker to serve as a liaison/link/intermediary between health/social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery"

Background

- In the evidence review, we found many terms for CHWs:
  - Community health advisors, community health ambassadors, community health navigators
  - Lay health educators, lay health workers
  - Peer advisors, peer coaches, peer supporters, peer counselors
  - Patient navigators
  - Health advocates
  - Outreach workers
  - Promotoras

Background

- The Oregon Health Authority and Oregon Home Care Commission certify CHWs and other traditional health workers
- Traditional health workers:
  - CHWs
  - Personal health navigators
  - Peer support specialists
  - Peer wellness specialists
  - Birth doulas
  - Family support specialists
  - Youth support specialists

Background

- Oregon certification requirements for CHWs:
  - 18 years or older
  - Not listed on the Medicaid provider exclusion list
  - Submit required documentation
  - Pass criminal background check
  - Complete approved training program, or meet minimum level of hours as CHW and submit letter of recommendation
- Every 3 years, certified CHWs must complete 20 hours of approved continuing education plus 1.5 to 3 hours of an oral health training

Scope Statement

- Populations
  - Adults or children with at least 1 of the following: asthma, diabetes, hypertension, heart failure, HIV, serious mental illness, high utilizers
    - Population scoping notes: Exclude studies from low- and middle-income countries
- Interventions
  - Engagement with a CHW
- Comparators
  - Usual care without a CHW; other methods of patient engagement and activation

Scope Statement

- Critical Outcomes
  - Disease-specific morbidity measures
  - Emergency department visits
  - Hospitalizations
- Important Outcomes
  - Medication adherence
  - Harms

Scope Statement

Key Questions

1. What is the effectiveness of CHWs for improving health outcomes and reducing health care utilization in adults and children with chronic diseases?
2. Does the effectiveness of CHWs vary by:
    a. Patient characteristics
    b. Type of chronic condition(s) being addressed
    c. Comorbid conditions
    d. Characteristics of CHW intervention (intensity, setting, methods of engagement)
    e. Characteristics of the CHWs
3. What are the harms of CHWs?

Evidence Sources

- Scott et al., 2018
  - Fair-quality meta-review that aggregates systematic reviews of CHW interventions published between 2005 and 2017, prepared for the World Health Organization
- Jack et al., 2016
  - Good-quality systematic review of the effects of CHWs on health care utilization in the U.S., not included in the Scott et al. meta-review
- Centers for Disease Control and Prevention (CDC) Community Guide, 2017
  - Unpublished systematic reviews of CHW interventions for diabetes management and cardiovascular disease

Evidence Summary

- Although results from individual studies are mixed, it appears that the preponderance of evidence supports the conclusion that CHWs in high-income countries:
  - Improve various chronic-disease-specific health outcomes
  - Reduce emergency department visits and hospitalizations
  - Are cost-saving or cost-effective at commonly established willingness-to-pay thresholds
- There is relatively more evidence in support of CHWs for children with asthma and adults with diabetes or hypertension
- There is relatively less evidence for patients with HIV or serious mental illness

Evidence Summary

- In some studies, greater improvement in outcomes was associated with
  - Higher-intensity interventions
  - Populations with more severe chronic disease at baseline
- In addition, some studies suggest that interventions targeting individuals with prior preventable utilization, longer interventions, and interventions that use CHWs as part of an integrated care team are associated with greater reductions in health care utilization.

Evidence Summary

- These conclusions are limited by an extraordinarily high degree of heterogeneity in many aspects of CHW studies, including
  - Target populations
  - CHW definitions
  - Intervention components
  - Intervention intensity
  - Theoretical basis of the intervention
- In some studies, CHW interventions were combined with other interventions such as case management or assertive community treatment, which makes it difficult to establish the precise contribution of CHWs to the observed effects
- Authors of several systematic reviews raised concerns about the possibility of publication bias in this body of literature
- Most authors regard CHW interventions as potentially promising for improving outcomes among underserved and vulnerable populations

Evidence Table

Outcomes	Estimate of Population Health Effect Evidence Type
Disease-specific morbidity measures *(Critical outcome)*	The preponderance of evidence supports the effectiveness of CHW interventions to improve disease-specific morbidity measures such as HbA1c, blood pressure, and asthma symptom-free days Evidence type: Systematic reviews of RCTs, observational studies, and quasi-experimental studies
Emergency department visits *(Critical outcome)*	The preponderance of evidence supports the effectiveness of CHW interventions for reducing preventable utilization of the emergency department, and economic analyses suggest that CHW interventions are cost-saving or cost-effective (at a willingness-to-pay threshold of $50,000 per QALY) Evidence type: Systematic reviews of RCTs, observational studies, quasi-experimental studies, and economic analyses

Evidence Table

Outcomes	Estimate of Population Health Effect Evidence Type
Hospitalizations *(Important outcome)*	The preponderance of evidence supports the effectiveness of CHW interventions for reducing hospitalizations, and economic analyses suggest that CHW interventions are cost-saving or cost-effective (at a willingness-to-pay threshold of $50,000 per QALY) Evidence type: Systematic reviews of RCTs, observational studies, quasi-experimental studies, and economic analyses
Medication adherence *(Important outcome)*	The preponderance of evidence supports the effectiveness of CHW interventions for improving medication adherence (particularly for antiretroviral and antihypertensive drugs) Evidence type: Systematic reviews of RCTs, observational studies, and quasi-experimental studies

Evidence Table

Outcomes	Estimate of Population Health Effect Evidence Type
Harms *(Important outcome)*	Harms of CHW interventions were generally not reported in the summary literature; although some studies found no evidence of effectiveness, very few studies identified negative effects of CHWs on reported outcomes Evidence type: Systematic reviews of RCTs, observational studies, and quasi-experimental studies

Policies

- The National Academy for State Health Policy (NASHP) online database of CHW models across the 50 states
  - About 25% of states have a certification program for CHWs, although the certification is voluntary in some states
  - At least 3 states, Oregon, Alaska, and Minnesota, require CHWs to be certified in order for these services to be reimbursed by Medicaid
  - Reimbursement and funding
    - About 50% of states pay for CHWs with Medicaid funds; most of these states are paying for CHWs through managed care contracts
    - Some states use other funding sources for CHW interventions, often hiring CHWs through federally qualified health centers (FQHCs), community-based organizations, and universities

Guidelines

- Community Preventive Services Task Force
  - Cardiovascular Disease Prevention (2015)
    - Strong evidence was found for effectiveness in improving blood pressure and cholesterol when CHWs are engaged in a team-based care model
    - Sufficient evidence was found for the effectiveness of CHW interventions for health education and to increase self-reported health behaviors in clients at increased risk for cardiovascular disease
  - Diabetes Management (2017)
    - Strong evidence was found for effectiveness of CHW interventions in improving glycemic and lipid control and reducing health care use among patients with type 2 diabetes
  - Diabetes Prevention (2016)
    - Sufficient evidence was found for effectiveness of CHW interventions in improving glycemic level control and weight-related outcomes among people at increased risk for type 2 diabetes

Guidelines

- The World Health Organization (WHO) 2018 guideline on health policy and system support for CHW programs concludes that there is some evidence of CHW effectiveness for:
  - Chronic diseases - behavior change (diet change, physical activity) and diabetes, hypertension, and asthma management and care
  - Communicable diseases, including treatment and care for HIV/AIDS
  - Maternal and newborn health
  - Child health
  - Mental health
  - Sexual and reproductive health

Discussion

Values and Preferences

Patients would likely strongly value culturally and linguistically specific interventions. There is likely moderate variability in patients' desire to engage with CHWs that is likely dependent on the location and type of intervention.

Discussion

Resource Allocation

Paying CHWs to engage in long duration, high-intensity interventions likely entails moderate cost. However, many of the studies indicate cost-effectiveness and sometimes cost-savings. Prioritizing the use of CHWs for patients with preventable utilization and more severe chronic disease is likely an effective use of resources.

Other Considerations

For Oregon's coordinated care organizations (CCOs), CHWs can be funded through health-related services, but there is variability among the CCOs in terms of funding and engagement of CHWs.

Discussion

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

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

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

Characteristics of effective interventions include:

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

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

- HIV
- Serious mental illness
- Congestive heart failure

Health Evidence Review Commission (HERC)

Multisector Intervention Report: Community Health Workers for Patients with Chronic Disease

DRAFT for HERC meeting 8/8/2019

Multisector Interventions

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

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- HIV
- Serious mental illness
- Congestive heart failure

Table of Contents

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 consideration of population-based health interventions from a variety of sectors in addition to individually focused clinical care. Multisector intervention reports will be developed to address these population-based health interventions or other types of interventions that occur outside of the typical clinical setting.

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.

Evidence Table for Community Health Worker Interventions

Outcomes	Estimate of Population Health Effect *Evidence Type*	Resource Allocation	Values and Preferences	Other Considerations
Disease-specific morbidity measures *(Critical outcome)*	The preponderance of evidence supports the effectiveness of CHW interventions to improve disease-specific morbidity measures such as HbA1c, blood pressure, and asthma symptom-free days. Evidence type: Systematic reviews of RCTs, observational studies, and quasi-experimental studies	Paying CHWs to engage in long duration, high-intensity interventions likely entails moderate cost. However, many of the studies indicate cost-effectiveness and sometimes cost-savings. Prioritizing the use of CHWs for patients with preventable utilization and more severe chronic disease is likely an effective use of resources.	Patients would likely strongly value culturally and linguistically specific interventions. There is likely moderate variability in patients' desire to engage with CHWs that is likely dependent on the location and type of intervention.	For Oregon's Coordinated Care Organizations (CCOs), CHWs can be funded through health-related services, but there is variability among the CCOs in terms of funding sources.
Emergency department visits *(Critical outcome)*	The preponderance of evidence supports the effectiveness of CHW interventions for reducing preventable utilization of the emergency department and inpatient care, and economic analyses suggest that CHW interventions are cost-saving or cost-effective (at a willingness-to-pay threshold of $50,000 per quality-adjusted life-year (QALY). Evidence type: Systematic reviews of RCTs, observational studies, quasi-experimental studies, and economic analyses			

Outcomes	Estimate of Population Health Effect *Evidence Type*	Resource Allocation	Values and Preferences	Other Considerations
Hospitalizations *(Important outcome)*	The preponderance of evidence supports the effectiveness of CHW interventions for reducing preventable utilization of the emergency department and inpatient care, and economic analyses suggest that CHW interventions are cost-saving or cost-effective (at a willingness-to-pay threshold of $50,000 per QALY). Evidence type: Systematic reviews of RCTs, observational studies, quasi-experimental studies, and economic analyses			
Medication adherence *(Important outcome)*	The preponderance of evidence supports the effectiveness of CHW interventions for improving medication adherence (particularly for antiretroviral and antihypertensive drugs). Evidence type: Systematic reviews of RCTs, observational studies, and quasi-experimental studies			
Harms *(Important outcome)*	Harms of CHW interventions were generally not reported in the summary literature; although some studies found no evidence of effectiveness, very few studies identified negative effects of CHWs on reported outcomes. Evidence type: Systematic reviews of RCTs, observational studies, and quasi-experimental studies			

Background

The American Public Health Association (APHA, 2018) defines a CHW as "a frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served. This trusting relationship enables the worker to serve as a liaison/link/intermediary between health/social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery."

In Oregon, CHWs can receive certification from the Oregon Health Authority (OHA) or the Oregon Home Care Commission. CHWs are part of a broader group of traditional health workers, which also includes personal health navigators, peer support specialists, peer wellness specialists, birth doulas, family support specialists, and youth support specialists (Oregon Department of Human Services, n.d.). To be certified as a CHW in Oregon, applicants must meet all these criteria:

- Be 18 years or older
- Not be listed on the Medicaid provider exclusion list
- Have successfully completed all training requirements for certification
- Submit all required documentation and a completed application
- Pass a criminal background check

In lieu of the training requirement, applicants can instead submit the following by June 30, 2021:

(A) A minimum of one letter of recommendation from any previous employer for whom traditional health worker services were provided between January 1, 2008, and June 30, 2021; and
(B) Verifiable evidence of working or volunteering in the capacity of a community health worker, peer wellness specialist, or personal health navigator for at least 3,000 hours between January 1, 2008, and June 30, 2021; or
(C) Verifiable evidence of working or volunteering in the capacity of a peer support specialist for at least 2,000 hours between January 1, 2008, and June 30, 2021 (OHA, n.d.).

To maintain certification status, all CHWs must complete 20 hours of approved continuing education plus one and half to three hours of an oral health training during every three-year renewal period (OAR 410-180-0325).

Evidence Review

Scott et al., 2018

This is a fair-quality meta-review that aggregates systematic reviews of CHW interventions published between 2005 and 2017. The review was prepared on behalf of the World Health Organization. The quality assessment reflects concerns about the overlapping inclusion of individual studies in the aggregated reviews and about the authors' search strategy failing to identify the Jack et al. systematic review (2016) that is summarized below. Overall, the authors identified 122 reviews, of which 29 were pertinent to CHW interventions in high-income countries (countries with gross national income exceeding approximately $12,000 per capita). The authors adopted a broad definition of CHWs as "health workers based in communities (i.e., conducting outreach from their homes and beyond primary health care facilities or based at peripheral health posts that are not staffed by doctors or nurses) who are either paid or volunteer, who are not professionals, and who have fewer than 2 years of training, but at least some training, if only for a few hours." The individual systematic reviews that were identified

through the meta-review as pertinent to the scope statement for this coverage guidance are summarized in Table 1.

Table1. Relevant Systematic Reviews Included in Scott et al., 2018

Author, Year Focus of review k (# of included studies) Study types QA (as assessed in the meta-review)	Definition of CHW and/or types of Interventions	Effectiveness and cost-effectiveness findings	Relevant subgroup analyses or patient characteristics
Viswanathan et al., 2009 AHRQ review of CHW interventions for multiple conditions or health promotion activities k = 68 RCTs and comparative observational studies High	"A CHW: • Performs health-related tasks to create a bridge between community members, especially hard-to-reach populations, and the health care system (i.e., performs tasks extending beyond peer counseling or peer support alone). • Has health training associated with the intervention; training is shorter than that of a professional worker (i.e., training does not form part of a tertiary education certificate). • Is recognized (or can be identified) as a member of the community in which he or she works, defined by but not limited to, geographic location,	Two studies in patients with diabetes found statistically significant improvements in HbA1c (range -0.5% to -2%) with CHW interventions; two studies found no difference in HbA1c Among three studies examining hypertension outcomes, one cohort study found that a CHW intervention improved the proportion of patients achieving blood pressure less than 160/95, but two RCTs did not find significant between-group differences in BP control; a fourth study found that patients who received CHW visits were more likely to follow-up on their blood pressure in the emergency department than a control group	The two studies that showed improvement in HbA1c used high-intensity interventions Three of the four hypertension studies focused on African American or Latino participants in large cities

	race or ethnicity, and exposure or disease status."	One RCT comparing assertive community treatment (ACT) to ACT plus CHWs or brokered case management for patients with serious mental illness found no significant difference in days in stable housing between the three groups, but the ACT and ACT+CHW arms showed significantly improved Brief Psychiatric Rating Scale Symptom scores compared to the case management group; there was no difference in health care utilization between the ACT and ACT+CHW arms; an economic analysis found no difference in total costs between arms over 18 months Two RCTs of high-intensity CHW interventions for children with persistent asthma reached mixed results; one trial (comparing high-intensity CHW to low-intensity CHW) found no significant differences in symptomatic days; the second trial (comparing high-intensity CHW to an educational booklet) found that the CHW intervention resulted in fewer symptoms among the group of children who were not on a	Participants in the SMI study were homeless or at risk of homelessness

		controller medication; both studies found significant reductions in unscheduled medical care for the high-intensity CHW arms; an economic analysis from the first trial suggested that high-intensity CHW interventions saved $57 to $80 per child over a two-month period and that the program would be cost-effective if the reduced utilization continued for three to four years	
Hunt et al., 2011 Review of community health advisors (CHA) for people with diabetes k = 16 RCTs, nonrandomized controlled trials, quasi-experimental studies Very low	Interventions describing the following were included: CHAs, lay health educators, peer advisors, peer coaches, CHWs, community diabetes advisors, community health ambassadors, church diabetes advisors, peer supporters, and promotoras CHA characteristics were "underreported" but generally were of the same ethnic group as participants Training for CHAs "varied greatly" across studies CHA roles and activities included supporting,	Among studies reporting on change in HbA1c, seven studies found significant reductions in HbA1c; one study found a statistically nonsignificant reduction in HbA1c Two studies assessing LDL and triglycerides found significant improvements in these indices Blood pressure was significantly reduced in one study; two studies found nonsignificant reductions in blood pressure In one study, a CHW intervention decreased mean expenditure for health service	

	educating, advocating, and facilitating	reimbursement through reductions in emergency department and inpatient utilization; in a second study a combined nurse care manager and CHW intervention reduced emergency department visits	The two studies reporting reductions in utilization studied African American patients and one examined Medicaid beneficiaries
Abbott et al., 2017 Review of home visiting programs (including but not limited to paraprofessionals and CHWs) to eliminate health disparities k = 39 Experimental or quasi-experimental designs Very low	Paraprofessionals and CHWs were not defined, but they were distinguished from other home visiting professionals including nurses, firefighters, physicians, pharmacists, and social workers	Two studies reported on asthma outcomes and one study reported on HIV outcomes The first study recruited children from 4 zip codes with a recent emergency department visit or hospitalization for asthma and found significant pre-post reductions in emergency department visits, hospitalizations, symptom scores, and missed school or work days after an intervention that included nurse case management and home visits by nurses or CHWs; using a comparison of the intervention group with a matched community cohort, the authors calculated that the intervention was cost-saving with a return on investment ratio of 1.46	Participants in this study were mainly low-income African Americans or Latinos

		The second study compared a CHW intervention (Healthy Homes program) to usual care for children with uncontrolled asthma; the intervention group had statistically significant increases in symptom-free days and reduced urgent health care visits The third study reported significantly greater antiretroviral adherence and viral suppression for patients receiving nurse and CHW structured home visits compared to a usual care group	The participants in this study were Medicaid beneficiaries and mainly Latino and African American The majority of patients in this study were over age 60
Palmas et al., 2015 Systematic review and meta-analysis of CHW interventions for people with diabetes k = 13 (9 with at least 12-month follow-up included for meta-analysis) RCTs High	Varied across included studies Eight studies examined CHW-only interventions; other interventions used CHWs in conjunction with certified diabetes educators, nurses, or dieticians CHW training varied significantly across studies CHW activities included education, support, and advocacy in most studies	For the primary meta-analysis of mean reduction in HbA1c at 12 months or beyond, CHW interventions resulted in greater HbA1c reduction than controls (mean difference -0.21%, 95% CI -0.11 to -0.32, I^2=37%)	Two studies with the greatest number of CHW contacts reported the largest reductions in HbA1c (-0.4% and -0.57%) Meta-regression showed participants with higher baseline HbA1c had the largest improvement with the intervention
Raphael et al., 2013	Lay health workers (LHWs) were defined as “individuals	Among seven studies deemed to be at low (or unclear) risk of	Most of the studies in pediatric asthma focused on urban minority

Systematic review of LHWs for pediatric chronic disease k = 17 RCTs	who were specifically trained to deliver a health-related intervention but who had no formal professional or paraprofessional training in health care" Theoretical frameworks included cognitive theory, self-efficacy theory, and social support theory Most LHWs were selected for "social congruence" with the study population; limited information on training or supervision LHW roles included support, education, modeling, and coaching, and modes of delivery included home visits, phone calls, group meetings, and e-mails "Interventions were heterogeneous in frequency, mode, and duration of interactions between lay health workers and subjects. Several interventions were multifaceted, including both one-on-one and group interactions."	bias examining LHW interventions for asthma, four found improvements in asthma symptoms; three reported no significant differences; one study found that LHW interventions decreased missed school or work days, whereas two studies did not find a difference in this outcome; among five studies reporting on urgent health care utilization, two found a statistically significant decrease in the LHW group, whereas three found no significant differences; one of the studies reported an incremental cost-effectiveness ratio for the LHW intervention of -$597 per asthma exacerbation-free day gained (indicating that the intervention was cost-saving) Among two studies reporting on clinical outcomes for children with type 1 diabetes, both reported that LHW interventions significantly improved glycemic control and reduced emergency department visits and hospitalizations	populations and populations with low socioeconomic status

Shommu et al., 2016 Scoping review of community navigators for immigrants and ethnic minorities k = 30 Study designs not specified Very low	"Community navigators are trained, culturally perceptive healthcare workers who serve as a link between patients and healthcare providers in order to reduce healthcare disparities. They may also be referred to as patient navigators, CHWs, outreach workers, promotoras, lay health educators, health advocates, peer counselors or medical assistants." "Navigators were selected from the community based on their cultural competence, interpersonal skills and helping attitude towards their community and were given comprehensive training by health professionals. Major roles of the navigators included providing culturally tailored health education, lifestyle workshops, self-care training and guidance to overcome barriers to accessing the healthcare system…The navigators also distributed educational materials and videos describing healthy diet, exercise, self-monitoring of health risk factors, handling	Two studies of Reaching Immigrants through Community Empowerment (RICE) that focused on Sikh and Korean immigrants at risk of diabetes examined glucose measurements; one study found a significant reduction in glucose levels; the other did not find a statistically significant difference Five studies of Spanish-speaking community navigators for patients with type 2 diabetes found statistically significant reductions in HbA1c and one study found a significant reduction in emergency department visits; in two other studies there was no significant difference in HbA1c between navigator and control groups; in one study reporting an economic analysis navigator interventions for diabetes had a cost-effectiveness of $33,319 per QALY gained Eight studies found that community navigators using the NHLBI Heart Health curriculum led to significant improvements	HbA1c reduction was positively correlated with more frequent navigator contacts in one of the studies These studies were conducted in Latino, Black, South Asian, and Filipino populations in the U.S.

	emergency conditions and medication adherence."	in cardiovascular risk factors including blood pressure and lipids	
Brownstein et al., 2007 Systematic review of CHW interventions for hypertension k = 14 RCTs, quasi-experimental, and observational studies Low	"Community health workers were broadly defined as any health workers who carried out functions related to healthcare delivery, were trained as part of an intervention, had no formal paraprofessional or professional designation, and had a relationship with the community being served." "The characteristics of CHWs were not as well described as those of the study participants. The CHWs, predominantly women, were recruited from the community, and resembled the participants in race/ethnicity and socioeconomic background." Roles included education, adherence assessment, BP measurement, and navigation/mediation	Five studies found significant improvements in antihypertensive adherence in the CHW groups Nine of the 10 studies reporting on blood pressure control found statistically significant improvements in blood pressure with the CHW intervention; one study did not find a significant difference in blood pressure control between the CHW and control arms	These studies mainly targeted middle-aged minority populations in the U.S., and four of the studies were exclusively conducted among African Americans living in Baltimore

The authors of the meta-review reached the following conclusions from the studies in Table 1 about CHW interventions in high-income countries:

- There is mixed evidence that CHW interventions modestly reduce hyperglycemia in diabetic patients
- There is inconsistent evidence that CHW interventions for children with asthma increase the number of symptom-free days, and insufficient evidence in adolescents with asthma
- CHW interventions may lead to modest reductions in health care utilization and fewer missed school days for children with chronic diseases
- CHW interventions may lead to improvements in blood pressure in adults with hypertension and improve adherence to antihypertensive medications

The authors made several observations that pertain to features associated with the success of various CHW outcomes, although in most cases these features were not studied to ascertain their effects on clinical outcomes:

- Although training improves the knowledge and skills of CHWs, there is no direct evidence linking training to health outcomes
- Few CHW programs adequately describe the details of supervisory structures, and this lack of attention to supervision could reduce CHW empowerment
- Although CHWs with higher levels of education may be more effective at certain tasks, these CHWs may also have higher rates of attrition
- There is "very little" evidence that supervisory performance evaluations for CHWs correlate with performance measured in research settings
- CHW satisfaction with incentives or remuneration is associated with CHW motivation and performance
- Community acceptance of CHWs is associated with CHW retention, motivation, and performance

Ultimately, the authors of the meta-review concluded that the evidence on CHW effectiveness can "help policymakers identify a range of options to consider," but they cautioned that evidence must be "contextualized and adapted in different contexts to inform policy practice."

Jack et al., 2016

This is a good-quality systematic review of the effects of CHWs on health care utilization in the United States. It was not included in the meta-review discussed above. The review included studies of CHW interventions for adults or children with at least one chronic disease. CHWs were defined as "individuals who work primarily in a health-related role, have no professional or paraprofessional training in healthcare or social work, and were selected for their role largely because of their familiarity with a community or population." Eligible studies were cohort studies, quasi-experimental studies, or RCTs that reported quantitatively on health care costs or utilization. Overall, the authors identified 34 studies: 16 RCTs, eight pre-post studies, six cohort studies, and four cost-effectiveness analyses. These studies examined CHW interventions of variable intensity for asthma (14 studies), diabetes (six studies), hypertension (one study), HIV (one study), and stroke (one study). Patients with "prior preventable health care use" were the focus of 14 studies, and 14 studies focused on low-income populations including Medicaid beneficiaries and uninsured patients. The following were the key findings:

- 19 studies examined changes in emergency department visits
    - Three of eight RCTs found significant reductions in emergency department visits with CHW interventions, the remaining five found no statistically significant differences
    - Five of eight pre-post studies found significant reductions in emergency department visits with CHW interventions, one found no statistically significant difference, and two did not report tests of statistical significance
    - Two of three cohort studies found significant reductions in emergency department visits with CHW interventions; one study found no statistically significant difference

- 17 studies examined changes in hospital admissions
    - Six of seven RCTs found no significant reductions in admissions with CHW interventions; one study found a statistically significant decrease in admissions
    - Five of seven pre-post studies found significant reductions in admissions with CHW interventions; two did not report tests of statistical significance
    - Two of three cohort studies found significant reductions in admissions with CHW interventions; one study reported decreased hospitalization costs without a test of statistical significance

- Eight studies examined changes in urgent care visits
    - Two of four RCTs found significant reductions in urgent care visits with CHW interventions; two found no statistically significant decreases
    - Three of four pre-post studies found significant reductions in urgent care visits with CHW interventions; one study showed a nonsignificant increase

- Nine studies examined changes in medication adherence
    - Three of three RCTs found no statistically significant differences in medication adherence with CHW interventions
    - Three of four pre-post studies found improved medication adherence with CHW interventions
    - One cohort study found improved medication adherence with CHW interventions

- Eight of 11 studies found that CHW interventions reduced overall costs; three studies concluded that CHW interventions did not result in cost savings

- Two studies reporting cost-effectiveness estimates of CHW interventions for patients with diabetes found that the cost per QALY ranged from $10,995 to $33,319

Jack et al. observed that certain groups appeared more likely to benefit from CHW interventions including children with asthma, diabetic patients, and patients with low socioeconomic status or public insurance. Comparing RCTs that showed significant reductions in utilization measures to those that found no significant differences, positive trials were more likely to focus on people with prior preventable utilization, describe the CHW as integrated into a care team, and have an intervention lasting at least one year.

The authors cautioned that the review was limited by the high degree of heterogeneity in the interventions, populations, and outcome measurements. They also raised the concern of publication bias, particularly among nonrandomized studies. Lastly, they noted that savings from CHW

interventions might accrue over many years and studies might not accurately estimate the long-term effects of these interventions.

Centers for Disease Control and Prevention (CDC) Community Guide, 2017

This is a non-published systematic review of CHW interventions for diabetes management prepared on behalf of the Community Preventive Services Taskforce, which included 44 studies.

Overall, the Community Guide estimated that CHW interventions for diabetes management led to a:

- Median increase of 6.6% in proportion of patients with HbA1c at goal of < 7.0% (seven studies)
- Median decrease in mean HbA1c of 0.49% (36 studies)
    - For patients with baseline HbA1c > 9%, the mean decrease in HbA1c was 1.85%
- 26% decrease in the number of emergency department visits (one study), 44% reduction in the rate of emergency department visits (one study), and 0.18 fewer emergency department visits per person (one study)
- 5% reduction in the rate of emergency department visits (one study) or 0.45 more admissions per person (one study)
- Median increase of 7% in proportion of patients with total cholesterol at goal (one study)

The authors observed that the improvement in glycemic control was similar for CHW interventions alone and when CHWs were integrated in team-based care models.

The authors also summarized 13 economic analyses and concluded that CHW interventions for diabetes management had a median cost per person of $585 per year (13 studies), resulted in a median change in per-person health care costs of -$72 per year (four studies), and that the median cost per QALY gained was $38,276 (five studies).

The Community Guide recommendations resulting from this evidence review are summarized in the guidelines section of this coverage guidance.

CDC Community Guide, 2015

This is a non-published systematic review of CHW interventions for cardiovascular disease prepared on behalf of the Community Preventive Services Taskforce. The methods are not specifically described on the CDC community guide website, but presumably followed the standard methods established by this group. The review identified 31 studies, of which 18 studies used designs considered to be of "greatest/moderate suitability" and 13 studies used designs deemed "least suitable."

For greatest/moderate suitability studies of CHWs in a team-based care model, the Community Guide estimated that CHW interventions led to a:

- Median increase of 17.6% in proportion of patients with blood pressure at goal (four studies)
- Median reduction of systolic blood pressure of 6.0 mmHg (six studies)
- Median reduction of diastolic blood pressure of 1.1 mmHg (six studies)
- Median increase of 7% in proportion of patients with total cholesterol at goal (one study)

The authors observed that other CHW intervention models resulted in smaller or nonsignificant improvements in these outcomes.

The authors also summarized nine economic analyses and concluded that CHW interventions had a median cost per person of $329 per year (eight studies), resulted in a median change in per person in health care costs of $82 per year (seven studies), and that the median cost per QALY gained was $17,670 (four studies).

The Community Guide recommendations resulting from this evidence review are summarized in the guidelines section of this coverage guidance.

Evidence Summary

Although results from individual studies are mixed and there are few meta-analytic estimates of effect owing to the high degree of heterogeneity in these studies, it appears that the preponderance of evidence related to CHW interventions for adults and children with chronic conditions in high-income countries supports the conclusion that CHWs improve various chronic-disease-specific health outcomes, reduce emergency department visits and hospitalizations, and are cost-saving or cost-effective at commonly established willingness-to-pay thresholds. There is relatively more evidence in support of CHWs for children with asthma and adults with diabetes or hypertension; there is relatively less evidence for patients with HIV or serious mental illness. In some studies, greater improvement in outcomes was associated with higher-intensity interventions or in populations with more severe chronic disease at baseline. In addition, some studies suggest that interventions targeting individuals with prior preventable utilization, longer interventions, and interventions that use CHWs as part of an integrated care team are associated with greater reductions in health care utilization.

These conclusions are limited by an extraordinarily high degree of heterogeneity in nearly every aspect of CHW studies (including heterogeneity in target populations, CHW definitions, intervention components, intervention intensity, and the theoretical basis of the intervention). In addition, authors of several systematic reviews raised concerns about the possibility of publication bias in this body of literature. Finally, in some studies, CHW interventions were combined with other interventions such as case management or assertive community treatment, which makes it difficult to establish the precise contribution of CHWs to the observed effects. In spite of these limitations, most authors regard CHW interventions as potentially promising for improving outcomes among underserved and vulnerable populations in high-income countries.

Policy Landscape

Policies

The National Academy for State Health Policy (NASHP) has an online database of CHW models across the 50 states (NASHP, 2018). About 25% of states have a certification program for CHWs, although the certification is voluntary in some states. At least three states, Oregon, Alaska, and Minnesota, require CHWs to be certified in order for these services to be reimbursed by Medicaid.

State Medicaid programs are diverse in their models for using and funding CHWs. About 50% of states pay for CHWs with Medicaid funds. Most of these states are paying for CHWs through managed care contracts. In states where Medicaid is not paying for CHWs, grants and other funding sources are

sometimes used to fund CHW interventions. In the states using other funds, CHWs are often hired through federally qualified health centers (FQHCs), community-based organizations, and universities.

Recommendations from Others

Two sources were identified in the search for recommendations on the use of CHWs: The Community Guide from the Community Preventive Services Task Force (CPSTF) and guidelines from the World Health Organization (WHO).

Community Preventive Services Task Force

The CPSTF recommends interventions that engage CHWs for cardiovascular disease prevention, diabetes prevention, and diabetes management. All three of these intervention areas were rated as being cost-effective (The Community Guide, n.d.).

The CPSTF defines CHWs as frontline public health workers who serve as a bridge between underserved communities and health care systems. CHWs can be from or have a unique understanding of the community being served.

Cardiovascular Disease Prevention

Strong evidence was found on effectiveness in improving blood pressure and cholesterol when CHWs are engaged in a team-based care model. Sufficient evidence was found for the effectiveness of CHW interventions for health education and to increase self-reported health behaviors in clients at increased risk for cardiovascular disease. These CHW interventions aim to reduce cardiovascular risk factors by providing culturally appropriate education, social support, informal counseling, and connection with services (The Community Guide, 2015).

Diabetes Prevention

Sufficient evidence was found on the effectiveness of CHW interventions in improving glycemic level control and weight-related outcomes among people at increased risk for type 2 diabetes. These interventions aim to reduce risk factors for type 2 diabetes by improving diet, physical activity, and weight management. The programs may include education about diabetes prevention and lifestyle changes, informal counseling, and extended support, delivered one-on-one or in group sessions in homes or community-based settings (The Community Guide, 2016).

Diabetes Management

Strong evidence was found on the effectiveness of CHW interventions in improving glycemic and lipid control and reducing health care use among patients with type 2 diabetes. These interventions aim to improve diabetes care and self-management behaviors among patients through education, coaching, or social support to improve diabetes testing and monitoring, medication adherence, diet, physical activity, or weight management. CHWs deliver these programs one-on-one or in group sessions in patients' homes, or in community or clinical settings (The Community Guide, 2017).

World Health Organization

The WHO published a guideline in 2018 on health policy and system support for CHW programs (WHO, 2018). The WHO guidelines list the following primary health care services for which there is some evidence of CHW effectiveness:

- Maternal and newborn health—Reducing neonatal mortality and morbidity through home-based preventive and curative care; promoting the uptake of reproductive, maternal,

newborn and child health behaviors and services, including antenatal care and promotion of breastfeeding

- Child health—Immunization uptake, integrated management of newborn and childhood illnesses (e.g., for malaria, pneumonia, and diarrhea); health education
- Communicable diseases—Prevention, diagnosis, treatment, and care of malaria and tuberculosis; counseling, treatment and care for HIV/AIDS; control of neglected tropical diseases (e.g., Buruli ulcer), influenza prevention
- Noncommunicable diseases—Behavior change (diet change, physical activity); increased care utilization (cancer screening, making and keeping appointments); diabetes, hypertension, and asthma management and care
- Public health and global health security—Working as cultural brokers and facilitating patient access to care for underserved groups
- Mental health—Providing psychosocial, and/or psychological interventions to treat or prevent mental, neurological, or substance abuse disorders
- Sexual and reproductive health—Providing contraception; increasing uptake of family planning

The WHO guideline also includes a series of recommendations in the areas of selection, education, and certification of CHWs, management and supervision, and integration into and support by health systems and communities.

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Appendix A. Evidence 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.

Appendix B. Methods

Scope Statement

Populations

Adults or children with at least one of the following: asthma, diabetes, hypertension, heart failure, HIV, serious mental illness, high utilizers

Population scoping notes: Exclude studies from low- and middle-income countries, patients with substance use disorders, doulas, prenatal programs

Interventions

Engagement with a community health worker (CHW)

Intervention exclusions: None

Comparators

Usual care without a CHW; other methods of patient engagement and activation

Outcomes

Critical: Disease-specific morbidity measures, emergency department visits, hospitalizations

Important: Medication adherence, harms

Considered but not selected for the GRADE table: Engagement or patient activation scores

Key Questions

KQ1: What is the effectiveness of CHWs for improving health outcomes and reducing health care utilization in adults and children with chronic diseases?

KQ2: Does the effectiveness of CHWs vary by:

a. Patient characteristics
b. Type of chronic condition(s) being addressed
c. Comorbid conditions
d. Characteristics of CHW intervention (intensity, setting, methods of engagement)
e. Characteristics of the CHWs

KQ3: What are the harms of CHWs?

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 2014.

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 using the search terms community health worker and traditional health worker. The search was limited to publications in English published since 2014.

Searches for clinical practice guidelines were limited to those published since 2014. 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 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 or clinical practice guidelines.

MSI Community Health Workers CHW

Question: Should the findings of the Multisector Intervention Report on Community Health Workers be appended to the end of the Prioritized List?

Question source: Evidence-based Guidelines Subcommittee (EbGS)

Issue: EbGS has approved a draft MSI on community health workers.

Multisector Interventions

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

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

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

Characteristics of effective interventions include:

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

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

- HIV
- Serious mental illness
- Congestive heart failure

Recommendations:

1) **Add a Multisector Intervention Statement**

MULTISECTOR INTERVENTION STATEMENT 4: COMMUNITY HEALTH WORKERS
To improve beneficial outcomes in patients with chronic conditions, the preponderance of evidence supports that community health workers (CHWs) serving as a part of an integrated care team appear to improve outcomes in:

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

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

Characteristics of effective interventions include:

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

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

- HIV
- Serious mental illness
- Congestive heart failure

This Multisector Interventions statement is based on a HERC evidence review, Community Health Workers for Patients with Chronic Disease https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx

2) Add numbers to the other Multisector Interventions statements

a. MULTISECTOR INTERVENTIONS STATEMENT 1: TOBACCO PREVENTION AND CESSATION, INCLUDING DURING PREGNANCY
b. MULTISECTOR INTERVENTIONS STATEMENT 2: PREVENTION OF EARLY CHILDHOOD CARIES
c. MULTISECTOR INTERVENTIONS STATEMENT 3: PREVENTION AND TREATMENT OF OBESITY

HERC Multisector Intervention Report:
Community Health Workers for Patients with Chronic Disease
Disposition of Public Comments

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Commenters

Identification	Stakeholder
A	Angie Kuzma, MPH, Policy & Data Manager, Oregon Community Health Workers Association *[Submitted March 1, 2019]*

Public Comments

ID/#	Comment	Disposition
A1	In Appendix B: Methods (p. 27) of the Multisector Interventions Report, it states "patients with substance use disorder" were excluded from the population scope. Why was this the case? I recommend that HERC include patients with substance use disorder in the population scope because community health workers do in fact work with this population.	*The scope of the evidence review was determined by EbGS and HERC. In order to make this very large topic more manageable, some conditions for which CHWs may be useful were excluded.*
A2	In Appendix B: Methods (p. 27) of the Multisector Interventions Report, the interventions scope appears to be limited to "engagement with a community health worker." a. I recommend that HERC also expand the intervention scope to include "navigator," "patient health navigator," "community navigator," and similar terms. The scope of work for community health workers and patient navigators overlaps considerably. This overlap results in varying degrees of conflation between community health workers and navigators, both in practice and in the literature.	*Our search strategy and the included sources captured interventions using the terms suggested here. In particular, the broad search strategy employed for the World Health Organization meta-review summarized evidence on several of these types of providers including navigators, health advisors, and promotores.*

ID/#	Comment	Disposition
	b. I recommend that HERC also expand the intervention scope to include "community health advisor," "community health representative," "promotore," and "promotores de salud" because community health workers are also referred to as these names in the literature.	
A3	It appears the Multisector Interventions Report did not include the American Journal of Public Health or the Health Resources and Services Administration website as core search sources, both of which include a large body of evidence regarding the effectiveness of community health workers for the conditions included in the scope of the Multisector Interventions Report.	*Individual studies or systematic reviews that have been published in the American Journal of Public Health were included in the meta-review conducted for WHO and/or were also included in the evidence reviewed by the Community Preventive Services Task Force. Our evidence searches are customarily limited to peer-reviewed published studies and a limited set of gray literature sources.*
A4	Regarding evidence demonstrating the effectiveness of community health workers for people living with HIV/AIDS: a. Please see the following citation and many other related articles available in the American Journal of Public Health: Serena Rajabiun et al. "The Influence of Housing Status on the HIV Continuum of Care: Results From a Multisite Study of Patient Navigation Models to Build a Medical Home for People Living With HIV Experiencing Homelessness," American Journal of Public Health 108, no. S7 (December 1, 2018): pp. S539-S545. DOI: 10.2105/AJPH.2018.304736 b. The Health Resources & Services Administration-funded Initiative: Building a Medical Home for Multiply-Diagnosed HIV-positive Homeless Populations, 2012-2017 is a wealth of evidence for how community health workers (again, sometimes called "navigators") improve antiretroviral adherence among people experiencing other co-morbidities and homelessness.	*Thank you for providing this citation. However, our usual methods only consider randomized controlled trials (RCTs) published after the systematic reviews that inform the coverage guidance. The citation included is a before-and-after study in which all patients received a health navigator intervention and the main comparison is for outcomes for patients who attained stable housing compared to those who continued to experience homelessness. Thus, it would be difficult to establish the precise contribution of the navigation intervention in improving outcomes.* *Thank you for highlighting the HRSA resource. However, as noted above, we consider limited gray literature sources in our reviews and the results of grant programs*

ID/#	Comment	Disposition
		do not inform our deliberations. The listed peer-reviewed publication associated with this grant program is a qualitative study involving interviews and focus groups with clinic staff and health navigators and would not meet our inclusion criteria. *Lastly, we would like to emphasize that our review does not conclude that CHWs are ineffective for patients in developed countries who have HIV, only that there is relatively less evidence in this population compared to those with other chronic conditions.*

References Provided by Commenters

ID	References
A	Serena Rajabiun et al. "The Influence of Housing Status on the HIV Continuum of Care: Results From a Multisite Study of Patient Navigation Models to Build a Medical Home for People Living With HIV Experiencing Homelessness," American Journal of Public Health 108, no. S7 (December 1, 2018): pp. S539-S545. DOI: 10.2105/AJPH.2018.304736

Section 5.0

Coverage Guidances

Health Evidence Review Commission (HERC)

Coverage Guidance: Temporary Percutaneous Mechanical Circulatory Support with Impella Devices

DRAFT for 8/8/2019 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 coronary artery bypass graft (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. Appropriate effort should be made to consult with a heart failure and transplant cardiologist, but coverage is recommended in circumstances where consultation cannot reasonably be obtained without endangering the patient's life and the treating physician believes the patient meets the criteria above.

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.

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/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
All-cause mortality *(Critical outcome)*	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 ●●○○ *(Low confidence, based on 1 RCT, n = 448)*	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/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Major adverse cardiovascular events *(Critical outcome)*	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 *(Important outcome)*	Not applicable			
Successful bridge to transplant *(Important outcome)*	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)*	No significant difference in major bleeding complications between Impella and IABP ●○○○ *(Very low confidence, based on 1 observational study, n = 75)* No significant difference in vascular complications between Impella and IABP ●○○○ *(Very low confidence, based on 1 observational study, n = 75)*			

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 weak recommendation because of the low confidence in the estimate of effect.

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 *(Critical outcome)*	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 *(Critical outcome)*	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 *(Important outcome)*	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)*	Range of reported vascular complications Impella: 3% to 25% IABP: 0% to 6.4% ●○○○ *(Very low confidence, based on 4 studies, n = 222)* Range of reported bleeding complications Impella: 8% to 38.4% IABP: 0% to 32.2% ●○○○ *(Very low confidence, based on 5 studies, n = 272)*			

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/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
Recommendation: 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. Appropriate effort should be made to consult with a heart failure and transplant cardiologist, but coverage is recommended in circumstances where consultation cannot reasonably be obtained without endangering the patient's life and the treating physician believes the patient meets the criteria above.				

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/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
All-cause mortality *(Critical outcome)*	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 *(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			

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/ *Confidence in Estimate*	Resource Allocation	Values and Preferences	Other Considerations
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.				
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 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
					Aortic rupture 0% Impella 1.6% IABP Bleeding 38.4% Impella 32.2% IABP CVA 0% Impella 3.2% IABP Bacteremia 0% Impella 4.7% IABP
Manzo-Silberman 2013 n = 78	Survival at day 3 34% Impella 67% IABP Survival with CPC score 1 at 28 days	NR	NR	NR	Hemolytic anemia 6% Impella 0% IABP Sustained ventricular arrhythmias

	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

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 end 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 ≥ 1.5m^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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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.

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 transseptal 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.

Temporary Percutaneous Mechanical Circulatory Support with Impella Devices

Question: Should the draft Coverage Guidance on Temporary Percutaneous Mechanical Circulatory Support with Impella Devices be adopted as previously recommended by EbGS or modified?

Question source: HERC, EbGS

Issue summary:

At the January 17, 2019 HERC meeting there was discussion of the draft coverage guidance approved by the Evidence-based Guidelines Subcommittee. HERC decided to table the decision for approving the draft coverage guidance based on compelling discussion with a number of interventional cardiologists and other stakeholders. HERC recommended revisiting the Coverage Guidance with more investigation into the implementation considerations and specific subpopulations who may be affected by the coverage guidance. Some of the concerns that were raised included:

1. Need for clarity about which patient circumstances would be affected by which coverage decisions
2. Clinical implementation concerns: With patients in cardiogenic shock, there may not be time to determine 1) if a patient is a candidate for LVAD or transplant and 2) connect with an Advanced Heart Failure and Cardiac Transplantation cardiologist (there are reportedly only 3 of these in Oregon)
3. The evidence does not support the utility of the Impella 2.5 device. Should coverage vary depending on type of devices?
4. Is there evidence that PCI improves angina symptoms in high-risk patients?

Following this HERC discussion, this topic was re-addressed at the April 2019 EbGS meeting. EbGS discussion focused on addressing the primary concerns above raised by HERC. Staff also identified some interim data that was published about harms of these devices.

Concern 1: Clarity about which patient circumstances would be affected by which coverage decisions

Population	Evidence	EbGS Draft Coverage Recommendation	Impact on patients
Elective high-risk PCI for chronic stable angina	No difference in effectiveness compared to IABP for mortality and Major Adverse Cardiovascular Events (MACE). No evidence on angina in this subpopulation, and a	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	May not get high-risk PCI. Options would be PCI without Impella, CABG or optimized medical therapy.

	benefit is controversial in a normal risk population.	artery disease (*weak recommendation*).	
NSTEMI without cardiogenic shock	No evidence	Impella 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%	CABG, high-risk PCI without Impella, or optimized medical therapy
Cardiogenic shock, ischemic	Ineffective. Higher risk of harms.	Only if bridge to LVAD or transplant	Very ill patients. Options would be IABP, ECMO, pressors
Cardiogenic shock, nonischemic	No evidence	Only if bridge to LVAD or transplant	Very ill patients. Options would be IABP, ECMO, pressors
Bridge to LVAD or transplant	None. None likely to come.	Recommended for coverage (*weak recommendation*) only for patients with cardiogenic shock who might be candidates for left	Very sick patients who may need to be transferred out of state.

		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.	

Concern 2: Timeliness of determination of candidacy for LVAD and transplant and availability of Advanced Heart Failure and Cardiac Transplantation Cardiologists in Oregon

There are reportedly only 3 Advanced Heart Failure and Cardiac Transplantation cardiologists in Oregon. However, two major health systems are actively developing cardiac transplant programs and it is possible these numbers will increase. In current practice, a phone conversation could be had with these specialists before deciding whether to place an Impella for many patients. However, EbGS discussed that sometimes a phone consultation would not be able to take place because of the acuity of the decision. EbGS members thought it was important to allow coverage in this scenario if the cardiologist believed that the patient would likely meet criteria and the urgency was very high. They also discussed that cardiologists would generally be able to quickly ascertain if the patient was clearly not a candidate for LVAD or transplant. EbGS therefore proposed adding the following language:

> Appropriate effort should be made to consult with a heart failure and transplant cardiologist, but coverage is recommended in circumstances where consultation cannot reasonably be obtained without endangering the patient's life and the treating physician believes the patient meets the criteria above.

Concern 3: Evidence regarding specific devices.

Given the evidence does not support the utility of the Impella 2.5 device, a question was raised about potentially having differential coverage recommendations of the different devices. EbGS discussed a recommendation for noncoverage of a device with proven lack of benefit (i.e. Impella 2.5), and a simultaneous positive coverage recommendation for devices with no evidence of benefit and thought this was not appropriate. The idea that unstudied devices could get a "free pass" seemed inappropriate. Therefore, EbGS recommended making no statements about which specific devices were recommended for coverage or noncoverage.

Concern 4: Is there evidence that PCI improves angina symptoms in high-risk patients?

Additional evidence considered (Dr. Obley reviewed, see separate document)

Conclusions: We did not identify any trials comparing high-risk PCI to medical management for relief of angina in patients with stable ischemic heart disease. The benefit of non-high-risk PCI over medical management for stable angina remains a subject of continued debate, and most studies comparing PCI to medical management are likely to be confounded by a well-established placebo effect on anginal symptoms.

Additional interim publications about harms

Additional publications that are relevant (published after search dates of the draft coverage guidance and would have not met inclusion criteria), for new information about harms:

Schrage, 2019

- Retrospective cohort study of IABP-SHOCK II patients in European tertiary care centers
- 237 patients matched to 237 patients from the IABG-SHOCK II trial
- Results:
    - No difference in 30-day all-cause mortality (48.5% versus 46.4%, *P*=0.64).
    - Severe or life-threatening bleeding (8.5% versus 3.0%, *P*<0.01) and peripheral vascular complications (9.8% versus 3.8%, *P*=0.01) occurred significantly more often in the Impella group.

FDA letter, February 4, 2019

- Letter of concern regarding Impella RP interim post-approval study (PAS)
- Higher mortality rate than previously observed in the pre-market clinical studies
- The primary endpoint is survival to 30 days post device explant or hospital discharge (whichever is longer), or to the start of next longer-term therapy
- Primary survival endpoint achieved in:
    - Pre-market studies: 44 out of 60 patients (73.3 percent) met the survival endpoint
    - Post-approval study: Only 4 out of the 23 enrolled PAS patients (17.4 percent) met the primary survival endpoint
- 16 of the 23 patients would not have met the pre-market study criteria. Specifically, before getting the Impella RP system implanted, patients in the PAS were more likely than the pre-market clinical study patients to have been in cardiogenic shock for longer than 48 hours, experienced an in-hospital cardiac arrest, been treated with an intra-aortic balloon pump, or suffered a pre-implant hypoxic or ischemic neurologic event.

EbGS discussion about these included recognizing that the FDA letter illustrates that the Impella RP system is being used much more broadly than the indications and criteria in the pre-market studies with remarkably poorer outcomes.

HERC Staff Recommendations

1. **Modify the draft Coverage Guidance box language as recommended by the Evidence-based Guidelines Subcommittee**

DRAFT 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. Appropriate effort should be made to consult with a heart failure and transplant cardiologist, but coverage is recommended in circumstances where consultation cannot reasonably be obtained without endangering the patient's life and the treating physician believes the patient meets the criteria above.

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

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 HEART DISEASE	Added in 2013 as part of CPT 2012 code review without discussion
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 CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE/TRANSPLANT
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
    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. Appropriate effort should be made to consult with a heart failure and transplant cardiologist, but coverage is recommended in circumstances where consultation cannot reasonably be obtained without endangering the patient's life and the treating physician believes the patient meets the criteria above.

Temporary percutaneous mechanical circulatory support with Impella devices is not included on this or any other line for elective high-risk PCI for patients with stable coronary artery disease.

High-risk PCI Evidence Summary

Subcommittee Question: What is the evidence that high-risk PCI for stable ischemic heart disease results in relief of angina or improves quality of life?

Response:

The strongest line of evidence that PCI improves anginal symptoms and/or quality of life comes from the COURAGE trial. As reported by Weintraub and colleagues in 2008[1], PCI with optimal medical management led to greater improvements in angina relief (as measured by freedom from angina and the Seattle Angina Questionnaire [SAC]) compared to optimal medication therapy alone. The incremental benefit of PCI was mainly apparent through 24 to 36 months of follow-up; beyond 36 months PCI did not confer an apparent symptomatic benefit over medical management. Some critics of COURAGE contend that the absence of more durable symptomatic relief may have resulted from the near-exclusive use of bare metal stents (which are more prone to in-stent restenosis). In any case, the population included in the COURAGE trial does not reflect the population that was considered for high-risk PCI in the PROTECT II study. Specifically, patients with LVEF <30% (or <35% with 3 vessel disease) and patients with unprotected left main disease were excluded from COURAGE, as were patients with coronary arteries deemed unsuitable or hazardous for PCI.

Other randomized trials of PCI compared to medical management for stable coronary disease have been conducted and were summarized in a systematic review by Stergiopolous and colleagues in 2014[2]. In the meta-analysis, the authors found that PCI did not reduce angina during follow-up compared with medical management (OR 0.90, 95% CI 0.57 to 1.44, I^2=72%). The major outlying trial with respect to angina relief was the FAME 2 study[3] which used fractional flow reserve to establish the presence of a physiologically significant stenosis prior to randomization and which found a significant improvement in the PCI group, albeit at a follow-up interval of just over 6 months. Like the COURAGE trial, all of the trials included in this systematic review and meta-analysis excluded patients who would generally be regarded as constituting a high-risk PCI group.

Most of the evidence establishing the symptomatic benefit of PCI over medical management is complicated by the existence of a significant placebo effect. This placebo effect has been well characterized in drug trials (for example, in the ERICA trial[4] patients treated with ranolazine experienced an improvement of 22.5 points on the SAQ angina frequency score compared with an improvement of 18.5 points in the placebo group). Mitigating the placebo effect in trials of procedures or devices requires sham controls and few such studies have been conducted. Indeed, the sham-controlled ORBITA study[5] has raised the question of whether PCI affords any symptomatic benefit over high-intensity medical management. It should be noted that the population studied in ORBITA would not meet the definition of high-risk PCI. Similarly, a procedure known as transmyocardial laser revascularization was largely abandoned after the sham controlled DIRECT trial[6] found no benefit for angina relief. Parenthetically, the DIRECT trial offers additional evidence of a substantial placebo effect on angina symptoms, and the magnitude of that placebo effect may be greater for procedural placebos than for drug placebos.

Conclusions:

We did not identify any trials comparing high-risk PCI to medical management for relief of angina in patients with stable ischemic heart disease. The benefit of non-high-risk PCI over medical management

for stable angina remains a subject of continued debate, and most studies comparing PCI to medical management are likely to be confounded by a well-established placebo effect on anginal symptoms.

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2. Stergiopoulos K, Boden WE, Hartigan P, et al. Percutaneous coronary intervention outcomes in patients with stable obstructive coronary artery disease and myocardial ischemia: a collaborative meta-analysis of contemporary randomized clinical trials. *JAMA Intern Med.* 2014;174(2):232-240. doi: 10.1001/jamainternmed.2013.12855.
3. De Bruyne B, Pijls NHJ, Kalesan B, et al. Fractional Flow Reserve–Guided PCI versus Medical Therapy in Stable Coronary Disease. *New England Journal of Medicine.* 2012;367(11):991-1001. doi: 10.1056/NEJMoa1205361.
4. Stone PH, Gratsiansky NA, Blokhin A, Huang IZ, Meng L. Antianginal efficacy of ranolazine when added to treatment with amlodipine: the ERICA (Efficacy of Ranolazine in Chronic Angina) trial. *J Am Coll Cardiol.* 2006;48(3):566-575. doi: 10.1016/j.jacc.2006.05.044.
5. Al-Lamee R, Thompson D, Dehbi HM, et al. Percutaneous coronary intervention in stable angina (ORBITA): a double-blind, randomised controlled trial. *Lancet.* 2018;391(10115):31-40. doi: 10.1016/s0140-6736(17)32714-9.
6. Leon MB, Kornowski R, Downey WE, et al. A blinded, randomized, placebo-controlled trial of percutaneous laser myocardial revascularization to improve angina symptoms in patients with severe coronary disease. *J Am Coll Cardiol.* 2005;46(10):1812-1819. doi: 10.1016/j.jacc.2005.06.079.

Circulation

ORIGINAL RESEARCH ARTICLE

Impella Support for Acute Myocardial Infarction Complicated by Cardiogenic Shock

Matched-Pair IABP-SHOCK II Trial 30-Day Mortality Analysis

Editorial, see p 1259

Benedikt Schrage, MD
et al

BACKGROUND: Percutaneous mechanical circulatory support devices are increasingly used in acute myocardial infarction complicated by cardiogenic shock (AMI-CS), despite limited evidence for their effectiveness. The aim of this study was to evaluate outcomes associated with use of the Impella device compared with intra-aortic balloon pump (IABP) and medical treatment in patients with AMI-CS.

METHODS: Data of patients with AMI-CS treated with the Impella device at European tertiary care hospitals were collected retrospectively. All patients underwent early revascularization and received optimal medical treatment. Using IABP-SHOCK II (Intraaortic Balloon Pump in Cardiogenic Shock II) trial inclusion and exclusion criteria, 372 patients were identified and included in this analysis. These patients were matched to 600 patients from the IABP-SHOCK II trial. The following baseline criteria were used as matching parameters: age, sex, mechanical ventilation, ejection fraction, prior cardiopulmonary resuscitation, and lactate. Primary end point was 30-day all-cause mortality.

RESULTS: In total, 237 patients treated with an Impella could be matched to 237 patients from the IABP-SHOCK II trial. Baseline parameters were similarly distributed after matching. There was no significant difference in 30-day all-cause mortality (48.5% versus 46.4%, P=0.64). Severe or life-threatening bleeding (8.5% versus 3.0%, P<0.01) and peripheral vascular complications (9.8% versus 3.8%, P=0.01) occurred significantly more often in the Impella group. Limiting the analysis to IABP-treated patients as a control group did not change the results.

CONCLUSIONS: In this retrospective analysis of patients with AMI-CS, the use of an Impella device was not associated with lower 30-day mortality compared with matched patients from the IABP-SHOCK II trial treated with an IABP or medical therapy. To further evaluate this, a large randomized trial is warranted to determine the effect of the Impella device on outcome in patients with AMI-CS.

CLINICAL TRIAL REGISTRATION: URL: https://www.clinicaltrials.gov. Unique identifier: NCT03313687.

The full author list is available on page 1257.

Key Words: cardiopulmonary resuscitation ■ Impella ■ intraaortic balloon pumping ■ myocardial infarction ■ shock, cardiogenic

Sources of Funding, see page 1257

https://www.ahajournals.org/journal/circ

Clinical Perspective

What Is New?

- This is the largest study to evaluate the Impella in the setting of acute myocardial infarction complicated by cardiogenic shock using a matched control group.
- Routine use of an Impella was not associated with a lower 30-day all-cause mortality rate compared with the use of intra-aortic balloon pump or medical treatment.
- The findings were consistent through the tested subgroups.
- The presented data indicate a higher incidence of vascular complications, relevant bleeding, and sepsis with the Impella.

What Are the Clinical Implications?

- To further evaluate the presented findings, a prospective, randomized trial of Impella treatment in acute myocardial infarction complicated by cardiogenic shock is warranted.
- Early Impella implantation, eg, preshock Impella implantation and Impella implantation before percutaneous coronary intervention, should be the focus of such a trial.

Despite the use of early revascularization, patients with acute myocardial infarction complicated by cardiogenic shock (CS) (AMI-CS) have a high mortality. Supportive medical therapies, like inotropes, have failed to improve outcome in this setting. Therefore, percutaneous mechanical circulatory support devices are widely used in clinical practice. The intra-aortic balloon pump (IABP) was the first and most extensively used device in this setting. Early studies suggested that the IABP induces a relevant afterload reduction and an improvement in coronary blood flow.[1] In 2012, the results of the IABP-SHOCK II trial (Intra-aortic Balloon Pump in Cardiogenic Shock), the first adequately sized randomized controlled trial on the usage of IABP in AMI-CS, were published. This trial randomized 600 patients with AMI-CS upon presentation to the hospital to receive either IABP or best available medical care. The trial, which is the second largest randomized trial in AMI-CS, showed no survival benefit for utilization of the IABP compared with best medical treatment. The results were consistent through all tested subgroups.[2]

The Impella (Abiomed, Danvers, MA), a catheter-based microaxial flow pump placed across the aortic valve into the left ventricle (LV), actively pumps blood from the LV into the aorta, thereby unloading the LV. From the Impella platform, 2 different device models (Impella 2.5 and CP) are increasingly used in the setting of AMI-CS.[3,4] Experimental studies and clinical case series have shown that this device increases cardiac output, unloads the LV, and improves coronary blood flow.[5–7]

The IMPRESS in Severe Shock trial (Impella Versus IABP Reduces Mortality in STEMI Patients Treated With Primary PCI in Severe Cardiogenic Shock) was the first randomized pilot trial to assess and compare the efficacy and safety of the Impella CP versus IABP in patients with AMI-CS. This trial, however, did not show a survival benefit in the 48 patients included.[8] As prespecified in the trial manual, this explorative study was not continued after no changes in outcome were reported. Importantly, most patients included presented with postresuscitation syndrome with high mortality rates.[9] Nevertheless, a recent meta-analysis, joining heterogeneous data from all the small trials available with a total of 95 patients with and without cardiogenic shock, also found a neutral outcome for this treatment option.[10]

Therefore, we performed a study to provide further insight of using percutaneous mechanical circulatory support devices for treatment of AMI-CS. A multinational database of AMI-CS cases treated with an Impella device was built to compare the outcome to patients from the IABP-SHOCK II trial in a matched fashion.

METHODS

Study Design

A multinational, retrospective registry was built to investigate outcomes associated with Impella treatment for AMI-CS (NCT03313687). From a total of 570 patients in the registry, those patients who were in accordance with the IABP-SHOCK II trial inclusion and exclusion criteria were selected.[2] Moreover, a matching to further harmonize baseline criteria to the IABP-SHOCK II trial population was performed in a 1:1 fashion (see below). The study was carried out according to the principles of the Declaration of Helsinki. Written informed consent was not obtained and was not needed by local law, as only anonymized patient data have been used. This approach was approved by the local ethics committee. The authors designed the study, gathered and analyzed the data, vouched for the data and analysis, wrote the paper, and decided to publish. The statistical analyses were made by independent personnel from the Myocardial Infarction Research Institute in Ludwigshafen, Germany. Abiomed Inc., the manufacturer of the Impella device family, did not have any involvement in the registry or the design of the study, the analysis of the data, the preparation of the manuscript, or the decision to submit the manuscript for publication. The presented data will not be made available to other researchers for purposes of reproducing the results.

Study Population

From 13 European centers and the EUROSHOCK registry,[11] patients with cardiogenic shock (definition in accordance with IABP-SHOCK II trial, systolic blood pressure below 90 mm Hg or need of inotropes, and clinical signs of pulmonary congestion, and signs of impaired end-organ perfusion[12]) complicating

acute myocardial infarction (either ST-segment–elevation myocardial infarction or non–ST-segment–elevation myocardial infarction) who were treated with an Impella device and who underwent early revascularization were included into the registry. Eligible devices were the Impella 2.5, which provides up to 2.5 L/min of cardiac support and is inserted via a 12 French sheath into the femoral artery, as well as the Impella CP, which provides up to 4.0 L/min of cardiac support and is inserted via a 14 French sheath. From this sample of patients, those patients who did not meet the IABP-SHOCK II trial inclusion criteria were excluded. Most importantly, patients above 90 years of age, patients who had undergone cardiopulmonary resuscitation (CPR) for more than 30 minutes, and patients who had onset of shock more than 12 hours before presenting to the hospital were excluded.[12] All patients were treated at a tertiary care hospital with sufficient experience in the usage of the Impella device and with access to an intensive care unit. Besides early revascularization and implantation of an Impella, all patients received best available medical care in accordance with guidelines.[13–16]

Study End Points

The primary end point of this analysis was 30-day all-cause mortality in the overall cohort. The secondary end point was 30-day all-cause mortality in the subgroup of Impella patients versus IABP-treated patients from the IABP-SHOCK II trial. The safety end points were reinfarction, stent thrombosis, ischemic or hemorrhagic stroke, peripheral ischemic complications requiring surgery or an intervention, life-threatening or severe bleeding, mild bleeding, and sepsis within the first 30 days after hospital admission. These end points are in accordance with those used in the IABP-SHOCK II trial.[12]

Matching With the IABP-SHOCK II Trial Population

Only the patients who met the IABP-SHOCK II trial inclusion and exclusion criteria were selected and matched to the original patients from the IABP-SHOCK II trial in a 1:1 fashion. As there were no differences between the control arm and the IABP arm regarding the primary or any of the secondary end points in the IABP-SHOCK II trial, all 600 patients were used for matching regardless of the randomized study arm. The following baseline criteria were used as matching parameters as they have been identified as statistically relevant by logistic regression or as clinically meaningful: age, sex, mechanical ventilation, ejection fraction (steps of 10%), prior CPR, and lactate (<2.5 mmol/L, 2.5–5.0 mmol/L, and >5 mmol/L) (Table I in the online-only Data Supplement). Only this matched cohort was used for the outcome analyses.

Statistical Analysis

Categorical variables were presented as counts and percentages and were compared by McNemar test. Continuous variables were presented as median and interquartile range or mean and SD and were compared by signed-rank test. Thirty-day mortality rates were estimated using the Kaplan-Meier method. Survival between groups was compared using the log-rank test. Forest plots were used to visualize the hazard ratio including 95% CI of the primary end point for specified subgroups. The Breslow-Day test was used to analyze the interaction of the treatment assignment and subgroup factors. Additionally, in-detail subgroup analyses were performed. All tests were 2-tailed, and P values <0.05 were considered significant. SAS statistical package version 9.4 (IBM, Cary, NC) was used for computations.

RESULTS

Patients

From the registry, a total of 372 patients with AMI-CS who were treated with an Impella device between July 2007 and December 2017 met the IABP-SHOCK II trial inclusion and exclusion criteria. The 30-day all-cause mortality rate of these 372 patients was 47.0%. These patients were assigned to the matching procedure. Two-hundred thirty-seven Impella patients were matched to 237 patients from the IABP-SHOCK II trial (Figure 1). Data on patients who did not meet the enrollment criteria and on patients who were not successfully matched are displayed in Tables II and III in the online-only Data Supplement.

Within the matched Impella group, 156 patients were treated with an Impella CP, and 74 patients were treated with an Impella 2.5 (with missing data on the used device in 7 cases). Within the IABP-SHOCK II trial group, 115 patients were treated with an IABP, and 122 patients were drawn from the control group. The Impella was implanted before the procedure in 38.1% as compared with an IABP implantation before the procedure in 5.8% (P<0.01).

The baseline characteristics, as well as the clinical presentation parameters, were well balanced between the matched groups (Tables 1 and 2). Notably, CPR (35.9%) and mechanical ventilation (55.3%) were equally present in both groups. Lactate (4.1 [2.4, 8.1] versus 3.9 [2.3, 7.8] mmol/L, P=0.12), mean blood pressure (67.0 [55.0, 76.0] versus 68.0 [60.0, 80.0] mm Hg, P=0.11), use of catecholamines (77.0% versus 76.5%, P=0.55), and ejection fraction (25% [20, 35] versus 25% [20, 35], P=0.40) were well comparable between the matched groups. However, significantly more IABP-SHOCK II patients were treated by thrombolysis within 24 hours before presentation (1.2% versus 8.9%, P<0.01) and presented with non–ST-segment–elevation myocardial infarction (30.9% versus 40.5%, P=0.04). Furthermore, there was a higher incidence of coronary 3-vessel disease (46.1% versus 55.7%, P=0.05) and a lower glomerular filtration rate (52.6 [36.0, 73.6] versus 49.9 [36.2, 65.6] mL/min, P=0.01) in the IABP-SHOCK II group. On the other hand, Impella-treated patients had a lower systolic blood pressure (88.0 [74.0, 100.0] versus 89.0 [79.0, 110.0] mm Hg, P=0.03) and diastolic blood pressure (51.0 [42.0, 61.0] versus 55.0 [45.0, 65.0] mm Hg, P=0.04). Limiting the analysis to IABP-treated patients from the IABP-SHOCK II trial versus matched Impella patients showed comparable results.

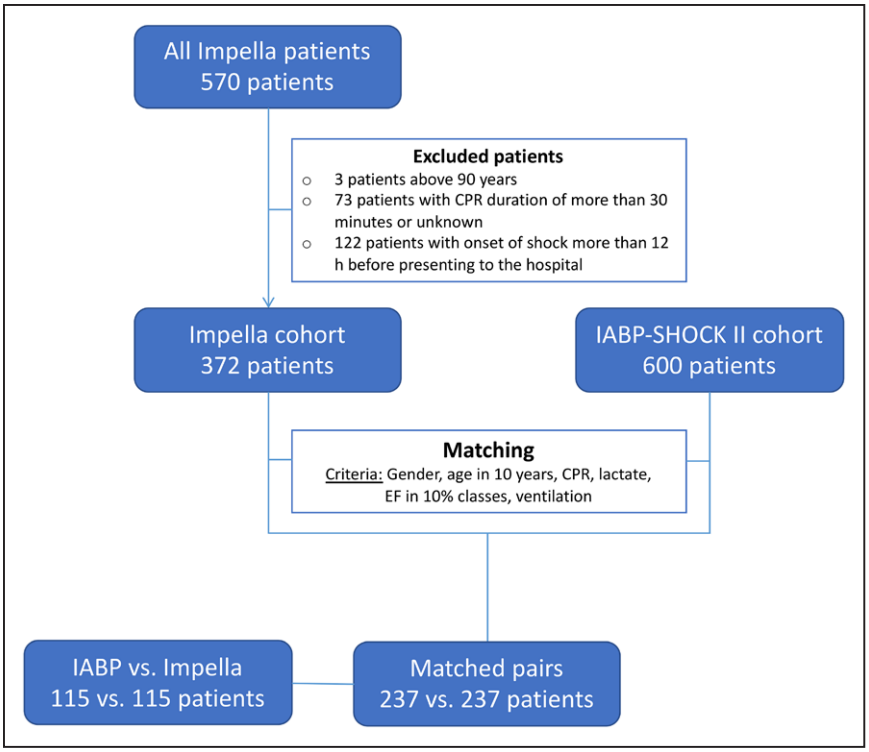

Figure 1. Flow chart of the matching procedure.
From a total of 570 patients in the registry, 372 met the IABP-SHOCK II inclusion and exclusion criteria. These patients were then matched to 600 patients from the IABP-SHOCK II trial. Hereafter, 237 matched pairs were used for the outcome analyses. Of these pairs, 115 compared IABP-treated patients versus matched Impella patients. CPR indicates cardiopulmonary resuscitation; EF, ejection fraction; IABP, intra-aortic balloon pump; and IABP-SHOCK II, Intra-aortic Balloon Pump in Cardiogenic Shock.

Outcome

All 474 (237 patients treated with an Impella and 237 control patients from the IABP-SHOCK II trial) matched patients were included into the outcome analysis, with information on 30-day all-cause mortality being available in all patients. At 30 days, there was no statistically significant difference in all-cause mortality between the Impella and the IABP-SHOCK II group (48.5% versus 46.4%, *P*=0.64; Figure 2). This result was consistent in all subgroups except patients without prior use of catecholamines, where a lower 30-day mortality rate was observed with Impella treatment (Figure 3). Regarding the secondary end points, there were no statistically significant differences regarding 30-day rates of reinfarction, stroke, stent thrombosis, or moderate bleeding. However, severe or life-threatening bleedings (8.5% versus 3.0%, *P*<0.01), peripheral vascular complications (9.8% versus 3.8%, *P*=0.01), and sepsis (35.3% versus 19.4%, *P*<0.01) were significantly higher within the Impella group (Table 3). Again, limiting the analysis to IABP-treated patients from the IABP-SHOCK II trial

Table 1. Baseline Characteristics of the Matched Patients

	Impella vs IABP-SHOCK II Trial Patients			Impella vs IABP-Treated Patients From the IABP-SHOCK II Trial		
	Impella Group (n=237)	Control (n=237)	*P* Value	Impella Group (n=115)	Control (n=115)	*P* Value
Age (y)	70.0 (60.0, 78.0)	71.0 (60.0, 78.0)	0.73	71.0 (60.0, 78.0)	73.0 (60.0, 78.0)	0.31
Sex (male)	162 (68.4)	162 (68.4)	1.00	76 (66.1)	76 (66.1)	1.00
Current smoking	52 (27.4)	78 (33.1)	0.36	24 (25.8)	36 (31.6)	0.25
Hypertension	142 (62.0)	168 (71.2)	0.03	73 (65.2)	86 (75.4)	0.07
Hypercholesterolemia	95 (43.0)	95 (40.4)	0.62	51 (47.7)	45 (39.8)	0.32
Diabetes mellitus	78 (34.1)	86 (36.3)	0.67	39 (34.8)	45 (39.1)	0.56
Prior myocardial infarction	46 (20.1)	62 (26.2)	0.10	18 (16.1)	32 (27.8)	0.03
Prior stroke	21 (9.1)	24 (10.1)	0.75	9 (8.0)	12 (10.4)	0.49
Known peripheral artery disease	33 (14.2)	33 (13.9)	0.89	14 (12.4)	18 (15.7)	0.47
Prior PCI	42 (21.1)	52 (22.0)	0.81	17 (17.2)	28 (24.6)	0.12
Prior CABG	17 (7.3)	15 (6.3)	0.71	6 (5.3)	8 (7.0)	0.59

Values are presented as frequencies (percentages) or median (interquartile range). CABG indicates coronary artery bypass graft; IABP-SHOCK II, Intraaortic Balloon Pump in Cardiogenic Shock; and PCI, percutaneous coronary intervention.

Table 2. Clinical Characteristics of the Matched Patients

	Impella vs IABP-SHOCK II Trial Patients			Impella vs IABP-Treated Patients From the IABP-SHOCK II Trial		
	Impella Group(n=237)	Control(n=237)	*P* Value	Impella Group(n=115)	Control(n=115)	*P* Value
Lactate (mmol/L)	4.1 (2.4, 8.1)	3.9 (2.3, 7.8)	0.12	3.5 (2.1, 6.5)	3.5 (2.1, 7.1)	0.57
Glomerular filtration rate (ml/min)	52.6 (36.0, 73.6)	49.9 (36.2, 65.6)	0.01	56.0 (35.7, 74.8)	46.1 (33.8, 61.1)	<0.01
Thrombolysis within 24 h	2 (1.2)	21 (8.9)	<0.01	0 (0.0)	13 (11.3)	<0.01
Cardiopulmonary resuscitation	85 (35.9)	85 (35.9)	1.00	42 (36.5)	42 (36.5)	1.00
Mechanical ventilation	131 (55.3)	131 (55.3)	1.00	63 (54.8)	63 (54.8)	1.00
Systolic blood pressure (mm Hg)	88.0 (74.0, 100.0)	89.0 (79.0, 110.0)	0.03	89.0 (79.5, 103.0)	88.5 (79.0, 104.0)	0.20
Diastolic blood pressure (mm Hg)	51.0 (42.0, 61.0)	55.0 (45.0, 65.0)	0.04	53.0 (42.0, 65.0)	55.0 (45.0, 66.0)	0.43
Mean blood pressure (mm Hg)	67.0 (55.0, 76.0)	68.0 (60.0, 80.0)	0.11	69.0 (60.0, 80.0)	68.0 (59.0, 80.0)	0.54
Use of catecholamines	181 (77.0)	166 (76.5)	0.55	93 (80.9)	83 (79.0)	0.60
Heart rate (bpm)	95.0 (78.0, 110.0)	93.0 (75.0, 110.0)	0.44	94.5 (78.0, 101.0)	94.5 (75.0, 110.0)	0.85
STEMI	139 (67.1)	141 (59.5)	0.10	60 (58.8)	64 (55.7)	0.65
NSTEMI	64 (30.9)	96 (40.5)	0.04	41 (40.2)	51 (44.3)	0.55
Diseased vessel: 1	56 (24.3)	50 (21.3)	0.42	27 (24.1)	22 (19.3)	0.29
Diseased vessel: 2	67 (29.1)	54 (23.0)	0.19	35 (31.3)	30 (26.3)	0.43
Diseased vessel: 3	106 (46.1)	131 (55.7)	0.05	50 (44.6)	62 (54.4)	0.11
Diseased vessel: none	1 (0.4)	2 (0.8)	0.56	0 (0.0)	1 (0.9)	1.00
Culprit-lesion only revascularization	136 (69.4)	157 (69.5)	1.00	66 (70.2)	73 (66.4)	0.86
Left ventricular ejection fraction (%)	25.0 (20.0, 35.0)	25.0 (20.0, 35.0)	0.40	27.0 (20.0, 35.0)	27.5 (20.0, 35.0)	0.66

Values are presented as frequencies (percentages) or median (interquartile range). IABP-SHOCK II indicates Intraaortic Balloon Pump in Cardiogenic Shock; NSTEMI, non–ST-segment–elevation myocardial infarction; and STEMI, ST-segment–elevation myocardial infarction.

versus matched Impella patients showed comparable results.

Subgroup Analyses

Patients With Cardiopulmonary Resuscitation

The subgroup analysis of patients with prior CPR showed similar results to those presented above. Within this subgroup, 85 Impella patients could be matched to 85 patients from the IABP-SHOCK II trial. Baseline criteria were without relevant differences between both groups. On presentation, mechanical ventilation was equally present in both groups (97.6%), and there were no differences in lactate (5.9 [3.7, 11.9] versus 5.2 [3.5, 10.0] mmol/L, *P*=0.27), use of catecholamines (86.9% versus 84.5%, *P*=0.67), or ejection fraction (27.5% [20.0, 34.0] versus 25.0% [20.0, 35.0], *P*=0.37). However, the mean blood pressure was lower in the Impella group (62.0 [47.0, 70.0] versus 70.0 [60.0, 81.0] mm Hg, *P*=0.02). Again, there was no significant difference in the 30-day all-cause mortality (52.9% versus 55.3%, *P*=0.75). Data on this subgroup are displayed in Table IV in the online-only Data Supplement.

Patients Without Cardiopulmonary Resuscitation

Among patients without prior CPR, 152 Impella patients could be matched to 152 patients from the IABP-SHOCK II trial. The baseline criteria were well balanced between both groups. On presentation, mechanical ventilation was present in 31.6% of the patients in both groups. Lactate (3.3 [2.0, 5.8] versus 3.2 [1.8, 6.8] mmol/L, *P*=0.86), glomerular filtration rate (49.8 [33.8, 70.0] versus 48.5 [35.0, 67.9] mL/min, *P*=0.55), mean blood pressure (70.0 [57.5, 79.0] versus 68.0 [59.5, 80.0] mm Hg, *P*=0.91), use of catecholamines (71.5% versus 71.4%, *P*=1.00), and ejection fraction (25.0% [20.0, 35.0] versus 25.0% [20.0, 35.0], *P*=0.67) were comparable. In this analysis, 30-day all-cause mortality was 46.1% in the Impella group compared with 41.4% in the IABP-SHOCK II group (*P*=0.42).

Timing of Device Implantation

To evaluate the impact of timing of Impella implantation on outcomes, subgroup analyses comparing patients with Impella implantation before percutaneous coronary intervention (PCI) and patients with Impella implantation after PCI with their respective matched pairs from the IABP-SHOCK II trial were performed. In both subgroups, the baseline criteria were balanced and comparable.

In the subanalysis of patients with Impella implantation after PCI versus the matched pairs from the IABP-SHOCK II trial, there was no difference regarding the primary end point of 30-day all-cause mortality (48.4% versus 49.2%, *P*=0.89). The subanalysis of patients with

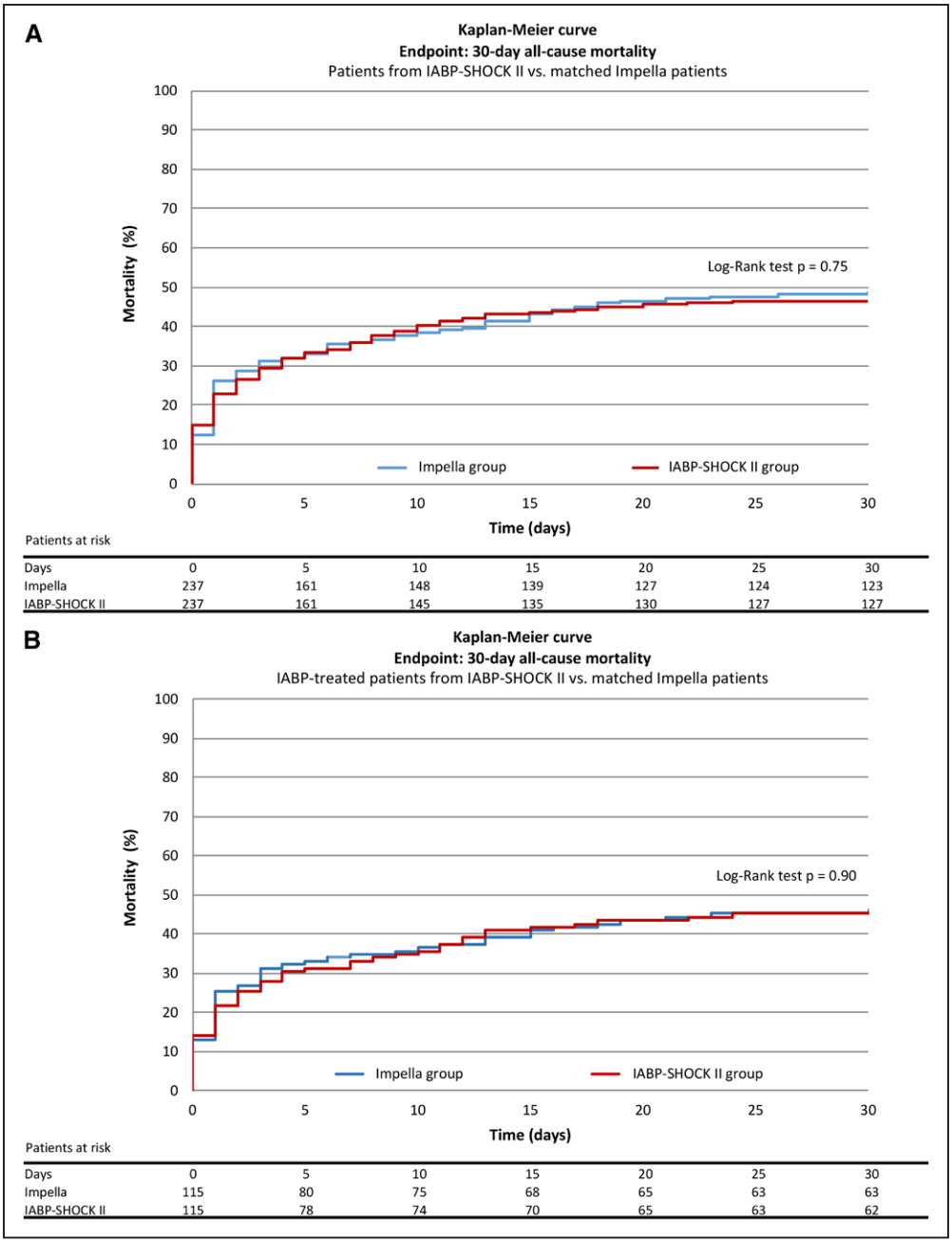

Figure 2. Kaplan-Meier curves for the primary end point.
The Kaplan-Meier method was used to assess the primary end point of 30-day all-cause mortality. (**A**) In this analysis, there were no significant differences between the Impella group (blue line) and the matched control group from the IABP-SHOCK II trial (red line). (**B**) Limiting this analysis to IABP-treated patients versus matched Impella patients did not change the results. IABP indicates intra-aortic balloon pump; and and IABP-SHOCK II, Intra-aortic Balloon Pump in Cardiogenic Shock.

Impella implantation before PCI versus the matched pairs from the IABP-SHOCK II trial also showed no statistically significant difference in 30-day all-cause mortality (42.7% versus 53.3%, *P*=0.18).

Impella CP and Impella 2.5

The Impella CP provides a higher cardiac output support as compared with the Impella 2.5. Therefore, subgroup analyses comparing patients treated with an Impella CP and patients treated with an Impella 2.5 with their respective matched pairs from the IABP-SHOCK II trial were performed.

Within both subgroups, there were no relevant differences regarding the baseline characteristics. Furthermore, both groups were well comparable after matching was performed. In both subanalyses, there were no statistically differences regarding the primary end point of 30-day all-cause mortality (41.9% versus 44.6%, *P*=0.73 for the matched Impella 2.5 subanalysis and

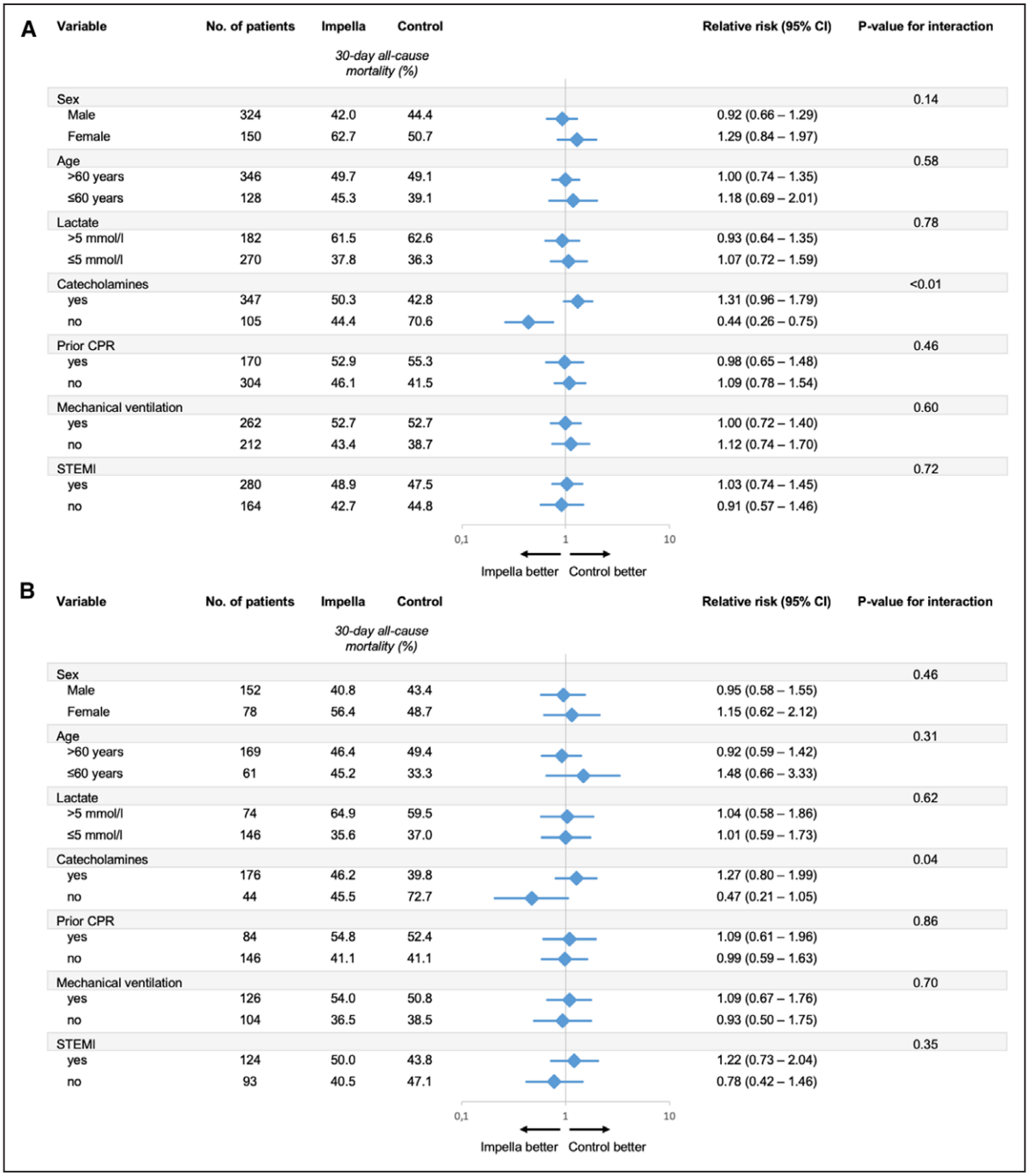

Figure 3. Subgroup analysis for the primary end point.
To evaluate the effect of Impella treatment for acute myocardial infarction complicated by cardiogenic shock in different subgroups, a forest plot showing the relative risk (with 95% CIs) of the primary end point 30-day all-cause mortality was used. In the subgroup of patients without prior treatment with catecholamines, Impella implantation improved the primary end point. (**A**) In all other tested subgroups, there were no significant differences regarding the primary end point. (**B**) Comparable results were observed when limiting the analysis to IABP-treated patients versus matched Impella patients. CPR indicates cardiopulmonary resuscitation; IABP, intra-aortic balloon pump; and STEMI, ST-segment–elevation myocardial infarction.

51.3% versus 46.8%, *P*=0.41 for the matched Impella CP subanalysis).

DISCUSSION

In this retrospective analysis of patients with AMI-CS, routine use of an Impella device was not associated with lower 30-day all-cause mortality as compared with matched patients from the IABP-SHOCK II trial.

Experimental studies have proven the beneficial effect of percutaneous mechanical circulatory support devices such as the Impella on cardiac hemodynamics in cardiogenic shock. Additionally, an augmentation of cardiac output with an increase in mean arterial pres-

Table 3. Clinical Outcome of the Matched Patients

	Impella vs IABP-SHOCK II Trial Patients			Impella vs IABP-Treated Patients From the IABP-SHOCK II Trial		
	Impella Group (n=237)	Control (n=237)	*P* Value	Impella Group (n=115)	Control (n=115)	*P* Value
30-day all-cause mortality	115 (48.5)	110 (46.4)	0.64	53 (46.1)	52 (45.2)	0.90
Reinfarction in hospital	7 (3.5)	6 (2.5)	0.56	4 (4.0)	4 (3.5)	0.71
Stent thrombosis in hospital	1 (0.6)	3 (1.3)	0.32	0 (0.0)	2 (1.7)	0.22
Stroke in hospital	6 (3.5)	6 (2.5)	0.76	2 (2.3)	1 (0.9)	0.56
Peripheral ischemic complications requiring intervention in hospital	23 (9.8)	9 (3.8)	0.01	11 (9.6)	4 (3.5)	0.05
Moderate bleeding in hospital	48 (20.3)	40 (16.9)	0.32	22 (19.1)	24 (20.9)	0.72
Life-threatening or severe bleeding in hospital	20 (8.5)	7 (3.0)	<0.01	12 (10.4)	2 (1.7)	<0.01
Sepsis in hospital	73 (35.3)	46 (19.4)	<0.01	39 (38.2)	20 (17.4)	<0.01

Values are presented as frequencies (percentages) or median (interquartile range). IABP-SHOCK II indicates Intraaortic Balloon Pump in Cardiogenic Shock.

sure with consistent improvement in end-organ perfusion could be shown in Impella-treated subjects in clinical case series.[5–7] With the increasing use of mechanical assist devices and registries, another retrospective study found a mortality benefit of early versus deferred Impella implantation in AMI-CS patients.[17] In addition, the randomized, controlled, and prospective IMPRESS in Severe Shock trial evaluated percutaneous mechanical circulatory support devices in AMI-CS. In this study, hemodynamic support with the Impella CP device, which delivers up to 4.0 L/min, was associated with a 30-day survival rate similar to that achieved with an IABP.[8] However, because of the explorative design, this study was underpowered, and a large proportion of postresuscitation cases might have influenced the results.[9]

Outcomes Associated With Impella Support in AMI-CS

With the lack of sufficiently powered randomized trials, the present analysis sought to compare a large consecutive cohort of AMI-CS patients from high-volume European centers treated with an Impella as adjunctive therapy in patients with AMI-CS and to compare it to a matched control group obtained from the IABP-SHOCK II trial. The study groups were well matched regarding baseline and clinical presentation criteria. In our analysis, there was no significant difference regarding 30-day all-cause mortality with Impella treatment as compared with the control group, and this finding was consistent among all tested subgroups. In addition to variables used for matching, other cardiogenic shock surrogate markers of outcomes were also comparable between groups. Most importantly, there were no significant differences regarding use of catecholamines or overall hemodynamic findings. Notably, there were no differences regarding culprit-lesion or multivessel PCI, which has recently been shown to affect outcomes with detrimental effects of attempted full revascularization in AMI-CS patients.[18]

A recent topic of discussion is the timing of mechanical support intervention in AMI-CS attributable to data suggesting improved outcomes with early Impella implantation. However, the support stems mainly from experimental data showing a reduction in myocardial infarct size scar with early LV unloading,[19] and was not observed in the present analysis. We found no suggestion of improved 30-day mortality in patients subjected with "early" Impella implantation before PCI, nor did we see any differences in outcomes between Impella 2.5 and Impella CP. Whereas the overall cohort provides sufficient statistical power for the primary end point analysis, the subgroups analysis should be interpreted with more caution. Additionally, it is important to recognize that patients included in this cohort were in profound cardiogenic shock. The effect of Impella implantation on preshock patients (eg, patients at a high risk of developing cardiogenic shock as identified by a predictive score[20]) cannot be answered from our data, but should be the subject of sufficiently powered future randomized trials. Theoretically, this patient group could be a possible future target and lead to a reevaluation of Impella treatment.

Safety Outcomes Associated With Impella Support in AMI-CS

All escalation of therapies beyond conservative medical approach in AMI-CS involves vascular access, often with large-diameter devices and catheters, which inevitably leads to vascular complication and reparative procedures. Our data provide a large experience regarding the safety outcomes of Impella implantation. As it is inevitably necessary to cross the aortic arch and the aortic valve to implant an Impella device, one might expect an increase in strokes. Fortunately, we found no signs of

an excessive stroke risk. Similarly, reinfarction and stent thrombosis did not differ between groups.

As expected, significantly higher rates of peripheral vascular complications and severe or life-threatening bleedings were found in the Impella group. This is in line with the findings of the IMPRESS in Severe Shock trial.[8] The increase in peripheral vascular and bleeding complications might be related to the relatively large-bore vascular access needed for the Impella devices; the Impella 2.5 and CP are placed via 12 and 14 French sheaths, respectively, as compared with the 7 to 8 French sheath or sheathless insertion for the IABP device. As the IABP-SHOCK II trial cohort included almost 10% of patients with prior thrombolysis, this might to some extent have mitigated the difference in bleeding complications. Furthermore, the difference in safety outcomes seems not to be influenced by the inclusion of medically treated patients in the control group, as the respective subgroup focusing on IABP-treated patients showed comparable results. Additionally, the higher incidence of sepsis in the Impella cohort might be a consequence of this increased rate of vascular complications as well as bleedings, known to increase infections. Therefore, it can be speculated that the positive hemodynamic effect provided by the Impella might be neutralized by the higher incidence of peripheral vascular complications, severe or life-threatening bleedings, and infections.

Limitations

The major limitation of this study is the lack of randomization. Furthermore, implantation of an Impella was left to the discretion of the treating physician and not directed by a study protocol. However, all contributing institutions have established protocols for Impella in AMI-CS, and furthermore, several cautionary measures were taken to reduce the impact of the retrospective nature of the study on the results: (1) the prospective, randomized IABP-SHOCK II trial was used as the control group with sufficient matching criteria; (2) patients were enrolled in the Impella group at multiple sites, thus limiting the extent of selection-bias; and (3) this is the largest Impella study with a comparator investigated thus far. Therefore, this cohort is likely to adequately represent an AMI-CS cohort without a major impact of oversized subgroups. Additionally, the fact that the results and outcome are in line with previous studies on AMI-CS further authenticates the presented findings. However, matching patient data in diseases with high event rates is difficult and might over- or underestimate treatment effects and does not replace the need for a randomized clinical trial. Last, all participating centers were early adopters of the Impella and used this device for high-risk PCI, thus creating experience in its usage, before using it for cardiogenic shock treatment. However, a specific case cut-off was not used, and the influence of a learning curve cannot be excluded.

CONCLUSIONS

In this retrospective analysis involving patients with AMI-CS, routine treatment with an Impella was not associated with lower 30-day all-cause mortality compared with a matched cohort from the IABP-SHOCK II trial. To further evaluate this, a large-scale randomized trial is warranted to determine the effect of the Impella device on outcome in patients with AMI-CS. Early implementation of Impella support should be emphasized in such a trial.

ARTICLE INFORMATION

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Increased Rate of Mortality in Patients Receiving Abiomed Impella RP System - Letter to Health Care Providers

February 4, 2019

Dear Cardiologists, Cardiothoracic Surgeons and Transplant Surgeons,

The FDA is evaluating recent interim post-approval study (PAS) results which suggest a higher mortality rate for patients treated with the Abiomed Impella RP System than the rate previously observed in the premarket clinical studies. The Impella RP System is a temporary right heart pump system intended to help patients maintain stable heart function without open chest surgery. The FDA wants to ensure you are aware of the mortality rate that has been observed in the ongoing PAS.

Although the FDA is concerned about the high mortality rate from the interim PAS results, we believe that when the device is used for the currently approved indication in appropriately selected patients, the benefits of the Impella RP system continue to outweigh the risks. Our current analysis of these results and recommendations for health care providers who may use the Impella RP System follow below.

BACKGROUND

The FDA approved the **Impella RP System (https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm581165.htm)** on September 20, 2017. The device is implanted centrally via peripheral access to help patients who require temporary emergency support of right ventricular function. Use of the device, which may be up to 14 days, requires patients to stay in the hospital.

In the **premarket clinical studies (https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170011B.pdf)**, where strict inclusion and exclusion criteria were followed, a total of 44 out of 60 patients (73.3 percent) survived to 30 days post device explant or hospital discharge (whichever was longer), or to the start of next longer term therapy, including heart transplant or implantation of a surgical right ventricular assist device (RVAD).

The FDA mandated the firm, Abiomed, to conduct a PAS as a condition of approval for the Impella RP System. The **Impella RP PAS (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=615919&c_id=4556)** will follow 60 newly treated patients for one year through the firm's cVAD registry. The primary endpoint is survival to 30 days post device explant or hospital discharge (whichever is longer), or to the start of next longer term therapy. Interim

results from the most recent PAS report, which reflect device use in a broader patient population, indicate that only 4 out of the 23 enrolled PAS patients (17.4 percent) met the primary survival endpoint.

The FDA required additional analyses from Abiomed, and data submitted by the firm in January 2019 suggest that the high mortality rate observed in the PAS may be primarily related to differences in pre-implant characteristics of the PAS patients compared to the patients in the premarket clinical studies. Sixteen (16) of the 23 patients enrolled in the PAS would not have met the enrollment criteria for the premarket clinical studies. Specifically, before getting the Impella RP system implanted, patients in the PAS were more likely than the premarket clinical study patients to have been in cardiogenic shock for longer than 48 hours, experienced an in-hospital cardiac arrest, been treated with an intra-aortic balloon pump, or suffered a pre-implant hypoxic or ischemic neurologic event.

It is important to note that the Impella RP PAS and FDA's evaluation into this issue are ongoing. We do not know the root cause for the high mortality rate, and the results are not adjusted for potential confounders.

RECOMMENDATIONS

The FDA has the following recommendations for health care providers:

- Be aware that FDA approval of the Impella RP System was based on the results of premarket clinical studies that included patients who had been in cardiogenic shock for less than 48 hours prior to device implant. Additionally, none of the patients in the premarket clinical studies experienced an in-hospital cardiac arrest, or were treated with an intra-aortic balloon pump, or suffered a hypoxic or ischemic neurologic event, prior to Impella RP being implanted. Although these clinical events may not preclude a clinical decision to use the device, physicians should be aware that the occurrence of one or more of these events prior to Impella RP implantation may decrease expected survival rate.
- Carefully consider these interim survival results from the ongoing PAS when making treatment decisions and discuss the risks and benefits of the Impella RP System with patients and their caregivers. Additionally, be aware that there are currently no other device interventions that have been approved by the FDA under the premarket application (PMA) process for the patient population demonstrating a higher mortality rate in the PAS and as such, other interventions pose risks, as well, that should be considered and discussed with patients and their caregivers.
- Report any adverse events or suspected adverse events experienced with the Impella RP System:
  - Voluntary reports can be submitted through **MedWatch, the (http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm)FDA Safety Information and Adverse Event Reporting program (http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm)**.
  - Device manufacturers and user facilities must comply with the applicable **Medical Device Reporting (MDR) regulations (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm)**.
  - Health care personnel employed by facilities that are subject to the **FDA's user facility reporting requirements (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuid-**

ance/PostmarketRequirements/ReportingAdverseEvents/default.htm) should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

FDA ACTIONS

The FDA will continue to review data from the ongoing PAS, and other available data sources as they become available. The FDA will work with Abiomed to ensure the product labeling addresses the PAS interim results. We will continue to keep the public informed if new or additional information becomes available.

CONTACT US

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at **DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV)**, 800-638-2041 or 301-796-7100.

Sincerely,
/s/
William Maisel, MD, MPH
CDRH Chief Medical Officer
Center for Devices and Radiological Health
U.S. Food and Drug Administration

More in Letters to Health Care Providers (/MedicalDevices/Safety/LetterstoHealthCareProviders/default.htm)

MINUTES

Evidence-based Guidelines Subcommittee

Clackamas Community College
Wilsonville Training Center, Rooms 210
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
April 4, 2019
2:00-5:00pm

Members Present: Devan Kansagara, MD, Chair; Eric Stecker, MD, MPH, Vice-Chair; Alison Little, MD, MPH; Angela Senders, ND; Lynnea Lindsey, PhD; Leslie Sutton.

Members Absent: none

Staff Present: Darren Coffman (by phone); Cat Livingston, MD, MPH; Jason Gingerich.

Also Attending: Adam Obley, MD, Val King MD, MPH, Moira Ray MD and Craig Mosbaek (OHSU Center for Evidence-based Policy); Stacey Bunk, Amir Medjamia, Jenn Weddell (Abiomed); Erik Schulwolf (Foley Hoag/Abiomed); Alice Taylor, CNM, Duncan Neilson (Legacy Health); Mohamed Abdiasis (Oregon Health Authority Office of Equity and Inclusion); Kim (Renae) Wentz (Oregon Health Authority Health Systems Division); Silke Akerson, Celeste Kersey (Oregon Midwifery Council); Missy Cheyney, PhD (Oregon State University, by phone).

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1. Call to Order

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

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2. Minutes Review

Minutes from the 2/7/2019 meeting were reviewed and approved as submitted, 6-0.

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3. Staff Report

Livingston reported Coffman is out sick, and Crispin Davies, the appointed expert for the Impella topic, is not able to attend, though he may call in. She reported the State Health Improvement Plan (SHIP) is looking at five categories: institutional bias, adversity, trauma and toxic stress, economic drivers of health, access to equitable preventive health care and behavioral health. This is different from prior SHIPs, which were related to more standard public health goals such as immunization and access to preventive services. The groups are meeting to develop the strategies and metrics. She encouraged EbGS members to get involved if they are interested and asked whether there are topics EbGS should take on in light of the SHIP.

Gingerich added Adler will be joining the subcommittee for the out-of-hospital birth topic. After that review, he may (or may not) return to the HTAS subcommittee.

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4. Temporary Percutaneous Mechanical Circulatory Support with Impella Devices

Kansagara reported on the deliberations of the Health Evidence Review Commission (HERC) members related to this topic. It was a lot for HERC to absorb, and concerns were raised about access to advanced heart failure and transplant cardiologists, as there are only a few in the state. The task is to revisit the Impella discussion in light of the previous review and expert testimony. The report would then return to a future VbBS and HERC meeting.

Livingston said there were three issues. The first was regarding the consultation mentioned by Kansagara. Staff has researched this, and these consultations can generally happen by phone, so it is not unreasonable. The subcommittee discussed the issue; Stecker said there may well be times when it's not possible to reach such a cardiologist by phone immediately. He said there's a fairly narrow group of VAD or transplant candidates experiencing cardiogenic shock, but if every cardiogenic shock patient would require a call to a transplant cardiologist, it would burden the transplant centers. There are, however, many patients who the average treating cardiologist would appropriately identify as not being candidates.

The second issue was a lack of clarity about which patients would be affected by the policy. Livingston created a table listing various patient groups and providing an assessment of the evidence. Livingston reviewed the additional table provided in the meeting materials, and Obley reviewed the information showing the lack of evidence to say whether there is a benefit of PCI for angina symptoms in high-risk patients.

Livingston said there are two pieces of observational evidence that have come out recently that focus on harms. The first had 237 patients with acute myocardial infarction and cardiogenic shock who received Impella compared to 237 who did not. It found no difference in 30-day mortality but much higher rates of life-threatening bleeding and peripheral vascular complications in the Impella group. We shouldn't look at this for effectiveness, but rather for harms. Obley said within the Impella group, 156 were treated with Impella CP (a newer, higher-volume model), and 74 with Impella 2.5. Subroup analysis showed no difference in mortality. Kansagara said the registry study, which showed a higher rate of bleeding, showed this result despite a larger portion of patients in the balloon pump group (which would increase a patient's risk of bleeding). The incremental risk of bleeding was on top of that imbalance in groups. This study doesn't include the high-risk PCI group.

The second piece of evidence was an FDA letter of concern about the Impella RP based on a much higher mortality rate than observed in pre-market studies. For the postmarket study, most of the patients would not have met the entry criteria for the pre-market studies. People are using this device (a right-sided device) for a broader range of patients than the device was approved for.

The third issue is that we have evidence that Impella 2.5 does not work, so there was a question about requiring the use of newer models. Livingston said it doesn't make sense to make recommendations

about different models; if the only device that has been studied is ineffective, it doesn't give the other devices a free pass.

Obley said since Davies is not present he would do his best to present Davies' perspective. He would say that there may be clinical scenarios where the Impella 2.5 is preferred, despite lower volume, due to smaller vascular access for a patient.

Senders said she understands there isn't any evidence to support the 3.5 device, but there isn't any evidence to support noncoverage either. She expressed concern based on how many people appeared at HERC. Lindsey said we are caught between when we know things might work for people and what we can look at in terms of evidence. We can revisit the topic if more evidence comes in, but we can't move ahead without evidence. Livingston said all the evidence we have does not support efficacy; typically, that would support a noncoverage recommendation. For the newer models, there is no randomized trial evidence at all; typically, devices without support of randomized trials are treated by the HERC, or by any insurer, as experimental.

Kansagara said the concern about precedent is important as there are iterations of devices in any field. If we get into recommendations around iterations of device, that leaves us open to covering any new iteration of a device. He agrees with a lot of the sticking points from a patient perspective, but the charge of the subcommittee is to recommend coverage for the population as a whole where there are limited resources. Use of these devices is increasing rapidly, so the amount of money is significant. Stecker said we would happily change these recommendations in light of a positive randomized controlled trial. Kansagara said the carveouts where there is no evidence is to protect against harm for the most vulnerable groups of patients.

Kansagara invited public comment.

Two representatives from Abiomed testified. Stacey Bunk, global director of healthcare economics for Abiomed spoke first. All the physicians who wanted to come are currently with patients, so one of them, Dr. Jason Wollmuth, asked her to read a statement.

Wolmath is a cardiologist at Providence. He urged continued coverage for Impella for patients requiring high-risk PCI and patients with cardiogenic shock. He cited the FDA indication and the Protect II trial, noting that the 90-day data in Protect II showed a significant reduction in adverse events. He said patients who were previously turned away from surgery either received medication or an unsupported PCI. These high-risk PCIs were often poorly-performed or incomplete procedures as they would try to get in and out with the minimum amount of work. This led to poor long-term outcomes. With Impella they can take more time and completely revascularize the patients. He has been practicing since 2002 and doing PCI since 2005. He has seen three dramatic advances in his career—drug-eluting stents, hybrid algorithm to treat chronically occluded arteries and the development of Impella.

Bunk also read a portion of a letter from Abiomed, which had been supplied to the subcommittee prior to the meeting. The letter covered the following points:

1. Recommended revisions to the Draft Guidance based on clinical evidence and Impella use in practice;
2. Impella's clinical use in a small, critically ill patient population;
3. Impella's FDA-approved indication for high risk PCI and cardiogenic shock;

4. Medicare and Medicaid coverage policies consistent with our recommended coverage criteria;
5. Clarification that payment for Impella is not made on a pass-through basis; and
6. Clarification on the FDA post-approval study for Impella RP.

Next Erik Schulwolf, an attorney at Foley Hoag LLP, spoke. He was representing Abiomed and highlighted the less restrictive coverage policies of other payers, including Medicare. He noted Abiomed recommended separating the cardiogenic shock recommendation from the bridge to transplant/LVAD recommendation, to remove consultation requirements for cardiogenic shock and myocardial infarction, and remove the 30% ejection fraction requirement for MI and recommend Impella for coverage of high-risk PCI for hemodynamically stable patients with severe coronary artery disease. These changes align with major payers, including Aetna, Moda and Cigna as well as Medicare. He said OHP would be the first payer in Europe or the U.S. to not make a positive coverage recommendation for Impella after a public hearing process, for a small but severely ill population of patients. The current recommendation would make Oregon Medicaid patients an outlier, receiving inferior coverage to other patients in Oregon and to patients in Washington.

Kansagara clarified one point about the Protect II trial; there was not a difference in 90-day outcomes. Rather, there was a trend towards reduced need for revascularization. That outcome was the major driver for the composite outcome at 90 days.

Senders suggested language be added to clarify that a consultation with an advanced heart failure and transplant cardiologist can be made by phone. There was also concern about the ability to reach such an expert in a timely fashion when the patient was rapidly deteriorating. Stecker agreed that delay could be problematic in many scenarios. He also said a retrospective review might result in the need to remove the Impella after insertion for a patient who is not a candidate for transplant or LVAD, which would actively facilitate the patient's death. After discussion, the subcommittee agreed to change the language to allow for situations where it's not possible to contact an appropriate cardiologist by the time a decision is needed. Little and others said the language may be more useful for retrospective review than for prospective review.

Stecker addressed the testimony about this policy being an outlier. We need to decide whether we want to be the first on the map. We need to be conscious of creating a second standard for Oregon Medicaid patients. Wentz said in hearings, judges recognize that Oregon's Prioritized List is absolutely unique. Stecker agreed, but said this is a rapidly moving train and we are approaching consensus without evidence among clinicians that this is an essential lifesaving treatment. We need to be cognizant of where that line is and if it is crossed, the topic would need to be readdressed. It is, however, a conundrum as we are the Evidence-based Guidelines Subcommittee. Kansagara said in the course of his year on the subcommittee he has come to appreciate the uniqueness of Oregon. He said the equity question can be argued the other way, as a policy like this can preserve equity for other treatments. Kansagara agreed the topic can be revisited as new evidence arises.

A motion was made to refer the draft coverage guidance back to VbBS and HERC, as amended. **Motion approved 5-0 (Adler abstained).**

DRAFT 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 agree~~s~~ that Impella should be used as a bridge to a decision for LVAD or a transplant. Appropriate effort should be made to consult with a heart failure and transplant cardiologist, but coverage is recommended in circumstances where consultation cannot reasonably be obtained without endangering the patient's life and the treating physician believes the patient meets the criteria above.

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5. Community Health Workers for Patients with Chronic Disease

Obley reviewed the public comment disposition. He also referenced a letter sent after the public comment deadline, praising the utility of the report. Mohamed Abdiasis, from OHA's Office of Equity and Inclusion spoke briefly in support of the report's relevance in the context of Oregon's CCO 2.0 procurement. After brief discussion, the subcommittee voted to refer the draft report to the Value-based Benefits Subcommittee and HERC. **Motion approved 6-0.**

DRAFT MULTISECTOR INTERVENTIONS

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

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

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

Characteristics of effective interventions include:

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

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

- HIV
- Serious mental illness
- Congestive heart failure

6. Planned Out-of-Hospital Birth

Livingston reminded the subcommittee of the introduction to this topic given at the previous meeting. No decisions will be made today, as the guidelines portion of the review is not complete. She said the discussion of the evidence review at today's meeting may be curtailed somewhat to ensure time for discussion of values and preferences and other issues around the topic.

Gingerich introduced Taylor, Cheyney and Neilson, who serve as ad hoc experts. He read the following statement regarding Taylor's qualifications and conflicts of interest, since she was appointed since the February meeting:

Alice Taylor, CNM, NP MPH *is a certified nurse midwife, recently retired. She previously practiced at Bright Eyes Midwifery and Wild Rivers Women's Health LLC in Gold Beach, Oregon. She also served on the medical staff of Curry General Hospital with independent privileges for normal vaginal birth and normal newborn care from November, 1978 to January, 2019. Since 2016, she has served as a Vice President for the American Association of Birth Centers; responsibilities include serving as the education chair and service on the Board.*

Ray reviewed the partial draft report that captured the evidence. Kansagara asked for a general sense of the typical methodological issues that would qualify these studies as poor. Ray said the issues were around the definitions of the groups as well as the lack of adjustments in some studies. In poor studies the groups were not contemporaneous or were subject to different protocols or were otherwise not comparable.

Adler asked about the cesearean group; he confirmed that the patients in the out-of-hospital group were low-risk patients, but in the hospital it is a mix of all patients. Ray said studies frame it differently, but the study he refers to is all comers in the hospital and there are adjusted risk differences to compensate for that. Ray said the hospital rate might still be a little high, but the out-of-hospital rate is likely true, and the hospital c-section rate is significantly higher.

In discussion of neonatal mortality, Wentz asked whether the Snowden study had a relative risk. Ray said it only has adjusted odds ratios. The issue is they did three different adjustment procedures, so it's adjusted differently than some of the other risk differences.

For neonatal morbidity, Sutton asked whether availability of NICU might be one of the reasons why the numbers are higher. Ray said they do not get into geography or availability of providers, though some studies get into length of stay.

In the noncomparative studies, Kansagara asked about the risk factors. Ray clarified that the noncomparative studies are all large registries for out-of-hospital settings, and while risk factors may be associated with certain outcomes, these kinds of studies cannot show causation. The same risk factors also exist for women in the hospital; we cannot say whether the risk increases more than in the hospital setting.

In discussion of the Grunebaum study about maternal risk factor subgroups, Kansagara asked whether the risk differences were significant. Ray said they are not performing subgroup analyses but rather reporting subgroup findings. The studies don't look for interaction. Some of the confidence intervals overlap. The relative risks in this study appear high because the comparator group is a very low-risk group (midwife-attended hospital births). Wentz asked whether hospital midwives would be allowed to do higher-risk patients than out-of-hospital attendants. Ray said they actually have a narrower scope compared to out-of-hospital. Taylor agreed.

Kansagara asked about the absolute numbers. Ray said there were 90,000 or so planned out-of-hospital births versus 1 million planned hospital births. When you break it into subpopulations, what are the event rates within subpopulations. Ray said you are looking at neonatal deaths, which are incredibly rare, and a single death may appear in multiple high-risk groups. King added that that number of neonatal deaths in intended home birth was 113 compared to 97,000 intended home births. The statistical analysis in the study is relatively unsophisticated because of the rare events. They didn't attempt a regression.

Ray said in the British Birthplace study, for the composite outcome, 4.2% of women had the outcome, but for nulliparous women, it's 9.3%. In freestanding birth centers the rate goes down all, and less for nulliparous women. Overall there was no difference between home and hospital births in this study, but the odds of the composite outcome did increase in the home setting for nulliparous women. In the U.S.-based Grunebaum study, they tried combining risk factors. This study found that nulliparous women over 35 and nulliparous over 41 weeks had the highest standardized mortality ratio. This study excluded women with several high-risk condition such as breech. However, it included all kinds of providers delivering out-of-hospital, including family members and friends.

Another issue with some of the U.S. based data is that it's based on birth certificates. The newer data identifies planned home birth, but if there is a transfer to the hospital, any associated bad outcomes

may get allocated to the hospital birth group. The studies don't try to address residual confounding by race, gestational diabetes, etc.

Ray said the new evidence affirms higher risk for groups identified in the previous coverage guidance. One study also finds higher risk for nulliparous women, women over 35 and women at 41 weeks or greater of pregnancy, though it has significant limitations.

Adler asked Ray to consider the effect of electronic fetal monitoring versus auscultation as a determinate of difference in cesarean section rate. Ray said she can't adjust for that. He said it may partially explain the difference.

Kansagara invited public comment. Silke Akerson of the Oregon Midwifery Council testified. She said it is frustrating to hear discussion of data which includes unattended out-of-hospital births. It would be like reviewing data around setting bones, where the data includes bones set by untrained family members. Family members aren't attendants but account for some of the deaths. She would like this fact acknowledged. This is the case in the Oregon biorecords data as well as the Snowden study. They account for 5 deaths in 6 years in the Oregon data. This is also the case in the Grunebaum studies (Editor's note: One of the Grunebaums studies is limited to births with attendants who have licensure). She would love to be able to know whether there is a variable harm to newborns, but it's hard to come to a conclusion based on faulty evidence.

Akerson said there was some self-identified quality problems in the 2012-2013 data in Oregon. In 2015-2017, since the quality program was started, the perinatal mortality rate for attended out-of-hospital birth (including community midwives) is 0.72 per thousand, very different from what is being presented.

Even though there aren't the studies that meet HERC requirements about breastfeeding, the MANA stats study shows a 98% breastfeeding rate at 6 weeks.

Finally, there is some misunderstanding of misattribution bias, that places other than Oregon aren't tracking births that are planned out-of-hospital but ended in a transfer to hospital. She's heard it said that this makes the mortality rate look lower than it actually is for planned out-of-hospital births. However, her understanding is that misattribution bias actually works in reverse; the majority of deaths in the Oregon dataset actually occur before transfer. What we are missing is a large denominator of births that transferred in non-emergent situations. There are a high number of transfers that are low-risk transfers. We're missing the high number of people who transfer for an epidural.

Akerson expressed empathy for the subcommittee trying to draw conclusions from such poor data. But it is frustrating to see that the data that is reviewed includes bad outcomes from unattended births.

Kansagara said that we haven't made any conclusions yet. The review team has appropriately identified a lot of the insufficiencies in the evidence base. It may be worth adding the issue about unattended births to the weaknesses in the evidence base.

Neilson said we also need to understand the systems issues. The hospital support for planned out-of-hospital birth varies within Oregon and in other settings. Dr. Cheyney has demonstrated a significant risk difference based on whether hospitals accept transfers. Using only U.S. data gives us part of the picture, but the non-U.S. data shows a much broader range of systems support. The Netherlands, for instance, has a highly integrated system. This is a major factor that doesn't come through in the evidence. Taylor

agreed, we have systems issue in our country. Women are cared for in such a way that they are more comfortable in the hospital; they understand that they will be cared for and respected and that the people that care for them will be respected in the hospital. She has enjoyed 40 years of integrated practice, and it worked similar to the UK, Canada and the Netherlands. She used similar criteria and consulted with hospital-based providers. She also had hospital privileges. Without an integrated system, there is a cutoff.

Livingston asked the subcommittee to discuss the other GRADE domains. For values and preferences, Lindsey said for many people choosing a birth place is part of the cultural norm. For others it's seeing birth as a natural phenomenon. Sometimes people prefer a birth center for similar reasons. There may be ethnic cultural factors as well, such as having an attendant who speaks your language. Livingston agreed, and the difficulty is how to weigh increase of neonatal harms versus the improved maternal outcomes and strong values and preferences. Sutton said in her work they look at risk in terms of dignity of risk. Sometimes it's not our job to do anything but inform people of their risk and accept that people are most successful when they live a way that they are choosing and have the supports that help them do what they want to in their life. She said she views it as a dignity of risk conversation with informed choice, where providers give the information to the women and families and allow them to choose. Kansagara said that way of phrasing it is helpful, but one of the challenges is that the numbers are based on very low confidence evidence. In terms of informing people of what the risk is, he hasn't even heard data that would help inform people. He asked the experts how they handle this.

Taylor said if she is doing a postdates discussion, she will start by saying women have gone overdue from the beginning of time. We shouldn't start with thinking this is the most normal thing. At some point in the discussion she has to say the word "stillbirth" so they understand that risk. It is a conversation that takes some time. She said there is also a cutoff in her birth center for how far postdate you can be; every risk factor requires an artful and evidence-based discussion.

Stecker asked Taylor if she is talking about maternal or fetal risk. Taylor said she addresses both types of risks at all stages of pregnancy and delivery. Stecker said individual autonomy is more complex when there are risks to both the baby and mother. Taylor said this does need to be addressed, and it is a delicate conversation where families typically value the interests of an infant more than they value those of a fetus. Stecker said the moment the fetus becomes an infant the parent's autonomy becomes constrainted. Taylor said this comes up in Group B strep prophylaxis. She talks about why screening is recommended for Group B strep and that antibiotics are recommended. The recommendations came about with some conflict between ACOG and AAP. You can't have the discussion with parents anticipating out-of-hospital birth without reviewing the history. In this case, it's about the child. If they make a decision not to accept antibiotics, they are going to have to hear about how a perfectly normal, healthy baby can deteriorate very quickly over a really short period of time. A community birth provider might describe the signs of a healthy newborn and say that the baby can go from good tone, lusty cry and pink color to be on death's door in 3 hours. Just because you have an appointment tomorrow, you can't wait to make that phone call.

Kansagara said he feels uncomfortable with the subcommittee trying to figure out values and preferences based on this discussion. He asked staff to look for literature on values and preferences. King said there is an enormous amount of literature on this. Kansagara asked staff to get a summary on this from Dr. Cheyney.

Lindsey and Stecker said it may be helpful to include a discussion of accepted bioethical principles. Kansagara agreed. Kansagara said we need to be clear that we don't know the absolute risk, that it's the dignity of accepting the uncertainty of risk. Finally, he asked the subcommittee to be mindful of steering in directions that are far afield of our usefulness. He said he believes systems improvements are important and where the opportunity for improvement lies but he doesn't know how much the subcommittee can inform this. He said the guidelines reviewed at the next meeting should inform the discussion.

Gingerich drew the subcommittee to the conclusion that there is evidence of benefit to the mother and some evidence in U.S. studies of neonatal harms. He said Livingston would need to write a statement on behalf of the subcommittee. He asked the subcommittee how the evidence should be weighed in a decision versus other factors as happened with the earlier Impella discussion. Kansagara said very low-quality evidence is a synonym for insufficient evidence. We could talk about the boundaries of the evidence, for example. It's not wrong to highlight uncertainty and the potential for increased risk.

Wentz said she has four years and three months of experience with OHP doing PA on out-of-hospital births. Three years and three months used the HERC guidelines. The Medicaid population is not the same as the statewide population. They have many disadvantages in terms of social determinants of health level. She is not advocating including Medicaid coverage itself a risk factor. However, looking at the outcomes, they are not as good as we would expect and not as good as statewide. We've had some transfers that happened because people became homeless or experienced domestic violence or relapsed into substance use disorder. Transfer for pain has not been significant in our population. In a 2.5-year population out of 70 patients who transferred, only 4 transferred for pain. The rest were urgent and for medical reasons. This adds more uncertainty, but we need to keep this in mind.

Kansagara said we don't have a methodology for this, but it underscores the utility of case reviews. That won't fall to this group to figure out, but there are opportunities for improving care based on this sort of analysis.

Little said the previous report was based on guidelines, and the subcommittee was to look at changes based on those guidelines, not looking at higher risk overall. Are we looking at the previously-identified high-risk subgroups and looking for changes in guideline recommendations? Livingston said yes. Gingerich agreed but reminded the subcommittee that HERC requested this review based on concerns about the Grunebaum and Snowden studies. If EbGS assesses that those are concerning, staff need to know that. Otherwise staff can continue to the guideline review. Livingston said it was the newer Grunebaum studies that changed things. King said the decision was based on the headline, not a deep dive, and asked EbGS to do the deep dive.

Sutton asked how much information we have about the deaths in Oregon for out-of-hospital births. Do we have more details about those? If those births had occurred in the hospital would those deaths have happened? The 2014 public health report included such a detailed review, but the newer report doesn't include that information. King said that the Center contacted Public Health about additional analysis. One of the criticisms we have heard is that the numbers presented include unattended births, but they didn't feel they could do an additional analysis.

7. Adjournment

The meeting was adjourned at 5:15 pm. The next meeting is scheduled for June 6, 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.