



Health Evidence Review Commission

October 4, 2018

1:00 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

Wilsonville Training Center, Rooms 111-112

29353 SW Town Center Loop E

Wilsonville, Oregon 97070

October 4, 2018

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 (8/9/18)	Kevin Olson	X
3	1:40 PM	Director's report	Darren Coffman	
4	1:50 PM	Value-based Benefits Subcommittee report	Ariel Smits Cat Livingston	X
5	2:20 PM	Single fraction radiotherapy for palliation of bone metastases <ul style="list-style-type: none">• Coverage guidance• Prioritized List changes	Adam Obley Wally Shaffer	X
6	3:15 PM	CardioMEMS for heart failure monitoring <ul style="list-style-type: none">• Coverage guidance• Prioritized List changes	Adam Obley Cat Livingston	X
7	4:15 PM	Other Business	Darren Coffman	
8	4:20 PM	Next steps <ul style="list-style-type: none">• Schedule next meeting – Nov. 8, 2018 Wilsonville Training Center, rooms 111-112	Kevin Olson	
9	4:30 PM	Adjournment	Kevin Olson	

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

MINUTES

HEALTH EVIDENCE REVIEW COMMISSION
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
August 9, 2018

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, Vice-Chair; Mark Gibson; Leda Garside, RN, MBA (by phone); Angela Senders, ND; Gary Allen, DMD; Leslie Sutton; Adriane Irwin, PharmD; Lynnea Lindsey, PhD.

Members Absent: Devan Kansagara, MD; Susan Williams, MD; Michael Adler, MD.

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

Also Attending: Adam Obley, MD, MPH (OHSU Center for Evidence-based Policy); Jay Wurschev & Deena Lougham (DHS Child Welfare); Edith Agoff, Karen Yeargain, Amara McCarthy & Shane Sinclair (Oregon Pain Advocacy Group); Wendy Sinclair (Oregon Pain Action Group); Kim Martin Thanislaus; Tim Harless; Lisa Tussell; Valorie Hawk (C-50/50 State Pain Advocacy Groups); Kelly Howard; David Basba & Sarah Gose (MH); Cindy Fletcher (Susan G. Komen OR & SW WA; Doug Riggs (OASCA).

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 May 17, 2018 meeting as presented. CARRIES 6-0. (Absent: Garside; Abstained: Sutton, Senders)

Director's Report

Subcommittee Membership

Coffman said during the last couple of months there has been a wide solicitation of subcommittee members with little results. The solicitation continues and hopefully will garner more interest. Today, he brought for consideration a urologist from OHSU, Dr. Brian Duty, who is interested in serving on the Health Technology Assessment Subcommittee (HTAS). He has been vetted and has no conflicts of interest.

MOTION: To appoint Dr. Duty to HTAS. CARRIES: 7-0. (Absent: Garside)

Follow-up

Coffman reported he was able to find a medical ethicist to assist the Commission in its difficult ethical decisions. Margaret Klein, RN, MSN, JD, who is also chairperson of the Palliative Care and Quality of Life Interdisciplinary Advisory Council (PCAC), has agreed to fill that volunteer role.

Livingston said the Evidence-based Guidelines Subcommittee recommended dropping a previously approved topic, ECMO, as a coverage guidance topic. She said given the type of evidence a preliminary literature search found and given that it is a high-stakes mortality situation, a coverage guidance is not likely to be of much value.

MOTION: To remove ECMO as a coverage guidance topic. CARRIES: 8-0.

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

[Meeting materials](#), pages 69-165

Ariel Smits reported the VbBS met earlier in the day, 8/9/2018. She and Cat Livingston summarized the subcommittee's recommendations.

RECOMMENDED CODE MOVEMENT (effective 10/1/2018 unless otherwise noted)

- Add neuropsychological testing done by computer or technician to various covered mental health lines
- Add 2019 ICD-10 codes to various covered and uncovered lines
- Add acne fulminans to a covered line (effective January 1, 2019)
- Add procedure codes for inserting drug eluting stents into coronary arteries to several heart disease lines
- Add the procedure code for Eustachian tube inflation to an uncovered line
- Makes the PET scan codes diagnostic and remove from lines; make the PET scan guideline into a diagnostic guideline
- Add the code for prediabetes from to Line 3 and recommended that it be removed from the Diagnostic Procedures File. Add a series of temporary codes for the delivery of the Diabetes Prevention Program to Line 3.
- Move several developmental and speech delay codes to the dysfunction lines
- Add the procedure code for nasal vestibular wall stenosis implants to an uncovered line
- Add the procedure code for computer assisted musculoskeletal surgery to an uncovered line
- Add procedure codes for insertion of buprenorphine implants to the substance disorder line
- Add the generic diagnosis code that can be used for adult human growth hormone deficiency to an uncovered line with a new coding specification that it is only on the uncovered line for that specific diagnosis
- Various straightforward coding and guideline note changes.

RECOMMENDED GUIDELINE CHANGES (effective 10/1/2018 unless otherwise noted)

- Edit the guideline for chemodenervation with botulinum toxin for chronic migraine to require medication overuse to be addressed and to modify the requirements for pharmacotherapies
- Edit the severe inflammatory skin disease line to update the step therapy requirements for atopic dermatitis
- Delete the guidelines regarding implantable buprenorphine and enzyme replacement therapy

- Edit the human growth hormone guideline to remove the restrictions on types of childhood diseases that are covered for treatment
- Edit the guideline for breast reconstruction after mastectomy to indicate that revision surgery is only covered for medical, not cosmetic, indications
- Add new guideline to clarify coverage for the treatment of prediabetes with the Diabetes Prevention Program when delivered by CDC-certified programs
- Edit the guideline on overweight and obesity to include reference to the new Diabetes Prevention Program guideline

BIENNIAL REVIEW CHANGES (effective 1/1/2020)

- Create a new line for severe acne which will be in the funded region, with a new guideline
- Reorganize the burn lines from 4 lines into 3

MOTION: To accept the VbBS recommendations on *Prioritized List changes not related to coverage guidances, as stated. See the VbBS minutes of 8/9/2018 for a full description. CARRIES: 8-0.*

Proposal from the Chronic Pain Task Force

Olson asked staff to give the slide show representation that was given at the VbBS meeting that morning to help frame public testimony. He said no decision would be made on the subject at this meeting.

Smits gave a presentation. She said the next Chronic Pain Task Force (CPTF) meeting was scheduled for September 20, 2018 and that any changes to the Oregon Health Plan (OHP) resulting from this process would take effect January 1, 2020.

The CPTF held a series of meetings in 2017-2018 and is comprised of pain specialists, acupuncturists, Medicaid managed care plan medical directors/primary care physicians, a physical therapist, a psychologist, an addictions specialist, a chiropractor, a pharmacist and a patient/advocate. They reviewed evidence reviews and expert guidelines and sought expert input.

Five chronic pain conditions are affected by this change. Until now, these conditions have been below the funding line, receiving no treatments other than office visits with a primary care physician and receive medications that do not have prior authorization (PA) restrictions.

ICD-10-CM codes:

G89.21 Chronic pain due to trauma

G89.29 Other Chronic pain

G89.28 Other chronic post procedural pain

M79.7 Fibromyalgia

G89.4 Chronic pain syndrome

Under the current proposal these conditions would create a new line in the funded region and receive treatments found to be evidence-based: cognitive behavioral therapy, acupuncture, health and behavior assessment, physical/occupational therapy, pain education, yoga, mindfulness based stress reduction, massage, supervised exercise, and intensive interdisciplinary rehab (if available). Additionally, patients would receive all FDA-approved non-opioid medications such as Tylenol, NSAIDS, duloxetine, pregabalin, antidepressants, etc. Medications would be paired with active therapy, including psychotherapy. The new line would be tied to Guideline Note 60 restricting opioid use, as there is evidence of harms in the

use of opioids for chronic pain. Patients on long-term opioid therapy would be required to taper within a year after the taper is begun.

The Task Force is looking for feedback regarding the proposed new line. Smits asked Commissioners to bring up concerns at the meeting or to contact her directly by email or phone.

There was a large volume of written public testimony on the subject. A summary of main themes of the topics include:

- Alternative therapies are not adequate or do not work
- Benefits of long-term opioid therapy:
 - improved function, ability to work and care for self or family
- Harms of involuntary taper from long-term opioid therapy:
 - reduced function and ability to work
 - increased pain
 - increased risk of suicide
 - increased use of illicit opioids or other drugs
- Patients on chronic opioids are not addicts
- The proposed taper policy is an overreaction to a few bad patients or doctors or illegal drug users
- Stories of bad experiences with forced tapers
- Opioid tapers should be decided between doctors and patients, not payers
- This discriminates against low-income patients/OHP patients

Sutton asked how the committee accepted the argument that this might discriminate against low income people or people on OHP. Smits said the group thought we may already discriminate against low income people by not allowing them access to acupuncture or access to certain drugs or CBT, which someone on a Blue Cross/Blue Shield would have access to. In some ways, this change would bring equity to OHP but the Task Force did not expressly address the inequity.

Olson said much of the public testimony heard at VbBS was around patients who are stable on opioids who are fearful of tapering off them because it is public policy; that thought has people nervous.

Coffman said this topic could come back to the VbBS and Commission as soon as October 2018 or as late as March of 2019.

Public Testimony

Tim Harless, chronic pain patient and advocate, who was cut off of opioids by the Veteran's Administration. He shared his life story and medical history.

Karen Yeargain, a public health nurse from Prineville, who is a chronic pain patient. She shared her personal and professional experience with chronic pain in Oregon. She strongly urged the Commission to not take away the option for opioids for chronic pain patients who are stable.

Valorie Hawk of C-50/50 State Pain Advocacy Groups shared her experiences with Washington State's taper policy, which includes a grandfather clause.

Olson said that most of the testimony at VbBS came from providers who care for patients with chronic pain.

Coffman clarified that palliative care treatments are not affected by this proposal.

Coverage Guidance Topic: Urine Drug Testing

[Meeting materials](#), pages 166-217

[Handout](#), pages 1-34

Obley presented an overview of the evidence. Livingston then read through the remainder of the GRADE Table (page 170) as well as the public comment disposition and the proposed coverage guidance from the Evidence-based Guidelines Subcommittee (EbGS).

Urine drug testing is a tool used to screen for drug use in patients who are being treated for a substance abuse disorder and for patients who are prescribed opioids for chronic pain to test for the presence of their prescribed medications or other medications that might affect their treatment plan. It can also be used in patients with unexplained alteration in mental status, which are not impacted by these recommendations.

Olson said VbBS heard testimony from DHS Child Welfare Programs about using these tests by the courts to determine child custody cases related to drug use. The vast majority of these tests are paid by Medicaid. VbBS proposed adding language to the coverage guidance to carve out this part: "Urine drug testing for the purposes of child welfare is outside the scope of this Coverage Guidance."

Public testimony

Deena Lougham, DHS Child Welfare, states she has no conflicts of interest. She said Child Welfare has an average daily population of 7,830 kids in foster care, of those 60% enter foster care because of parental substance abuse. She said they use urine drug testing for child safety and require confirmed testing to prevent additional child trauma. She asked for Child Welfare to be exempt from the coverage guidance and guidelines.

Jay Wurschev, DHS Child Welfare, added all the concerns he has heard expressed about expenditures on drug testing don't exist for them. They use a 6-test panel. They have had their own caps in place for the last 8 years and they are monitored carefully. There is a process for caseworkers to order tests and a clinical guideline. Any exceptions must come through the Salem office. They don't want to make a decision involving a child based on anything other than confirmed tests.

Sutton asked if negative tests are also confirmed. Wurschev replied no, only positive tests are confirmed.

Olson said VbBS supports adding the language to exempt DHS Child Welfare from the coverage guidance.

Lindsey said EbGS had robust conversations about medical necessity verses forensic discovery bodies and finding a compromise between hard and soft limits.

There was some discussion about how it might work to have child welfare included in the coverage guidance. Gibson argued that the stakes are family-inflicted harms or state-inflicted harms on a child. We should take the child's side on this and not change the system that currently works. He fears the unforeseen consequences. Allen agreed their current process is working. Olson and others supported the carve-out proposal.

Sutton asked Wurschev if adding the term "when medically necessary" language cause problems in the child welfare world. He said that language is already in administrative rule.

After some discussion and wordsmithing, this phrase was added to the diagnostic guideline note: "Urine drug testing conducted in accordance with policy of the DHS Office of Child Welfare Programs, when medically necessary, is also covered in excess of these limitations."

MOTION: To approve the proposed coverage guidance for Urine Drug Testing as amended. CARRIES 8-0.

MOTION: To approve the proposed diagnostic guideline and coding changes for the Prioritized List as amended. CARRIES 8-0.

Approved Coverage Guidance:

HERC Coverage Guidance

Urine drug testing (UDT) using presumptive testing is recommended for coverage (*weak recommendation*) when the results will affect treatment planning.

Definitive testing is recommended for coverage as a confirmatory test only when the result of the presumptive testing is inconsistent with the patient's history, presentation, or current prescribed medication plan, and the results would change management.

Definitive testing other than to confirm the results of a presumptive test as specified above is not recommended for coverage (*weak recommendation*), unless the clinician suspects use of a substance that is inadequately detected by presumptive UDT (e.g., fentanyl).

Definitive testing is recommended for coverage for no more than seven substances per day.

In patients receiving treatment for a substance use disorder, random UDT is recommended for coverage (*weak recommendation*). Up to 36 presumptive tests and 12 definitive tests are recommended per year. These limits must be applied in accordance with mental health parity law.

In patients receiving chronic opioid therapy for chronic pain, random UDT is recommended for coverage (*weak recommendation*), with frequency of testing depending on the patient's risk level (using a validated opioid risk assessment tool). Definitive testing should be conducted only for confirmatory purposes as described above and should not exceed 12 tests per year:

- Low Risk: Random presumptive testing up to two times per year
- Moderate Risk: Random presumptive testing up to four times per year
- High Risk: Random presumptive testing up to 12 times per year

In patients with unexplained alteration of mental status and when knowledge of drug use is necessary for medical management (e.g., emergency department evaluation for altered mental status), UDT (presumptive and confirmatory definitive testing, if indicated) is recommended for coverage not subject to the above limitations (weak recommendation).

Urine drug testing for the purposes of child welfare is outside the scope of this Coverage Guidance.

Changes for the Prioritized List of Health Services:

- 1) Advise HSD to move the urine drug testing CPT and HCPCS codes from Ancillary File to the Diagnostic Procedures File. Signs and symptoms codes may be used as well as unfunded diagnoses.
- 2) Add HCPCS codes G0481 (definitive testing of 8-14 drug classes), G0482 (definitive testing of 15-21 drug classes) and G0483 (definitive testing of 22 or more drug classes) to Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS. Advise HSD to remove from the Ancillary File.
- 3) Advise HSD to consider adding G0659 (definitive drug testing) to the Diagnostic Procedures File
- 4) Add a diagnostic guideline:

DIAGNOSTIC GUIDELINE XX URINE DRUG TESTING

Urine drug testing (UDT) using presumptive testing is a covered diagnostic benefit when the results will affect treatment planning. Definitive testing is covered as a confirmatory test only when the result of the presumptive testing is inconsistent with the patient's history, presentation, or current prescribed medication plan, and the results would change management.

Definitive testing other than to confirm the results of a presumptive test as specified above is not covered, unless the clinician suspects use of a substance that is inadequately detected by presumptive UDT (e.g., fentanyl). Definitive testing is limited to no more than seven drug classes per date of service.

For patients receiving treatment for a substance use disorder, presumptive testing on up to 36 dates of service and definitive testing on up to 12 dates of service per year are covered. These limits must be applied in accordance with mental health parity law.

For patients receiving chronic opioid therapy for chronic pain, frequency of testing depending on the patient's risk level (using a validated opioid risk assessment tool) is covered. Definitive testing should be conducted only for confirmatory purposes as described above and should not exceed 12 dates of service per year:

- Low Risk: Random presumptive testing on up to two dates of service per year
- Moderate Risk: Random presumptive testing on up to four dates of service per year
- High Risk: Random presumptive testing on up to 12 dates of service per year

In patients with unexplained alteration of mental status and when knowledge of drug use is necessary for medical management (e.g., emergency department evaluation for altered mental status), UDT (presumptive and confirmatory definitive testing, if indicated) is covered in excess of the above limitations.

Urine drug testing conducted in accordance with policy of the DHS Office of Child Welfare Programs, when medically necessary, is also covered in excess of these limitations.

Topic: Review Scope statement on Temporary Percutaneous Mechanical Circulatory Support (Impella)
[Meeting materials](#), pages 219-220

Obley said this scope statement, vetted through EbGS, was a topic suggested by a cardiologist member of that subcommittee. The goal today is to make sure the scoping statement is correct. EbGS would like to start reviewing a draft coverage guidance on this topic at their next meeting. There is a new family of devices that may have broadening FDA indications for their use.

MOTION: To approve the scope statement for Temporary Percutaneous Mechanical Circulatory Support. CARRIES 8:0.

Topic: Continued development of report required by HB 3391 (Women's Reproductive Health)
[Meeting materials](#), pages 222-231

Livingston said House Bill 3391, also called the Reproductive Health Equity Act, was passed in 2017 to ensure coverage of reproductive health services in Oregon. It requires health plan coverage of many screening and other services without a deductible, coinsurance, copayment, or any other cost-sharing requirement.

In May, HERC identified opportunities for improvement in the Act's Section 2; however, they would not be critical changes. If the Act will be reconsidered for other reasons, staff suggests there are 4 areas to recommend to the legislature to update:

1. Update the date referencing USPSTF and HRSA to January 1, 2018.
 - a. Adds screening for preeclampsia, vision, & obesity, falls prevention, and skin cancer counseling
2. Add risk-based aneuploidy screening
 - a. Screening for aneuploidy with any of five screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, and contingency]
 - b. Cell-free fetal DNA testing for evaluation of aneuploidy in women who have an elevated risk of a fetus with aneuploidy (maternal age >34, family history or elevated risk based on screening)
3. Clarify the requirement to cover postpartum long-acting reversible contraceptive (LARC) placement as a separate reimbursable service
 - a. DCBS has a draft bulletin that is going out for public comment that would address this concern. If this bulletin meets the needs of requiring payments for postpartum LARC, staff would omit this recommendation from the report to the legislature.
4. Clarify that preventive services in Section 2 should be covered in accordance with national evidence-based standards (e.g., USPSTF).

Coffman said the report is due to the Legislature by November 1, 2018. The report will have to go through a potentially lengthy internal review process before it can be submitted to the Legislature.

Sutton asked why we would remove the recommendation for LARC placement if DCBS's bulletin goes forward. Coffman said it does not make sense to keep it in the recommendation unless it is not addressed in the bulletin, since it is already a service listed in the statute.

MOTION: To accept the concepts as presented for inclusion in a report to the legislature on HB 3391, giving staff permission to edit as necessary. CARRIES 8:0.

Topic: Workplan for progress report required by HB 4020 (Extended Stay Centers)

[Meeting materials](#), pages 232-241

[Handout](#), pages 35-41

Shaffer said extended stay centers (ESCs) are a new kind of facility that will be licensed in Oregon according to the requirements of House Bill 4020. They will operate in conjunction with, but as separate entities from, ambulatory surgery centers (ASCs). Patients could stay up to 48 hours (including time in an ASC), rather than the 24 hours current allowed at an ASC. Certain patients who would currently get their surgery in a hospital setting would have the option of receiving the surgery in an ASC. In the ESC, they might receive help with pain management, nausea or other postsurgical symptoms that might be difficult or uncomfortable to receive in a home setting but which would not require hospitalization.

There was a [survey of stakeholders \(pages 35-41\)](#) collected June 15- July 16, 2018. The survey was sent to the public health email list as well as HERC's listserv; there were 47 responses. Many commenters mentioned cost savings (to patients and society), safety (reduced infections, reduced readmissions), comfort and convenience. Others mentioned more attention/personal care by physicians and nurses than would be available in a hospital. There were concerns expressed over patient selection, staffing, required services, accreditation and treatment concerns.

Gingerich said some of the work will be completed using contractors. We will plan to bring a draft to the January meeting. The January draft will include:

- Evidence map illustrating available outcomes data for surgical procedures likely to be performed in an ASC (with or without an ESC or similar entity). Would exclude procedures unlikely to be associated with an ESC stay.
- Summary of ESC (or similar facility) policies from other states
- Summary of relevant portions of professional surgery guidelines
- Summary of Oregon and national safety data for ASCs
- Brief analysis of accreditation programs as they might relate to ESCs
- List and describe commonly-used surgical risk stratification tools
- Horizon scan for anticipated changes to the ESC market and procedures likely to be offered at future Oregon facilities
- 12 procedures recommended for more in-depth analysis in a March draft

The March draft will include requested revisions to January draft, plus additional information below:

- Summary of procedure-specific risks using risk calculators based on 6 hypothetical patient profiles for 12 selected procedures
- Brief summary of safety outcomes from published literature (up to 24 outcomes in total distributed among the 12 surgeries)

- Staff recommendations based on above information. Recommendations would be limited to the scope of HB 4020 and would not affect licensing or coverage for ASCs or ESCs unless additional actions were taken outside HERC.
- Additional research on specific procedures/outcomes if needed

Gingerich asked for areas of concern and thoughts. Olson said he thinks all you will find is observational data with no comparator, which is not good quality evidence. He said you will have to look for literature on procedures that take longer than 24 hours in otherwise healthy patients who care could be moved to an ESC.

Further, Olson wonders if we want to have a separate workgroup to look at this issue. Discussion centered on the idea of having this topic go through HTAS before bringing final recommendations to HERC. Olson said if it feels like too big of a task, he suggests that HTAS complete the parts of it that are reasonable. Gingerich said the soonest they could bring the topic to HTAS would be November.

Sutton asked if the medical ethicist should be involved and what kind of ad hoc experts should be recruited. Olson asked about contacting a Patient Safety Committee. Nurse care coordinators were also mentioned.

Coverage Guidance Topic: Single Fraction Radiotherapy for Palliation of Bone Metastases
[Meeting materials](#), pages 243-286

This topic was tabled until a future meeting.

Public Comment

There was no additional public comment at this time.

Adjournment

Meeting adjourned at 4:30 pm. Next meeting will be from 1:30-4:30 pm on Thursday, October 4, 2018 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 August 9, 2018**

For specific coding recommendations and guideline wording, please see the text of the 8/9/2018 VbBS minutes.

RECOMMENDED CODE MOVEMENT (effective 10/1/2018 unless otherwise noted)

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RECOMMENDED GUIDELINE CHANGES (effective 10/1/2018 unless otherwise noted)

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- Edit the severe inflammatory skin disease line to update the step therapy requirements for atopic dermatitis
- Edit the guideline note on biomarker tests of cancer tissue
- Add a new diagnostic guideline note on urine drug testing
- Edit the guideline for breast reconstruction after mastectomy to indicate that revision surgery is only covered for medical, not cosmetic, indications
- Delete the guidelines regarding implantable buprenorphine and enzyme replacement therapy (effective January 1, 2019)
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BIENNIAL REVIEW CHANGES (effective 1/1/2020)

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- Reorganize the burn lines from 4 lines into 3

DRAFT

VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
August 9, 2018
8:00 AM – 1:00 PM

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

Members Absent: Susan Williams, MD

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Wally Shaffer, MD; Daphne Peck; Mark Altenhofen

Also Attending: Napua Catriz (OHA); Adam Obley, MD (Center for Evidence-based Medicine); Dr. Julie Dhossche and Dr. Tracy Funk (OHSU); Carolyn Concion, NP; Rob Twillman (Academy of Integrative Pain Medicine); Karen Yeargain; Edith Agoff; Ginevra Liptan MD (Frida Center for Fibromyalgia); Allan Chino, PhD; Windy Sinclair; Shane Sinclair; Amara McCarthy; Kim Martin Thanislaus; Karl Probst; Patrick Starnes; Steven Hix; Zane Six; Laura A Dolph; Rick Schmitt; Amanda Siebe (Disables Americans for Change); Helen Turner; Kelly Howard; Leonard Ramey; Laura Stallard; BJ Cavnor (One in Four); Margaret Olmon and Laura Jeffcoat (Abbvie); Becky Harison (BioMartin); Deena Loughany and Jay Wurschev (DHS Child Welfare); Sara Gore (Millennium); David Balham (Genentech); David Barba.

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

The meeting was called to order at 8:00 am and roll was called. Minutes from the May 17, 2018 VbBS meeting were reviewed and approved. Staff noted that the minutes included in the meeting packet had some typos in the line placements for the HCPCS “C” code issue; these line numbers have been corrected.

Smits brought the errata document to the attention of the subcommittee members. There were no comments or discussion.

➤ **Topic: Straightforward/Consent Agenda**

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

Recommended Actions:

- 1) Add ICD-10 Z45.42 (Encounter for adjustment and management of neuropacemaker) to line 250 PARKINSON'S DISEASE
- 2) Remove ICD-10 N43.4 series (Spermatocoele of epididymis) from line 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
- 3) Add G0270-G0271 (Medical nutrition therapy) to line 320 OBESITY IN ADULTS AND CHILDREN; OVERWEIGHT STATUS IN ADULTS WITH CARDIOVASCULAR RISK FACTORS

- 4) Add H0023 (Behavioral health outreach service (planned approach to reach a targeted population)) to line 4 SUBSTANCE USE DISORDER
- 5) Add N18.5 (Chronic kidney disease, stage 5) to line 59 END STAGE RENAL DISEASE
 - 1) Remove N18.5 from line 339 CHRONIC KIDNEY DISEASE
- 6) Add 50389 (Removal of nephrostomy tube, requiring fluoroscopic guidance), 50432 (Placement of nephrostomy catheter, percutaneous), 50435 (Exchange nephrostomy catheter, percutaneous) and 50695 (Placement of ureteral stent, percutaneous) to line 25 VESICoureteral REFLUX
- 7) Add 11004 (Debridement of skin, subcutaneous tissue, muscle and fascia for necrotizing soft tissue infection; external genitalia and perineum), 11006 (Debridement of skin, subcutaneous tissue, muscle and fascia for necrotizing soft tissue infection; external genitalia, perineum and abdominal wall, with or without fascial closure), 11042 (Debridement, subcutaneous tissue (includes epidermis and dermis, if performed); first 20 sq cm or less), 13131-1313 (Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia), 15004-15005 (Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar) and 55150 (Resection of scrotum) to line 47 DEEP ABSCESES, INCLUDING APPENDICITIS AND PERIORBITAL ABSCESS
- 8) Add 57420-57421 (Colposcopy of the entire vagina, with cervix if present) to line 25 DYSPLASIA OF CERVIX AND CERVICAL CARCINOMA IN SITU, CERVICAL CONDYLOMA
- 9) Add 49020 (Drainage of peritoneal abscess or localized peritonitis, exclusive of appendiceal abscess, open), 49322 (Laparoscopy, surgical; with aspiration of cavity or cyst (eg, ovarian cyst)) and 49406-49407 (Image-guided fluid collection drainage by catheter) to line 51 ACUTE PELVIC INFLAMMATORY DISEASE
- 10) Revise Guideline Note 148 as shown in Appendix A
- 11) Modify GN173 as shown in Appendix A

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

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

Discussion: Smits reviewed the summary documents. There was no discussion regarding the general recommendations.

There was discussion regarding the recommendations about a guideline for ICD-10 F39 (Unspecified mood [affective] disorder). Hodges felt that adopting the proposed guideline would make the exceptions process more streamlined. Gibson felt that the relative lack of use for more than a few visits did not require the adoption of a new guideline note. There were questions about whether the CCOs would find this guideline useful. Staff reported that the medical directors and CCOs were not specifically consulted on this topic. Staff were directed to consult with the CCO medical directors and see if the proposed guideline would be helpful and bring back this topic for further discussion in October.

Recommended Actions:

- 1) Add HCPCS H2014 (Skills training and development, per 15 minutes) to line 121 ABUSE AND NEGLECT
- 2) Add ER CPT codes (99281-99285) to lines 204 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE, 290 ACUTE STRESS DISORDER, and 391 PANIC DISORDER; AGORAPHOBIA

- 3) Remove ER CPT codes (99281-99285) from line 521 SEXUAL DYSFUNCTION
- 4) Remove inpatient CPT codes (99218-99226, 99331-99239) from lines 204 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE, 448 REACTIVE ATTACHMENT DISORDER OF INFANCY OR EARLY CHILDHOOD, 468 ENCOPRESIS NOT DUE TO A PHYSIOLOGICAL CONDITION, and 521 SEXUAL DYSFUNCTION
- 5) Add CPT 96118 (Neuropsychological testing (eg, Halstead-Reitan Neuropsychological Battery, Wechsler Memory Scales and Wisconsin Card Sorting Test), per hour of the psychologist's or physician's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report) to line 173 POSTTRAUMATIC STRESS DISORDER
- 6) Add a new guideline note to line 173 as shown in Appendix B
- 7) Add CPT 96119 (Neuropsychological testing... administered by technician, per hour of technician time, face-to-face) and 96120 (Neuropsychological testing (eg, Wisconsin Card Sorting Test), administered by a computer, with qualified health care professional interpretation and report) to lines 92 SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS, 173 POSTTRAUMATIC STRESS DISORDER, 193 AUTISM SPECTRUM DISORDERS, and 202 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS
- 8) Remove CPT 96119 (Neuropsychological testing... administered by technician, per hour of technician time, face-to-face) and 96120 (Neuropsychological testing (eg, Wisconsin Card Sorting Test), administered by a computer, with qualified health care professional interpretation and report) from line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS and remove entry to GN173.
- 9) Staff to review the proposed guideline for ICD-10 F39 with CCO medical directors and bring back to the October 2018 VBBS meeting

MOTION: To recommend the code and guideline note changes as presented other than those related to ICD-10 F39. CARRIES 6-0.

➤ **Topic: Chronic Pain Task Force report**

Discussion: Smits gave an overview of the Task Force recommendations, including details of the proposed new line for fibromyalgia and chronic pain (diagnoses and treatments), the proposed accompanying guideline note, and changes recommended to the opioid guideline. She also summarized the major themes in the large number of public comments received on this topic. Saboe then commented on reports lack of inclusion of chiropractic care. "So, on the original recommendations of non-pharmaceutical interventions you mentioned that chiropractic is not covered, that they had recommended. And again, the mistake is being made that chiropractic is synonymous with a single-modality -- spinal manipulation. And so the recommendation is also physical therapy. That's a broad brush. That's not only a profession, but there's a whole cascade of interventions that fall under physical therapy. Might just as well say "Physical medicine." So, passive/active, supervised exercise, therapeutic procedures, neuromuscular education, the modalities of mobilization, manipulation, manual traction. And then all the modalities all follow under physical therapy. And so to make the statement chiropractic's not covered is an error. We provide most of all of these things are within our scope of license to provide, not just manipulation. So there needs to be some type of rewording

that, in fact, when they say they've done the evidence and physical therapy is effective... that's a broad brush. What modalities, what interventions are they speaking of? And so, in most all of those, I'm certain, are within the scope of the licensure of naturopathic physicians as well. So there needs to be some amendment of that language of those recommendations, because we would not want this going through and, and... the connotations of those interventions that fall under physical therapy or physical medicine are only to be provided by a physical therapist."

Smits responded that the spinal manipulation CPT codes were not proposed for inclusion on the new line; however, if a chiropractor did PT services or office visit care, those CPT codes would be covered.

Kim Jones, PhD gave a presentation regarding the state of the evidence supporting coverage for treatments for fibromyalgia.

Public testimony

Carolyn Concion, NP, testified that patients are stabilized on opioids for years. Then providers taper medications, frequently involuntarily. Patients are also rejected by providers due to their chronic pain.

Rob Twillman, Academy of Integrated Pain Management, testified in support of moving chronic pain above the current funding line, but opposes forcing opioid tapers. He requested that the subcommittee look at outcomes for chronic back pain patients tapered off opioids: functionality, suicides, mental health issues, etc. He noted that improved function is a criterion for the first 90 days of opioids in the opioid guideline, but improved function is not considered after 90 days. He feels that the opioid guideline needs criteria for pausing, stopping or reversing tapers.

Karen Yeargain, patient/public health nurse from Prineville, testified that it's not diverted prescription drugs that are causing overdose problems, but rather street drugs. Oregon has decreased prescribing of opioids and is seeing increased suicides, but no increase in street drugs in chronic pain patients. Opioids increase functionality.

Ginevra Liptan, MD, an internal medicine physician with a focus on fibromyalgia, testified, noting that she is also a chronic pain patient. Opioids are imperfect. She agreed that the HERC should cover fibromyalgia and noted that Oregon is the only state without Medicaid funding for fibromyalgia care. She requested that the commission add tools that are helpful but do not take away the tool that has been helpful (opioids).

Allan Chino, PhD, a clinical health psychologist and pain specialist, testified about the need to move fibromyalgia above the line and have tools to help these patients. He noted that outcomes are superior when a range of treatment options are available, including opioids. Decisions should be based on individual patients. He noted that he has never seen hyperalgesia in his practice.

Karl Probst, a VA patient, testified about the new VA policy that requested patients get off opioids. Patients are offered suboxone instead. He feels that he has a better quality of life though opioids.

Patrick Starnes, an independent candidate for Oregon Governor, testified. He asked that the Committee not lump addicts with chronic pain sufferers. He stated that the commission needs more pain patient representation on the Task Force.

Steven Hix, a patient, testified. He is very frightened about what is happening locally and nationally with opioids. He has tried all of the proposed modalities without success. Hydrotherapy was the most successful. He notes that it is very easy to lose hope, and become depressed. The most vulnerable people in this country are suffering. Taking away people's medicine will not magically make their pain go away. This is a matter of human decency. There is a huge problem when one is labeled as a drug seeker. Health care insurance is a huge expense.

Helen Turner, a clinical nurse specialist caring for children with chronic pain, testified that opioids help children go to school and have improved quality of life. Evidence for opioids is messy at best, and does not apply to all patients. She is trying to get as many kids off opioids as she can, but some cannot be taken off.

Amanda Siebe, a patient with complex regional pain syndrome, testified. She brought in boxes of medical records, which include her treatment with all types of modalities. Only methadone helps her pain. Taking away opioids drives patients to suicide and street drugs. This takes away hope and functionality, giving nothing in exchange. <3% of patients on opioids become addicted.

BJ Cavnor, the executive director of One in Four, testified about his concern about restrictions on opioids in the guideline note. Pain patients are not addicts. Chronic pain patients are stigmatized. The PDMP database monitors drugs. Patients and providers should decide the best treatment strategy between them. This is a reactive policy at the state and national level, and does not help the overall opioid crisis.

Julia (no last name given) testified that this conversation was not public knowledge. She has tried all non-opioid medications, procedures and modalities; none work other than opioids.

Coffman gave the next steps in the process, as well as how to find out public meeting information, materials for public meetings, and how to provide written and oral testimony. The next meeting of the Chronic Pain Task Force will be September 20, 2018. The Task Force will have one or more meetings, and then forward their revised recommendations to VBBS at a future meeting. Any changes regarding chronic pain will need to be made by the March 2019 HERC meeting and would take effect with the January 1, 2020 Biennial Review changes.

Recommended Actions:

- 1) HERC staff will take the public testimony, subcommittee input, and HERC input to the September Chronic Pain Task Force meeting and work with the Task Force to revise their recommendations

➤ **Topic: 2019 ICD-10 Code Review**

Discussion: There was no discussion of the straightforward code placements or the codes on the code issues summary.

There was discussion regarding the staff recommendations around brow ptosis repair and blepharoplasty. Hodges stated that the ophthalmologic jargon in these guidelines make them very difficult to interpret by non-ophthalmology medical reviewers and medical directors. The group requested that VBBS staff work with ophthalmology experts to rewrite the blepharoplasty guideline

and the proposed brow ptosis repair guideline to clarify the requirements in non-jargon type language.

Recommended Actions:

- 1) Add 2019 ICD-10 code placements as shown in Appendix C
- 2) Staff to work the ophthalmology experts on the brow ptosis code placement and repair issues, as well as the blepharoplasty guideline

MOTION: To recommend the code placements as presented. CARRIES 6-0.

➤ **Topic: 2020 Biennial Review – Severe Acne**

Discussion: Smits reviewed the summary document. There was public testimony heard about hydranitis suppurativa, which is a future review topic. There was no subcommittee discussion about the severe acne proposal.

Recommended Actions:

Effective January 1, 2019

- 1) Change line title for line 373 ACNE CONGLOBATA (~~SEVERE CYSTIC ACNE~~) AND ACNE FULMINANS
- 2) Add ICD-10 L70.0 (acne vulgaris) to line 373
- 3) Modify GN 132 as shown in Appendix A

Effective January 1, 2020

- 1) Create a new line and guideline for severe acne as shown below
- 2) Score this new line as shown below
- 3) Change the line title for line 520 to ROSACEA; MILD/MODERATE ACNE

Line XXX SEVERE CYSTIC ACNE

Treatment: MEDICAL AND SURGICAL TREATMENT

- a. ICD-10 codes: L70 (acne)
- b. CPT/HCPCS codes: all included currently on line 373 ACNE CONGLOBATA (SEVERE CYSTIC ACNE)

GUIDELINE NOTE XXX SEVERE CYSTIC ACNE

Line XXX,520

Acne is only included on Line XXX if it is severe, defined as the presence of the following characteristics: persistent or recurrent inflammatory nodules and cysts AND ongoing scarring. Otherwise, acne diagnoses are included on line 520.

Note that acne with recurrent abscesses or communicating sinuses is covered according to Guideline Note 132 ACNE CONGLOBATA AND ACNE FULMINANS.

Line scoring

Category 7

Impact on Healthy Life Years 1

Impact on Pain and Suffering 3
Population effects 0
Vulnerable populations 0
Tertiary prevention 0
Effectiveness 4
Need for treatment 0.8
Net cost 3
SCORE 256, PUTS ON LINE 451

MOTION: To recommend the code and guideline note changes as presented. To recommend the biennial review changes for the severe acne line as presented. CARRIES 6-0.

➤ **Topic: 2020 Biennial Review – Burn Line Reorganization**

Discussion: Smits reviewed the proposed burn line reorganization. There was no discussion.

Recommended Actions:

Effective January 1, 2020

- 1) Modify line 57 BURN, FULL THICKNESS GREATER THAN 10% OF BODY SURFACE as shown below
- 2) Merge lines 72 BURN, PARTIAL THICKNESS GREATER THAN 30% OF BODY SURFACE OR WITH VITAL SITE; FULL THICKNESS, LESS THAN 10% OF BODY SURFACE and 197 BURN, PARTIAL THICKNESS WITHOUT VITAL SITE REQUIRING GRAFTING, UP TO 30% OF BODY SURFACE into a new line as shown below with the line scoring as shown below
- 3) Modify line 602 MINOR BURNS as shown below
- 4) Delete the newly adopted GUIDELINE NOTE XXX MODERATE/SEVERE BURNS

Line 57 SEVERE BURNS BURN, FULL THICKNESS GREATER THAN 10% OF BODY SURFACE

Treatment: FREE SKIN GRAFT, MEDICAL THERAPY

ICD-10 All currently on line 57 (third degree burn and corrosion codes; burns of eyes, trachea, larynx, GI tract, ears)

CPT: all currently on line 57

HCPCS: all currently on line 57

LINE XXX MODERATE BURNS Treatment: FREE SKIN GRAFT, MEDICAL THERAPY

ICD-10: all second degree burn codes [remove all 3rd degree burn codes, L00 (Staphylococcal scalded skin syndrome) and L49.7 (Exfoliation due to erythematous condition involving 70-79 percent of body surface) and leave only on line 57] [Add L55.1 (Sunburn of second degree)]

CPT: all currently on line 72 or 197

HCPCS: all currently on line 72 or 197

Line scoring for LINE XXX MODERATE BURNS

Category 6

Impact on Healthy Life Years 7

Impact on Pain and Suffering 3

Population effects 0

Vulnerable populations 0

Tertiary prevention 3

Effectiveness 4

Need for treatment 1

Net cost 2

SCORE 2080, PUTS ON LINE 127

602 MINOR BURNS Treatment: MEDICAL THERAPY

ICD-10 All first degree and unspecified degree burn codes [remove all 2nd degree burn codes, L00 (Staphylococcal scalded skin syndrome) and L55.1 (Sunburn of second degree)]

CPT: all currently on line 602

HCPCS: all currently on line 602

MOTION: To recommend the biennial review changes for the burns as presented. CARRIES 6-0.

DRAFT

➤ **Topic: Drug eluting stents**

Discussion: Smits reviewed the summary document. Gibson asked whether the final evidence review concluded that drug eluting stents were more cost effective than bare metal stents. Smits replied that the evidence supported that drug eluting stents were at least no more expensive, and likely more cost effective based on the evidence reviewed.

Recommended Actions:

- 1) Add HCPCS C9600-C9608 (Drug eluting stent percutaneous coronary interventions) to lines
 - a. 45 CORONARY ARTERY ANOMALY
 - b. 69 ACUTE AND SUBACUTE ISCHEMIC HEART DISEASE, MYOCARDIAL INFARCTION, 98 HEART FAILURE
 - c. 189 CHRONIC ISCHEMIC HEART DISEASE
 - d. 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT

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

➤ **Topic: Eustachian tube inflation**

Discussion: Smits reviewed the summary document. There was discussion about whether this procedure belonged on line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS or line 652 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY. The argument in favor of line 660 was that this procedure was experimental. Line 652 might be easier to administer, because it clearly shows that the pairing of Eustachian tube inflation with Eustachian tube dysfunction was not covered. Hodges reported that her CCO had no issues with administering these types of codes when they are on line 660.

Recommended Actions:

- 1) Add Eustachian tube dilation (HCPCS C9745) 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 GN173 as shown in Appendix A

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

➤ **Topic: Severe inflammatory skin disease guideline**

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

Recommended Actions:

- 1) Modify GN21 as shown in Appendix A

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

➤ **Topic: Diagnostic indications and the PET guideline**

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

Recommended Actions:

- 1) Remove PET scan CPT codes (CPT 78608-78609, 78811-78816) from all current lines on the Prioritized List
 - a. Advise HSD to place on the Diagnostic Procedures File
- 2) Change the current PET guideline to a diagnostic guideline as shown in Appendix A

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

➤ **Topic: Absorbable implants for nasal vestibular wall stenosis**

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

Recommended Actions:

- 1) Add HCPCS C9749 Repair of nasal vestibular lateral wall stenosis with implant(s) to line 660
CONDITIONS FOR WHICH CERTAIN TREATMENTS HAVE NO CLINICALLY IMPORTANT BENEFIT OR
HAVE HARMS THAT OUTWEIGH BENEFITS; UNPROVEN TREATMENTS
- 2) Add an entry to GN173 as shown in Appendix A

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

➤ **Topic: Migraine and botulinum toxin guideline edit**

Discussion: Livingston presented the issue summary. Irwin queried how the requirement for failing 3 medications would be evaluated. For example, riboflavin and magnesium could be a good choice for some patients, and if these were used, would the 3 additional pharmacotherapies be required to have been tried. Livingston mentioned it may be variably interpreted by plans. Hodges clarified that each of the 3 pharmacotherapies would have to be evidence-based to count against the 3 required pharmacotherapies. They amended the staff recommendations to include the use of “e.g.” demonstrating that additional therapies could be an option, if evidence-based (and/or if there are contraindications to some of the drug classes).

Recommended Actions:

- 1) Modify Guideline Note 42 as shown in Appendix A

MOTION: To recommend the guideline note changes as amended. CARRIES 6-0.

➤ **Topic: Computer assisted musculoskeletal surgery**

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

Recommended Actions:

- 1) Place CPT 20985 (Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less) on line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
 - a. Advise HSD to remove CPT 20985 from the Ancillary File
- 2) Add an entry to GN173 as shown in Appendix A

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

➤ **Topic: Prioritization of FDA-approved drugs on unfunded lines on the Prioritized List; Human Growth Hormone Deficiency**

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

Recommended Actions:

Changes effective January 1, 2019

- 1) Remove an entry to GN172 as shown in Appendix A
- 2) Remove an entry to GN173 as shown in Appendix A
- 3) Add buprenorphine implant insertion procedure codes to line 4 SUBSTANCE USE DISORDER
 - a. CPT 11981-11983 (Insertion, removal, and removal with re-insertion, non-biodegradable drug delivery implant)
 - b. HCPCS G0516-G0518 (Insertion removal, and removal with re-insertion, of non-biodegradable drug delivery implants, 4 or more)
- 4) Delete GN67
- 5) Delete the following ICD-10 codes from Line 650, ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY.
 - a. E75.21 Fabry (-Anderson) disease
 - b. E75.22 Gaucher disease
 - c. E75.24 Niemann-Pick disease
 - d. E76 series (Disorders of glycosaminoglycan metabolism)
- 6) Add ICD-10 E23.0 (Hypopituitarism) to line 650 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
- 7) Add the following coding specifications to lines 40 PANHYPOPITUITARISM, IATROGENIC AND OTHER PITUITARY DISORDERS and 386 PITUITARY DWARFISM
 - a. "ICD-10 E23.0 is included on this line for conditions other than adult human growth hormone deficiency."
- 8) Add the following coding specification to line 650
 - a. "ICD-10 E23.0 is included on this line only for adult human growth hormone deficiency."
- 9) Modify GN74 as shown in Appendix A

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

➤ **Topic: Diabetes Prevention Program (DPP)**

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

Recommended Actions:

Effective January 1, 2019

1. Add R73.03 *Prediabetes* to Line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
 - a. Recommend HSD remove R73.03 from the Diagnostic File
2. Add Z86.32 *Personal history of gestational diabetes* to Line 3
3. Add 98962 *Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; 5-8 patients* to Line 3
4. Add the temporary codes for DPP to Line 3
 - a. 0403T *Preventive behavior change, intensive program of prevention of diabetes using a standardized diabetes prevention program curriculum, provided to individuals in a group setting, minimum 60 minutes, per day*
 - b. 0488T *Preventive behavior change, online/electronic intensive program of prevention of diabetes using a standardized diabetes prevention program curriculum, provided to an individual, per 30 days*
5. Adopt GUIDELINE NOTE XXX Diabetes Prevention Program as shown in Appendix B
6. Modify the Guideline Note on overweight and obesity as shown in Appendix A

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

➤ **Topic: Coverage of developmental diagnoses**

Discussion: Livingston reviewed the summary document. There were questions about how many children the code changes may impact. A data run suggested that there is significant utilization of these codes, despite being currently located in the Diagnostic File. Staff clarified that this is helping to correct a wrong with schools, but will have impact in community settings as well. Irwin discussed the importance of prioritizing treatment for children. The group agreed that F88 was also appropriate to move into the funded region.

Recommended Actions:

- 1) Add R62.0 *Delayed milestone in childhood* to dysfunction lines: 292, 345, and 377.
 - a. Add a coding specification as follows:
"R62.0 is included on lines 292, 345, and 377 for children 8 and under."
- 2) Add F80.9 *Developmental disorder of speech and language, unspecified* to dysfunction line 345.
- 3) Add F88 *Other disorders of psychological development* to lines 292, 345, and 377.
 - a. Add a coding specification as follows:
"F88 is included on these lines for developmental delay. When it is used to indicate sensory integration disorder or sensory processing disorder, it is included on Line 659."
- 4) HSD staff to work with schools to help with identifying appropriate diagnoses
- 5) Place F82 *Specific developmental disorder of motor function* on Line 659 rather than in the Undefined File.

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

➤ **Topic: Postpartum depression screening**

Discussion: This topic was tabled until October 2018

➤ **Topic: Revisions to breast reconstruction guideline**

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

Recommended Actions:

- 1) Revise GN79 as shown in Appendix A

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

➤ **Topic: Cardiac MRI**

Discussion: This topic was tabled until October 2018

➤ **Topic: Coverage Guidance— Single fraction radiation for palliation of bone metastases**

Discussion: Shaffer introduced the summary document. Obley reviewed the evidence report. There was no discussion.

Recommended Actions:

- 1) Guideline Note 12 was modified as shown in Appendix A
- 2) Statement of Intent 1 was modified as shown in Appendix A

MOTION: To approve the recommended changes to the Prioritized List based on the draft Single Fraction Radiotherapy for Palliation of Bone Metastases coverage guidance scheduled for review by HERC at their August 9, 2018 meeting. CARRIES 6-0. Note: Discussion by HERC was postponed until their October 4, 2018 meeting.

➤ **Topic: Coverage Guidance— Urine drug testing**

Discussion: Obley, Gingerich, and Livingston presented the information in the meeting materials. Olson asked about the limit on definitive tests of 7 substances per day. Gingerich clarified that the coding for these definitive tests is based on the number of drug classes examined per day. Livingston confirmed there is no evidence that looking for 20 drug classes is more effective than looking for seven; in fact, there is no evidence of effectiveness for urine drug testing at all—the recommendations are guideline-driven. Irwin asked about testing for various opioids and metabolites. She has seen separate charges for various drugs and metabolites within a class (e.g., hydrocodone and each norhydrocodone and other metabolites).

After discussion, David Barba, a representative of Millennium Health, a urine drug testing lab, clarified that for Oregon Medicaid, tests are billed according to the number of drug classes assayed (e.g., opiates) but the results may, for instance, report on 5 metabolites within a class. He said an older billing methodology charged separately per substance tested for, but this methodology is no longer used by most payers. He suggested changing the language to refer to drug classes rather than drugs. For example, a test might test for ten benzodiazepines, which would be counted as a single drug class. With opioids, there is one class for most opioids, but there are separate classes for each synthetic opioid. Drugs such as fentanyl and tramadol aren't picked up in presumptive tests. He said that many labs offer standard panels of tests which allows a provider to test for many classes by checking a single box on the order form. He said Millennium moved away from panels three years ago.

Based on this discussion, the subcommittee agreed to change the recommendation language to refer to seven drug classes rather than seven drugs.

Deena Loughany, Child Safety Program Manager for the Oregon Department of Human Services Child Welfare, offered public testimony. She also introduced Jay Wurscher, who works in her office. She said parental substance use is the number one child safety issue in Oregon and nationally, and the primary reason her agency is forced to terminate parental rights is the inability of parents to enter substance use disorder treatment. DHS uses urine drug tests as a key component in determining whether it is safe for a child to be in parent's home. All tests must be confirmed because of the negative consequences that could result from a false positive test. All these drug tests are medically necessary from the child's perspective. She recommended excluding tests related to child welfare from the coverage limits. DHS does not abuse testing or test excessively, but DHS parents need more testing than most patients in the health system. DHS child welfare already has administrative rules which govern these tests. She said there have been many rash and harmful decisions related to child placement made based upon testing that did not include confirmations. If not covered by Medicaid, funding for these tests would come out of the state budget without federal matching funds.

In response to clarifying questions, Wurscher said that the vast majority of testing goes to Legacy Laboratories. There is a six-panel test, and no variation from that test can happen without his approval. He said almost all the tests ordered are for OHP recipients; last year only \$60,000 worth of testing was done for people who were not OHP recipients. He said DHS put caps on testing years ago; total testing went down to about \$35,000 per month, but has risen recently due to better partnerships with drug courts and substance use disorder treatment providers. Testing is requested by DHS and performed at Legacy Lab and then billed to OHP, whether fee-for-service or for CCOs.

Olson asked how much this was considered at EbGS. Livingston said there was more discussion about drug courts, but this discussion was included as well. EbGS felt that drug courts were outside the purview, but did not discuss child welfare testing extensively. Olson suggested excluding child welfare testing. After discussion, the subcommittee recommended excluding these tests. Because of time limitations, the subcommittee did not draft this language in the meeting but recommended that HERC draft specific language. Hodges asked Wurscher for the document showing the DHS limits on testing. Wurscher said he would provide it.

Hodges asked about using the term “medically necessary” when there is no doctor involved. What changes medically based on the result? Gibson said this scenario also arises in drug court. Wurscher said that people who test positive are offered or ordered to receive treatment. They have whole groups of staff pushing people towards treatment. Olson suggested that HERC take up this discussion in the afternoon.

Recommended Actions:

- 1) Advise the Health Systems Division to move codes G0659 and G0477-G0480 to the Diagnostic Procedures File and remove them from the Ancillary File.
- 2) Add HCPCS codes G0481 (definitive testing of 8-14 drug classes), G0482 (definitive testing of 15-21 drug classes) and G0483 (definitive testing of 22 or more drug classes) to Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS. Advise HSD to remove these codes from the Ancillary File.
- 3) Add a diagnostic guideline note as shown in Appendix A, with the expectation that HERC will consider addition of language excluding tests related to child welfare from the limits.

MOTION: To approve the recommended changes to the Prioritized List, as amended, based on the draft coverage guidance on Urine Drug Testing, with continued discussion of specific language related to child welfare at HERC. CARRIES 6-0.

➤ **Public Comment:**

Andy Kranenburg, MD from Medford, called in to testify regarding the treatment of sacroiliac joint pain and dysfunction. Currently, there is a guideline on the Prioritized List regarding when treatment is appropriate, but the diagnosis is on an uncovered line. He requested reconsideration of the prioritization of sacroiliac joint dysfunction to a line above the funding line. He reviewed the HERC prioritization methodology, and SI joint dysfunction ended up with a very high score according to him and his colleagues, higher than many conditions that are currently covered. SI joint pain is a highly burdensome health state.

HERC staff will provide subcommittee members with Dr. Kranenburg’s written testimony, with review of the proposed and current line scoring. Smits will provide Dr. Kranenburg with the current scoring for this line.

➤ **Issues for next meeting:**

- Chronic Pain Task Force updates
- Coverage of ICD-10 F39
- Brow ptosis repair
- Blepharoplasty
- Postpartum depression screening
- Cardiac MRI
- SI joint dysfunction prioritization

➤ **Next meeting:**

October 4, 2018 at Clackamas Community College, Wilsonville Training Center, Wilsonville, Oregon, Rooms 111-112.

➤ **Adjournment:**

The meeting adjourned at 1:17 PM.

DRAFT

Appendix A

Revised Guideline Notes

Effective October 1, 2018

STATEMENT OF INTENT 1: PALLIATIVE CARE [Editor's note: HERC did not review this recommendation for inclusion on the 10/1/2018 Prioritized List. HERC will review it at a later date.]

It is the intent of the Commission that palliative care services are covered for patients with a life-threatening or serious progressive illness to alleviate symptoms and improve quality of life.

Palliative care services should include culturally appropriate discussions and medical decision making aligned with patient's personal goals of therapy, assessment of symptom burden, assistance with advance care planning, care coordination, emotional, psychosocial and spiritual support for patients and their families. Palliative care services may be provided concurrently with life prolonging/curative treatments.

Some examples of services associated with an encounter for palliative care (ICD-10 Z51.5) that should be available to patients without regard to Prioritized List line placement:

- A) Inpatient palliative care consultations
 - 1) Hospital Care E&M (CPT 99218-99233)
- B) Outpatient palliative care consultations provided in either the office or home setting
 - 1) E&M Services (CPT 99201-99215)
 - 2) Transitional Care Management Services (CPT 99495-6)
 - 3) Advance Care Planning (CPT 99497-8)
 - 4) Chronic Care Management (CPT 99487-99490)
- C) Psychological support and grief counseling (CPT 99201-99215)
- D) Medical equipment and supplies for the management of symptomatic complications or support activities of daily living
- E) Medications or acupuncture to reduce pain and symptom burden
- F) Surgical procedures or therapeutic interventions ([for example, palliative radiation therapy](#)) to relieve pain or symptom burden

Other services associated with palliative care includes:

- A) Social Work
- B) Clinical Chaplain/ Spiritual Care
- C) Care Coordination

It is NOT the intent of the Commission that coverage for palliative care encompasses those treatments that seek to prolong life despite substantial burdens of treatment and limited chance of benefit. See Guideline Note 12 [PATIENT-CENTERED CARE OF ADVANCED CANCER](#) ~~TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT.~~

~~GUIDELINE NOTE 19~~ [DIAGNOSTIC GUIDELINE XX](#), PET SCAN GUIDELINES

~~Lines 113,116,133,135,157,158,163,174,200,201,211,230,260,263,276,287,314~~

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

- Solitary pulmonary nodules and non-small cell lung cancer

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- Evaluation of cervical lymph node metastases when CT or MRI do not demonstrate an obvious primary tumor.

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

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

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

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

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

Restaging is covered only for cancers for which staging is covered and for thyroid cancer if recurrence is suspected and I131 scintigraphy is negative. For restaging, PET is covered after completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence or to determine the extent of a known recurrence. PET is not covered to monitor tumor response during the planned course of therapy. PET scans are NOT indicated for routine follow up of cancer treatment or routine surveillance in asymptomatic patients.

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

GUIDELINE NOTE 12, [PATIENT-CENTERED CARE OF ADVANCED CANCER](#) ~~TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT~~ [Editor's note: HERC did not review this recommendation for inclusion on the 10/1/2018 Prioritized List. HERC will review it at a later date.]

Cancer is a complex group of diseases with treatments that vary depending on the specific subtype of cancer and the patient's unique medical and social situation. Goals of appropriate cancer therapy can vary from intent to cure, disease burden reduction, disease stabilization and control of symptoms. Cancer care must always take place in the context of the patient's support systems, overall health, and core values. Patients should have access to appropriate peer-reviewed clinical trials of cancer therapies. A comprehensive multidisciplinary approach to treatment should be offered including palliative care services (see STATEMENT OF INTENT 1, PALLIATIVE CARE).

Treatment with intent to prolong survival is not a covered service for patients who have progressive metastatic cancer with

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- A) Severe co-morbidities unrelated to the cancer that result in significant impairment in two or more major organ systems which would affect efficacy and/or toxicity of therapy; OR
- B) A continued decline in spite of best available therapy with a non-reversible Karnofsky Performance Status or Palliative Performance score of <50% with ECOG performance status of 3 or higher which are not due to a pre-existing disability.

Treatments with intent to relieve symptoms or improve quality of life are covered as defined in STATEMENT OF INTENT 1, PALLIATIVE CARE.

Examples include:

- A) Single-dose radiation therapy for painful bone metastases with the intent to relieve pain and improve quality of life. [Single fraction radiotherapy should be given strong consideration for use over multiple fraction radiotherapy when clinically appropriate \(e.g., not contraindicated by risk of imminent pathologic fracture, worsening neurologic compromise or radioresistant histologies such as sarcoma, melanoma, and renal cell carcinoma\).](#)
- B) Surgical decompression for malignant bowel obstruction.
- C) Medication therapy such as chemotherapy with low toxicity/low side effect agents with the goal to decrease pain from bulky disease or other identified complications. Cost of chemotherapy and alternative medication(s) should also be considered.

To qualify for treatment coverage, the cancer patient must have a documented discussion about treatment goals, treatment prognosis and the side effects, and knowledge of the realistic expectations of treatment efficacy. This discussion may take place with the patient's oncologist, primary care provider, or other health care provider, but preferably in a collaborative interdisciplinary care coordination discussion. Treatment must be provided via evidence-driven pathways (such as NCCN, ASCO, ASH, ASBMT, or NIH Guidelines) when available.

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

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

Lines 424,480,502,530,539,654

Inflammatory skin conditions included in this guideline are:

- A) Psoriasis
- B) Atopic dermatitis
- C) Lichen planus
- D) Darier disease
- E) Pityriasis rubra pilaris
- F) Discoid lupus

The conditions above are included on line 424 if severe, defined as having functional impairment (e.g. inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction) AND one or more of the following:

- A) At least 10% of body surface area involved
- B) Hand, foot or mucous membrane involvement.

Otherwise, these conditions above are included on Lines 480, 502, 530, 539 and 654.

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

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

GUIDELINE NOTE 42, CHEMODENERVATION FOR CHRONIC MIGRAINE

Line 409

Chemodeneration for treatment of chronic migraine (CPT 64615) is included on this line for prophylactic treatment of adults who meet all of the following criteria:

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

Treatment is limited to two injections given 3 months apart. Additional treatment requires documented positive response to therapy. Positive response to therapy is defined as a reduction of at least 7 headache days per month compared to baseline headache frequency.

GUIDELINE NOTE 79, BREAST RECONSTRUCTION

Line 191

Breast reconstruction is only covered after mastectomy as a treatment for breast cancer or as prophylactic treatment for the prevention of breast cancer in a woman who qualifies under Guideline Note 3, and must be completed within 5 years of initial mastectomy. [Revision of previous reconstruction is only covered in cases where the revision is required to address complications of the surgery \(wound dehiscence, fistula, chronic pain directly related to the surgery, etc.\)](#). Revisions are not covered solely for cosmetic issues.

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Breast reconstruction may include contralateral reduction mammoplasty (CPT 19318) or contralateral mastopexy (CPT 19316). Mastopexy is only to be covered when contralateral reduction mammoplasty is inappropriate for breast reconstruction and mastopexy will accomplish the desired reconstruction result.

GUIDELINE NOTE 148, BIOMARKER TESTS OF CANCER TISSUE

Lines 157,184,191,230,263,271,329,660

The use of ~~multiple molecular testing~~ tissue of origin testing ~~to select targeted cancer therapy~~ (e.g., CPT 81504) is included on line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

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

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

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

Oncotype DX Breast DCIS Score (CPT 81479) and Breast Cancer Index (may use CPT 81479, 81599, 84999, S3854) are included on Line 660.

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

For lung cancer, epidermal growth factor receptor (EGFR) gene mutation testing (CPT 81235) is included on Line 263 CANCER OF LUNG, BRONCHUS, PLEURA, TRACHEA, MEDIASTINUM AND OTHER RESPIRATORY ORGANS only for non-small cell lung cancer. KRAS gene mutation testing (CPT 81275) is not included on Line 263.

For colorectal cancer, KRAS gene mutation testing (CPT 81275) is included on Line 157. BRAF (CPT 81210) and Oncotype DX (81525) are not included on Line 157. Microsatellite instability (MSI) is included on line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

For bladder cancer, Urovysion (88120, 88121) testing is included on line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

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For prostate cancer, Oncotype DX Genomic Prostate Score (81479), Prolaris Score Assay (81541), and Decipher RP (81479) are included on Line 660.

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

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
C9745	Nasal endoscopy, surgical; balloon dilation of Eustachian tube	Insufficient evidence of effectiveness	May, 2018
C9749	Repair of nasal vestibular lateral wall stenosis with implant(s)	Unproven treatment	August, 2018
20985	Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less	Insufficient evidence of effectiveness	August 2018
G0481-G0483	Urine drug testing, definitive for >7 drug classes	<i>(Note: Not specified at this time; see will be addressed in future errata)</i>	August, 2018
Breast Cancer Gene Expression tests billed with nonspecific codes (e.g. 81479, 81599, 84999, S3854)	<ul style="list-style-type: none"> • Mammostrat • Oncotype DX Breast DCIS Score • Breast Cancer Index • IHC4 	Unproven Intervention	May, 2018 (breast cancer) Coverage Guidance Blog (Breast)
Prostate Cancer Gene Expression tests billed with nonspecific codes (e.g. 81479, 81599, 84999)	<ul style="list-style-type: none"> • Oncotype DX Genomic Prostate Score • Decipher RP for prostate cancer 	Unproven Intervention	January, 2018 (prostate) Coverage Guidance Blog (Prostate)
81301	Microsatellite instability (MSI) for colorectal cancer	Unproven Intervention	August, 2015 Coverage Guidance Blog

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81479	<ul style="list-style-type: none"> • Oncotype-DX Breast DCIS Score • Breast Cancer Index • Oncotype-DX Genomic Prostate Score • Decipher RP for prostate cancer 	Unproven Intervention	<p>May, 2018 (breast)</p> <p>Coverage Guidance Blog (Breast)</p> <p>January, 2018 (prostate)</p>
81504	Oncology (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores)	Unproven Intervention	August, 2015
81525	Oncotype DX for colon cancer	Insufficient evidence of effectiveness	November, 2015
88120, 88121	Urovysion for bladder cancer	Insufficient evidence of effectiveness	
96119	Neuropsychological testing (eg, Halstead-Reitan Neuropsychological Battery, Wechsler Memory Scales and Wisconsin Card Sorting Test)	No evidence of effectiveness	January, 2014
96120	Neuropsychological testing (eg, Wisconsin Card Sorting Test)		

Appendix A

For implementation January 1, 2019

GUIDELINE NOTE 5, OBESITY AND OVERWEIGHT

Line 320

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

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

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

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

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

~~GUIDELINE NOTE 67, ENZYME REPLACEMENT THERAPY~~

~~*Lines 60,147,660*~~

~~Enzyme replacement therapy for infantile Pompe's disease is included on Line 147. All other enzyme replacement therapies for inborn errors of metabolism are included on Line 660.~~

GUIDELINE NOTE 74, GROWTH HORMONE TREATMENT

Lines 40,386,467,650

~~Treatment with growth hormone is included only for children with: pituitary dwarfism, Turner's syndrome, Prader-Willi syndrome, Noonan's syndrome, short stature homeobox-containing gene (SHOX), chronic kidney disease (stages 3, 4, 5 or 6) and those with renal transplant. Treatment with growth hormone should continue only until adult height as determined by bone age is achieved. Treatment is not included for isolated deficiency of human growth hormone or other conditions in adults.~~

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GUIDELINE NOTE 132, ACNE CONGLOBATA AND ACNE FULMINANS

Line 373

Acne conglobata is only included on Line 373 if it involves recurrent abscesses or communicating sinuses. [ICD-10 L70.0 is included on line 373 only for acne fulminans.](#)

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
11981 G0516, G0518	Implantable buprenorphine for opioid use disorder for patients who are clinically stable on 8 mg daily or less of buprenorphine or equivalent for at least 6 months	Not cost effective compared to equally efficacious alternative formulations	November, 2017

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
S9357	Enzyme replacement therapy (e.g. idursulfase and similar medications) for all inborn error of metabolism conditions except infantile Pompe's disease	No clinically important benefit	<u>August, 2012</u>
11981 G0516, G0518	Implantable buprenorphine for opioid use disorder for patients other than those who are clinically stable on 8 mg daily or less of buprenorphine or equivalent for at least 6 months	Unproven treatment	November, 2017

Appendix B

New Guideline Notes

Effective October 1, 2018

DIAGNOSTIC GUIDELINE D23 URINE DRUG TESTING *[Editor's Note: The language in green below was adopted at the HERC meeting later the same day]*

Urine drug testing (UDT) using presumptive testing is a covered diagnostic benefit when the results will affect treatment planning. Definitive testing is covered as a confirmatory test only when the result of the presumptive testing is inconsistent with the patient's history, presentation, or current prescribed medication plan, and the results would change management.

Definitive testing other than to confirm the results of a presumptive test as specified above is not covered, unless the clinician suspects use of a substance that is inadequately detected by presumptive UDT (e.g., fentanyl). Definitive testing is limited to no more than seven drug classes per date of service.

For patients receiving treatment for a substance use disorder, presumptive testing on up to 36 dates of service and definitive testing on up to 12 dates of service per year are covered. These limits must be applied in accordance with mental health parity law.

For patients receiving chronic opioid therapy for chronic pain, frequency of testing depending on the patient's risk level (using a validated opioid risk assessment tool). Definitive testing should be conducted only for confirmatory purposes as described above and should not exceed 12 dates of service per year:

- Low Risk: Random presumptive testing on up to two dates of service per year
- Moderate Risk: Random presumptive testing on up to four dates of service per year
- High Risk: Random presumptive testing on up to 12 dates of service per year

In patients with unexplained alteration of mental status and when knowledge of drug use is necessary for medical management (e.g., emergency department evaluation for altered mental status), UDT (presumptive and confirmatory definitive testing, if indicated) is covered in excess of the above limitations.

Urine drug testing conducted in accordance with policy of the DHS Office of Child Welfare Programs, when medically necessary, is also covered in excess of these limitations.

GUIDELINE NOTE 19 NEUROPSYCHOLOGICAL TESTING FOR PTSD

Line 173

Neuropsychological testing is included on this line only when there is question of cognitive deficit or impairment and such testing is required to assist in making the correct diagnosis.

Appendix B

Effective January 1, 2019

GUIDELINE NOTE XXX DIABETES PREVENTION PROGRAM

Line 3

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

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

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

Effective January 1, 2020

GUIDELINE NOTE XXX SEVERE CYSTIC ACNE

Line XXX,520

Acne is only included on Line XXX if it is severe, defined as the presence of the following characteristics: persistent or recurrent inflammatory nodules and cysts AND ongoing scarring. Otherwise, acne diagnoses are included on line 520.

Appendix C

2019 ICD-10 Code Placement

[insert Excel document from the minutes folder here]

DRAFT

MINUTES

Evidence-based Guidelines Subcommittee

Clackamas Community College
Wilsonville Training Center, Rooms 111-112
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
September 6, 2018
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 (by phone until 2:50 pm); Leslie Sutton.

Members Absent: None.

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

Also Attending: Adam Obley, MD, Val King MD, MPH, and Craig Mosbaek (OHSU Center for Evidence-based Policy), Crispin Davies, MD (OHSU, Veteran's Administration).

1. CALL TO ORDER

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

2. MINUTES REVIEW

Minutes from the 7-12-2018 meeting were reviewed and approved 5-0 (Sutton abstained).

3. STAFF REPORT

Coffman reported that the plan to bring a scope statement on Out-of-Hospital Birth has been delayed in order to coordinate with other OHA efforts. At this point, the plan is to put it out for comment in October and bring it to the November 1 meeting. The topic would be developed in 2019 if the rescan indicates updating the Coverage Guidance is warranted.

4. Review draft coverage guidance: Newer Interventions for Osteoarthritis of the Knee

Obley and Livingston presented the draft Coverage Guidance based on the meeting materials. Kansagara said that transcutaneous electrical nerve stimulation (TENS) and whole body vibration (WBV) both have low strength evidence. Livingston said TENS had evidence of no benefit, whereas WBV has limited evidence which does suggest a benefit. Little asked about the threshold for minimum clinically important difference. Obley said this is explained in the AHRQ report, reproduced in an appendix to the coverage guidance. This was based on the threshold defined by the underlying studies. Stecker said power of studies could influence strength of recommendation as well. Kansagara said he is raising the issue for consistency about how we apply strength of recommendation. Obley said optimal information size is factored into the GRADE ratings, and the GRADE ratings in this report are adopted from AHRQ, which doesn't have a "very low confidence" rating. Thus the precision issue is already factored in to the confidence rating. After discussion the subcommittee changed the strength of the recommendation against coverage to "strong" for both interventions since neither had evidence of a clinically-important difference. They also added a statement in the "other factors" column for all of the interventions indicating that due to the prevalence of the condition, availability of other treatments and the ease of conducting a study, the subcommittee would require moderate evidence of clinically significant benefit in order to recommend coverage.

In review of glucosamine-chondroitin (both combined and separate), several items were discussed. Members questioned the clinical importance of intermediate, but not long-term benefits in a chronic degenerative condition. There were concerns raised about implementation of coverage of a treatment with only intermediate-term, but not long-term benefit. It would be challenging to stop treatment for a patient taking a drug who believes it is working, even if the evidence suggests it would no longer be effective. There could be administrative challenges as well.

Another concern was raised about the lack of standardization of dietary supplements and members decided to add a statement to the other factors column of the GRADE table indicating that because these are regulated as dietary supplements, available supplements may vary substantially in quality.

They discussed whether this concern might discourage use of prenatal vitamins and other supplements, but decided that this was a valid concern for any dietary supplement. By itself, the lack of regulation would not necessarily preclude coverage.

Sutton asked about how dosage and length of treatment prior to conducting the study played a role. Obley said he didn't know for each study, though typically patients who had already been taking the supplements had a period without the supplements prior to the start of the study.

After discussion, the group agreed that the results were mixed and accepted the recommendations as proposed for glucosamine, chondroitin and glucosamine-chondroitin.

For platelet rich plasma, Little asked about the duration of treatment. Obley said it was a series of 3 weekly injections.

A motion was made to refer the draft coverage guidance to be posted as amended for public comment.
Motion approved 5-0 (Lindsey absent).

DRAFT HERC Coverage Guidance

Whole body vibration

Whole body vibration is not recommended for coverage (*strong recommendation*).

TENS

TENS is not recommended for coverage (*strong recommendation*).

Glucosamine/chondroitin

Glucosamine/chondroitin is not recommended for coverage (*weak recommendation*).

Glucosamine alone is not recommended for coverage (*strong recommendation*).

Chondroitin alone is not recommended for coverage (*weak recommendation*).

Platelet-rich plasma

Platelet-rich plasma is not recommended for coverage (*weak recommendation*)

5. Temporary Percutaneous Mechanical Circulatory Support with Impella Devices

Coffman introduced Dr. Crispin Davies, the appointed expert for this topic. Crispin Davies, MD has served as cardiac catheterization lab director at OHSU and the Portland VA Medical Center for fifteen years. His lab has a program that includes Impella-supported percutaneous coronary intervention (PCI). The is a member of the VA's national CART Major Adverse Event Committee and has taught medicine for over 25 years. He uses Impella devices in his practice but reported no conflicts of interest.

Obley reviewed the evidence in the draft Coverage Guidance. Sutton asked about the use of these devices in people needing a bridge to transplant or recovery. Obley said that there is no comparative evidence in this area, but that the recommendation as drafted would allow for coverage in these situations. She asked what the setting is for this. Obley explained that these are more temporary than the durable left ventricular assist devices (LVADs) that are used as destination therapy or as a bridge to transplant. They could be used on a temporary device while making decisions about a transplant or an LVAD.

Kansagara asked about prior authorization of these devices. Obley said that it would likely be possible in the setting of high-risk PCI but not in the setting of acute cardiogenic shock, since the latter is an emergency situation.

Stecker asked about the implication of the coverage policy based on payment policy. Gingerich said he looked at this in a fair bit of depth, and Medicaid fee-for-service pays many hospitals using the DRG payment system, where payment for the hospitalization is bundled based on the patient's condition. However, some CCOs contract with hospitals to pay a percentage of billed charges. In the latter setting,

this policy would affect hospital charges. Little said that even in the DRG methodology there are outlier payments which would likely be triggered by an Impella device. Stecker suggested that CCOs could also use a coverage guidance to encourage hospitals to use cost-effective treatments.

In discussion of the guidelines and other payer coverage, Stecker noted that the Washington Medicaid policy was much more liberal than the society guidelines, which is a unique situation. The society guidelines are fairly nuanced and conservative.

Davies said that it's important to know that balloon pumps don't work except in very rare situations, based on widespread data. The volume of blood pumped by a balloon pump is too low to affect outcomes. Livingston asked whether there is a better comparator than intra-aortic balloon pumps. Davies said there is not.

Livingston reviewed the patient values and preferences, resource allocation and recommendation against coverage for both populations.

Kansagara said that the reviews discounted the noncomparative observational studies. This would be true for mortality and major adverse cardiac event (MACE) outcomes. Kansagara said these studies would be useful for harms. Obley said that the Health Ontario study relied on these observational studies for the bleeding and vascular complications, which didn't appear to be different for high-risk PCI but were higher in cardiogenic shock. Kansagara said there were impressive results on vascular harms. He then invited Dr. Davies to share his thoughts.

Davies said he couldn't fault the summary of the data. He said the question is whether the data is so poor that it's telling you nothing. There's a mismatch here between the data and what is seen in practice. He noted that there are only four studies, two by the same author in the same year, and that the cardiogenic shock studies are incredibly small. It is all about Protect 2 for high-risk PCI. The trial is deeply flawed. It was terminated early for futility, but after it was terminated they put in an extra 20 percent of patients. They used a smaller device, which is probably inadequate. They never gave the centers a device to practice with, so the first time the center used the device was the first case in the trial. These are big, difficult devices and difficult to place. He said that if you were to exclude the first balloon pump and the first Impella from the results you would get a benefit. There is every reason to believe the trial is underpowered, stopped prematurely and was done by people who were not facile with the device during the trial.

Davies said that interventionalists are now more accustomed to placing larger devices. He also said patients in the real world tend to be more sick than patients in the trial which may be another reason it didn't show a benefit. Still he shares the frustration about the lack of evidence. He also said the intention-to-treat approach is appropriate in drug studies, but not in devices since they can't work unless inserted. Obley said there was statistically significant difference in the composite outcome for the per-protocol analysis but the subcomponents were not listed. Davies said that if you retrospectively exclude the first patients as well as patients who got an additional intervention they wouldn't have gotten without the Impella and analyze per protocol, Impella appears to show a benefit for the outcome of low blood pressure. Kansagara said that if there is improvement in blood pressure there should be improvement in myocardial infarctions or strokes. Davies agreed, but said the definition of infarctions was robust. Still, the results aren't impressive.

He explained that the reason interventional cardiologists like these devices so much is because the headline data for the hemodynamics are so much better than the balloon pump. The average cardiac output is 5 L. A balloon pump produces 0.3 to 0.5 L of augmentation; an Impella produces 2.5, 3.5 or 5 L. That's big enough support human circulation and to rest the heart during the procedure. From a practical point of view there are many cases that an interventionalist simply will not do without an Impella. The clinical reality is just so much better. People have adopted these with abandon and the number being placed in Oregon are really very large. Some of the people are even lower risk than Protect 2 standards. That said, if a procedure goes wrong the first question asked is "why didn't you use an Impella?" There is a dilemma between the terrible data, the fact that it seems to make cases go better and that when it goes wrong everyone wants to know why you didn't use an Impella. He doesn't have a satisfactory answer.

Kansagara asked Davies to explain the link between the intermediate outcome of cardiac output and a health outcome. What does it mean that the procedure goes better in terms of clinical outcome? Davies said it's the tolerability. Normally you are operating on one of the three arteries and the heart is still beating. The heart has six beats of squeeze in it. When you work on an artery, you block that artery, which is ok since the other arteries still work. You can push that to a certain point. If you work on the whole heart circulation (left main artery with a blocked right coronary artery, for instance), you only have six beats of time during which to place a stent. If there's a hiccup and it doesn't work, the patient just dies. The Impella allows the heart to maintain cardiac output, allowing the surgeon more time to place the stent correctly.

Davies said that this is illustrated by the Protect 2 study, because since they had more time, the surgeons did a really nice job, fixing all the narrowings of the arteries and grinding away to get a nice result. That's one of the reasons they didn't come out ahead for acute outcomes. Obley said to that point, the results table in the intention to treat population, the only subcomponent of the composite outcome that achieved statistical significance was revascularization.

Kansagara asked what definition of myocardial infarction (MI) was used in the study. Kansagara said it is a relatively harsh definition, which would not pick up minor MIs.

Kansagara said that if something goes wrong in the six beats, the consequence is dire. Therefore, the ability to detect an adverse outcome should be pretty high since the adverse outcome will be death. Davies said that in practice, this would be true except that surgeons won't even take the case on if they don't think it will go well. People want procedures to be risk-free. He agreed that in a trial it should have been much easier to show a benefit. Now that the trial is over we have missed the opportunity for a long time. No one would randomize themselves to not receive a device that is ubiquitous. Obley said this is true; there is a study of Impella that is underway but it is having difficulty recruiting patients.

Stecker said he was concerned about this topic because of heavy marketing, expense and the potential for indication creep when the device has dubious data. That said there are expenses he incurs on behalf of patients that don't have good data, but seem to improve efficacy and safety somewhat. Undoubtedly, there are patients who are bridged to survival or did not die during the intervention because of Impella. But there are also patients who never get an Impella but survive, and we don't know why. He said the subcommittee must consider the fact that patients will not be able to get high-risk PCI if Impella is not available.

Davies said the alternative is coronary artery bypass grafts, which are not indicated for 70 percent of these people. If you don't do Impella-assisted PCI, you are saying you are not going to treat patients with these conditions. Still he said "creep" is not the right word; use of Impella is mushrooming for poor indications. He said it's well-reimbursed and there's no brake in the system. There is no competitor.

Sutton asked about alternatives. Davies said there is the balloon pump which is ineffective. There was the TandemHeart, which enjoyed a brief flourish but has no better data and is hard to use. You can put people on bypass but it doesn't work very well, has no data and does not rest the heart. Impella is undoubtedly the best physiologic approach and there is no competitor in sight. Kansagara asked what would have been done before these were available. Davies said the options were high-risk surgery, or nothing at all. Impella is attractive, especially with the aging population for whom comorbidities are an issue.

Stecker said it makes it difficult since the guidelines offer weak support. Davies said he believes the guidelines are honest and say reasonable things. Kansagara said it's almost compelled coverage since the patients won't be treated without Impella, which raises ethical issues. Stecker said this may be a situation like urine drug testing where the recommendation is based on something besides evidence.

Little said that the subcommittee has no option but to put the draft out for public comment and allow the company to convince the subcommittee otherwise.

Davies said for the bridge to recovery and bridge to transplant populations, there is no evidence as the populations are very small. He said experts in the field would be passionate that these devices make a difference in small numbers of selected, young patients. Kansagara said that is a different situation where there is no data and it would be different to study. Obley said there is an observational trial in this population, but these reports were negative and insufficient to draw conclusions.

The subcommittee agreed to add a statement excluding patients using Impella as a bridge to transplant or a more durable LVAD, regardless of whether they were in cardiogenic shock.

For PCI, Kansagara said there would be an inpatient high-risk PCI group and an outpatient elective PCI. Obley asked Davies about placing these devices unplanned. Davies said he would try not to for many reasons, but this avoidance of unplanned Impella placement results in interventionists placing them when they may not be needed. He has placed about 80 percent of the devices for patients in an inpatient setting, but other interventionalists are likely less conservative.

Stecker said that patients with refractory angina or acute MI in the setting of left main or last remaining conduit with ejection fraction < 35 % are ones who conceivably could benefit but who may not be able to get PCI without an Impella. Kansagara asked whether use in the community extended beyond those settings. Davies said he is not sure. Protect 2 is probably not the exact correct population but is a step in the right direction. The key factor is that patients with an ejection fraction of less than 30% have a thirty-fold risk (at least this is what is commonly said). That said, if the risk is that high, why has the manufacturer not been able to show benefit? He said Washington's statement would be where most academic cardiologists would find themselves. Stecker said that with respect to PCI it is hard to disagree.

Kansagara suggested that this might lead others to release devices without supporting data in order to make conducting a trial difficult. Stecker advocated for a time-limited coverage policy which would require evidence development for continued coverage.

Stecker asked whether the patients who would be eligible for surgery should be required to have surgery rather than high-risk PCI with Impella. Davies said that with surgeons' results under a microscope, surgeons are reluctant to take on high-risk cases. Secondly, the population is getting older. People who weren't treated 20 years ago are now treated and expect to go on to live fulfilling lives.

Kansagara said he hoped there were some surgeons who would practice based on an evidence-based recommendation. Stecker said that for a patient at high risk for bad outcomes, physicians won't accept the legal risk of treatment without a device like Impella which may reduce risk and is considered standard of care. For elective procedures, health systems won't allow them without such a device.

If we're unclear whether revascularization would improve outcomes in the nonrefractory angina patient, that gets into what Alison says, "Would medical management be reasonable?" Davies said stenting doesn't improve hard outcomes at all, though it may improve ability to function without chest pain. But some patients come in with an NSTEMI and have "smoldering" symptoms. He doesn't believe PCI affects "hard" outcomes such as death and MI in stable patients except possibly in patients with high SYNTAX scores.

There was extensive discussion about several groups:

- Patients with chronic refractory angina who are not candidates for coronary artery bypass but who have left main or last remaining conduit disease with low ejection fraction. Davies said these patients might experience quality of life benefits but would not likely have a reduced risk of death or major cardiac event from such a PCI. Coverage policy is most likely to affect this population as it is an elective procedure.
- Patients with STEMI heart attacks in cardiogenic shock. Davies said that surgeons are likely to use the device regardless of coverage policy when they think it is appropriate regardless of payment policy or evidence, even though it may not help. There is no good evidence in this population.
- Patients with NSTEMI heart attacks with "smoldering" symptoms. Davies suggested these patients may be most likely to benefit because Impella would improve perfusion, but again there is no evidence.
- Patients with non-ischemic cardiogenic shock. Davies stated that these devices are uniquely suited to ischemic rather than non-ischemic cardiogenic shock. Patients with non-ischemic cardiogenic shock are mostly young patients and would be difficult to deny Impella for, but there is no evidence and the situation is extremely rare. Impella would likely be used as a bridge to transplant or recovery or a more durable LVAD.

Kansagara suggested several options. One would be to recommend against coverage for the remaining groups. The second would be to use the Washington recommendation and add chronic refractory angina as a third bullet as well as adding something requiring the patients not to be candidates for CABG.

After discussion, the subcommittee decided to recommend against coverage for all forms of cardiogenic shock and add a note excluding patients bridging to a decision for a transplant or a more durable LVAD from the recommendation (regardless of whether they had cardiogenic shock). They decided to make it a weak recommendation because of the clinical nuances discussed with potential catastrophic outcomes, and noncoverage may result in barriers to access. They will address potential changes to the recommendation based on public comment.

A motion was made to post the draft coverage guidance for comment as amended. **Motion approved 5-0 (Lindsey absent).**

DRAFT HERC Coverage Guidance

Temporary percutaneous mechanical circulatory support with Impella devices is not recommended for coverage for patients receiving high-risk percutaneous coronary interventions or with cardiogenic shock (*weak recommendation*).

Note: This recommendation does not address Impella for patients bridging to decision for a transplant or a more durable LVAD.

7. ADJOURNMENT

Due to time constraints, the subcommittee was unable to discuss the multisector intervention scope statements, which will be carried to the next meeting. The meeting was adjourned at 5:00 pm. The next meeting is scheduled for November 1, 2018 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

VbBS Report

Consent Agenda Issues—October 2018

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
H93.8X	Other specified disorders of ear	444 HEARING LOSS - OVER AGE OF FIVE	H93.8X is found on line 311 for hearing loss under the age of 5, but not on line 444. A similar code (H94.8) is on both lines. This code has few subdiagnoses.	Add ICD-10 H93.8X to line 444
Z87.891	Personal history of nicotine dependence	INFORMATIONAL DIAGNOSIS FILE	Z87.891 is informational, but it is used as a primary diagnosis when ordering a screening lung CT for people with a history of 30 pack years of smoking. This is a USPSTF recommendation. G0297 Low dose ct scan (ldct) for lung cancer screening is on Line 3.	Add Z87.891 to Line 3 Preventive Services
58541-58544	Laparoscopy, surgical, supracervical hysterectomy	395 ENDOMETRIOSIS AND ADENOMYOSIS	Line 395 is missing several hysterectomy CPT codes; other hysterectomy codes appear on this line.	Add 58541-58544 to line 395
33724	Repair of isolated partial anomalous pulmonary venous return (eg, Scimitar Syndrome)	105 TETRALOGY OF FALLOT (TOF); CONGENITAL VENOUS ABNORMALITIES	ICD10 Q26.8 (Other congenital malformations of great veins) which, which is used for Scimitar Syndrome, is on line 105. CPT 33724 is on line 130 TOTAL ANOMALOUS PULMONARY VENOUS CONNECTION. These codes should pair.	Add 33724 to line 105
L55.2	Sunburn of third degree	57 SEVERE BURNS 181 CONDITIONS INVOLVING EXPOSURE TO NATURAL ELEMENTS (E.G., LIGHTNING STRIKE, HEATSTROKE)	In August, 2018, HERC created a new third degree burn line, effective Jan 1, 2020. L55.2 was not considered. It's currently on line 181 but should be on new line 57.	Add ICD-10 L55.2 to the new line 57 SEVERE BURNS effective Jan 1, 2020; remove from line 181 at that time.

Consent Agenda Issues—October 2018

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
L73.0	Acne keloid	373 ACNE CONGLOBATA (SEVERE CYSTIC ACNE)	ICD-10 L73.0 was mistakenly added to line 373 and should be removed. It should remain on line 520 ROSACEA; ACNE	Remove ICD-10 L73.0 from line 373

VbBS Issue Summaries 10-4-2018

Straightforward Guideline Note Changes
October 2018

- 1) Guideline note 65 lists a series of telephone and email consultation CPT codes (CPT 98966-98969 Telephone assessment and management service provided by a qualified nonphysician health care professional to an established patient, parent, or guardian....). There is another set of telephone consultation codes not included in this guideline that are appropriate, CPT 99441-99443 (Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian...). These codes should be added to the GN as shown below.

GUIDELINE NOTE 65, TELEPHONE AND EMAIL CONSULTATIONS

Included on all lines with evaluation & management (E&M) codes

Telephone and email consultations (CPT 98966-98969, [99441-99443](#)) must meet the following criteria:

- 1) Patient must have a pre-existing relationship with the provider as demonstrated by at least one prior office visit within the past 12 months.
 - 2) E-visits must be provided by a physician or licensed provider within their scope of practice.
 - 3) Documentation should model SOAP charting; must include patient history, provider assessment, and treatment plan; follow up instructions; be adequate so that the information provided supports the assessment and plan; must be retained in the patient's medical record and be retrievable.
 - 4) Telephone and email consultations must involve permanent storage (electronic or hard copy) of the encounter.
 - 5) Telephone and email consultations must meet HIPAA standards for privacy.
 - 6) There needs to be a patient-clinician agreement of informed consent for E-visits by email. This should be discussed with and signed by the patient and documented in the medical record.
-
- 2) Add GN166 to line 401 CONDITIONS OF THE BACK AND SPINE. GN166 is currently only attached to line 558 MACROMASTIA, which has raised questions by some providers.

GUIDELINE NOTE 166, BREAST REDUCTION SURGERY FOR MACROMASTIA

Line [401](#), 558

Breast reduction surgery for macromastia is not covered as a treatment for neck or back pain resulting from the macromastia due to lack of high quality evidence of effectiveness.

S86 Series Review

Issue: The orthopedic ICD-10 review never completed their review of all orthopedic-related codes. The S86 series was never reviewed and several diagnoses appear to be on inappropriate lines. This topic was brought to our attention by a CCO medical director question.

The lines proposed for placement have a guideline which determines when the diagnosis is on the covered line and when on the lower line.

GUIDELINE NOTE 98, SIGNIFICANT INJURIES TO LIGAMENTS, TENDONS AND MENISCI

Lines 376,430,605

Significant injuries to ligaments, tendons and/or menisci are those that result in clinically demonstrable joint instability or mechanical interference with motion. Significant injuries are covered on Line 376 or Line 430 for both medical and surgical interventions and non-significant injuries are included on Line 605.

Iliotibial (IT) band syndrome (ICD10 M76.3) is included on Line 376 only for pairing with 2 physical therapy visits with a provider licensed to provide physical therapy services, anti-inflammatory medications, and primary care office visits. Otherwise, it is included on Line 605.

HERC staff recommendation:

- 1) Move the codes below to the recommended line(s)

ICD-10 Code	Code Description	Current line(s)	Recommended Line(s)
S86.11	Strain of other muscle(s) and tendon(s) of posterior muscle group at lower leg level	430 Internal derangement of knee and ligamentous disruptions of the knee, resulting in significant injury/impairment 605 Sprains and strains of adjacent muscles and joints, minor	376 DISRUPTIONS OF THE LIGAMENTS AND TENDONS OF THE ARMS AND LEGS, EXCLUDING THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT 605
S86.21	Strain of muscle(s) and tendon(s) of anterior muscle group at lower leg level	430, 605	376, 605
S86.31	Strain of muscle(s) and tendon(s) of peroneal muscle group at lower leg level, right le	430, 605	376, 605
S86.81	Strain of other muscle(s) and tendon(s) at lower leg level	430, 605	376, 605
S86.91	Strain of unspecified muscle(s) and tendon(s) at lower leg level	430, 605	376, 605

**Gender Dysphoria Coding Issues
October 2018**

Question: Should various procedures be added to the gender dysphoria line?

Question source: Various providers

Issue: Various non-pairings have arisen with line 312 GENDER DYSPHORIA/TRANSEXUALISM. These questions mainly involve the types of PT included on the line, as well as lack of inclusion for several urethral procedures. These procedures have been discussed with gender dysphoria experts. The expert and HERC staff recommendations are shown below. These CPT codes all appear on a variety of other covered lines.

Urethroplasty codes not appearing on line 312:

- 53405 Urethroplasty; second stage (formation of urethra), including urinary diversion
- 53410 Urethroplasty, 1-stage reconstruction of male anterior urethra

PT codes not appearing on line 312:

- 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
- 97116 Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)
- 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

Expert input:

Daniel Dugi, MD, OHSU surgery

All of the gender-affirming genital surgeries (vaginoplasty/vulvoplasty, metoidioplasty, phalloplasty) involve extensive operation on the urethra, hence a urethroplasty code, which captures time and effort not described by other codes. The 2nd stage code is used particularly with phalloplasty—in the first stage phalloplasty we create the phallus for the penile portion, but we don't connect it to the native urethral position until a second stage surgery. Additional, for phalloplasty patients who have complications of fistula or stricture, we often need to address that in 2 stages, hence the need for a 2nd stage procedure code.

These other PT codes seem to relate to physical therapists more holistic approach to rehab, especially after a major surgery that requires people to limit their walking. I don't think they are really specific to gender dysphoria treatment but helpful instead for recovery after these major surgeries.

HERC staff recommendations:

- 1) Add CPT 53405 (Urethroplasty; second stage (formation of urethra), including urinary diversion) and 53410 (Urethroplasty, 1-stage reconstruction of male anterior urethra) to line 312 GENDER DYSPHORIA/TRANSEXUALISM
- 2) Do not add the PT codes as they are not indicated for gender dysphoria treatment

Unspecified Mood Disorder

Question: Should restrictions be placed on the utilization of ICD-10 F39 (Unspecified mood disorder)?

Question source: Lea Forsman; OHA behavioral health team

Issue: Until 2015, F39 (Unspecified mood [affective] disorder) had a guideline note restricting use to children 18 years and under, with pairings allowed only with a few procedure codes (see the historical GN28 below). This guideline was removed in 2015 due to concerns that under the ACA, such restrictions would be considered age discrimination without a medical justification. Additionally, HERC staff felt that mental health parity rules would not allow restriction of use of the F39 code to only a few services. F39 is currently on line 204 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE.

There was discussion at the August 2018 VBBS meeting regarding this topic. Hodges felt that the staff proposed guideline note would make the exceptions process more streamlined. Gibson felt that a guideline note was not needed based on what appeared to be generally appropriate utilization. HERC staff was directed to consult the CCO medical directors to determine if a guideline note was desirable and useful for the CCOs.

Material included in August 2018 issue summary:

BHAP discussed this topic at their June 2018 meeting. It was noted that this code is often used when a patient is developing a disorder, but has not had enough symptoms to meet diagnostic criteria for any specific disorder. Bradshaw, however, noted that he sees this diagnosis used for years on end and no more specific diagnosis is ever made. There was agreement that this diagnosis could be overused. Savicki recalled that this diagnosis had a guideline to initially restrict to kids due to not wanting to give diagnosis to kids like bipolar disorder or other disorder which might lead to overtreatment, etc. Cobb reflected that overuse might not be a problem if it reflects more people getting into initial treatment.

BHAP requested that HERC staff reach out to the OHA team to get additional information about the overutilization they reported. Is the overuse just more initial diagnoses of more patients, or is it being used for a long time for single patients, which would be sloppy coding. Staff reached out to the OHA behavioral health team and did a utilization review (below).

BHAP members were divided on the need for a guideline for F39. In general, members were supportive of a guideline; however, some felt that there should be somewhat broad leeway for clinicians to see a patient multiple times to determine an exact diagnosis. Rural areas may have more need for this code due to a relative lack of behavioral health workforce to assist in making a definitive diagnosis.

Utilization data:

2017 data, FFS and CCO

Of 4220 individuals. 1 had 106 unique dates of service (DOS). 14 had >30; 142 had >10, 358 had >5, 967 had 3 or more. 2472 had 1, 781 had 2. Therefore 77% of patients had this diagnosis used 1 or 2 times. The majority of claims were for outpatient clinic visits. Psychotherapy, lab tests, ER visits, and inpatient treatment were also billed with this code.

Unspecified Mood Disorder

Proposed guideline note:

GUIDELINE NOTE XXX UNSPECIFIED MOOD DISORDER

Line 204

ICD-10 F39 (Unspecified mood [affective] disorder) is included on line 204 only when

- 1) A person is in the diagnostic phase of a workup, OR
- 2) A person is seen in an urgent/emergency care setting where the focus is on directing the person to the correct provider, OR
- 3) Used for services for pre-verbal children or patients who are non-verbal, OR
- 4) It is not possible to give a more specific diagnosis due to cultural/stigma considerations.

CCO responses:

- 1) CareOregon: our consensus is that use of F39 does not present enough of a problem to warrant an intervention by HERC, either a new guideline note or visit limit
- 2) Pacific Source: recommended adoption of the guideline with removal of #4
- 3) FFS: did not recommend adoption of the guideline as limits may not be appropriate

HERC staff summary

BHAP and the CCOs were split on the need for a new guideline for F39 Unspecified mood disorder. Given this split in opinion, HERC staff recommend no guideline at this time, with review of utilization in a year or two. If utilization is seen as problematic, then a guideline can be considered at that time.

BHAP/HERC staff recommendation:

- 1) Do not adopt a new guideline regarding F39 (unspecified mood disorder) for line 204
DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE

Brow Ptosis
2019 ICD-10 Code Placement Issues

Issue: ICD10 H57.81 (Brow ptosis) was discussed at the August 2018 VBBS meeting. The staff recommendation was to add the new code to 3 lines with appropriate CPT codes, with a new guideline to specify when the diagnosis is on each line. One covered line would be for congenital cases in children, the second covered line would be for acquired cases in older patients that caused significant visual issues, and the uncovered line would be for cosmetic brow ptosis. The proposed guideline was written with the assistance of pediatric and adult ophthalmologists.

At the August meeting, VBBS members felt that the pediatric placement and section of the guideline were appropriate. However, the wording of the guideline for the adult acquired section was felt to be too “jargon-y” and difficult to understand by non-ophthalmology reviewers. HERC staff was instructed to work with ophthalmologists to try to make the wording more understandable by the average reviewer.

HERC staff have worked with CCO medical directors and ophthalmologists. There has been a dichotomy of thoughts on simplifying the brow ptosis guideline. Some medical directors and all the ophthalmologists thought that using the common wording that is included in CMS guidelines and most private insurer guidelines is preferable, as this is what ophthalmologists are used to documenting. Other CCO medical directors felt that simplification would be preferable and assist in reviewing these types of claims.

There was also a couple of responses from CCO medical directors who felt that brow ptosis was a low priority issue and who objected to the placement on a covered line.

Definition: Brow ptosis is decent of the brow and brow fat pad and typically occurs with advancing age. Drooping of the eyebrows can occur to such an extent that excess tissue is pushed into the upper eyelid that may cause mechanical blepharoptosis and/or dermatochalasis. In the most severe cases, the drooping can obstruct the visual field and cause positional head changes. There are 2 types of ptosis: acquired and congenital. Ptosis in early childhood can lead to amblyopia. Ptosis may occur because the levator muscle's attachment to the lid is weakening with age. Acquired ptosis can also be caused by a number of different things, such as disease that impairs the nerves, diabetes, injury, tumors, inflammation, or aneurysms. Congenital ptosis may be caused by a problem with nerve innervation or a weak muscle. Drooping eyelids may also be the result of diseases such as myotonic dystrophy or myasthenia gravis. It is considered a cosmetic issue unless the visual field is impacted. The treatment is surgical repair (blepharoptosis).

Similar Codes:

- 1) CPT 67900 (Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)) is on lines 351 STRABISMUS DUE TO NEUROLOGIC DISORDER and 469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT.
- 2) ICD-10 Q10.0 (Congenital ptosis) is on lines 393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN and 469.
- 3) GN130 details criteria for the similar procedure of blepharoplasty (upper eyelid surgery)

Brow Ptosis
2019 ICD-10 Code Placement Issues

GUIDELINE NOTE 130, BLEPHAROPLASTY

Line 469

Blepharoplasty is covered when 1) visual fields demonstrate an absolute superior defect to within 15 degrees of fixation, 2) upper eyelid position contributes to difficulty tolerating a prosthesis in an anophthalmic socket, 3) essential blepharospasm or hemifacial spasm is present, OR 4) when there is significant ptosis in the downgaze reading position.

HERC staff recommendations:

- 1) Place H57.81 (Brow ptosis) on line 393 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN for congenital brow ptosis and on lines 469 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT Treatment PTOSIS REPAIR and line 652 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY for acquired brow ptosis
 - a. Will pair with repair CPT codes
- 2) Remove ICD-10 Q10.0 (Congenital ptosis) from line 469 and leave only on line 393
- 3) Adopt one of the two options below as a new guideline note:

OPTION 1: preferred by ophthalmology as consistent with other payer guidelines:

GUIDELINE NOTE XXX BROW PTOSIS

Lines 393,469,652

Brow ptosis repair is included on line 393 for congenital brow ptosis in children only when ALL the following criteria are met:

- 1) The condition developed within the first year of life, and
- 2) Ptosis interferes with field of vision, and
- 3) The child has abnormal head posture (e.g., head tilt or turn, chin up or chin down), amblyopia or strabismus or is at high risk for development of amblyopia.

Brow ptosis repair is included on line 469 for acquired brow ptosis only when ALL the following criteria are present:

- 1) Brow ptosis is causing a functional impairment of upper/outer visual fields with documented complaints of interference with vision or visual field related activities such as difficulty reading or driving due to upper brow drooping, looking through eyelashes, or seeing the upper eyelid skin, and
- 2) Photographs show the eyebrow below the supraorbital rim, and
- 3) Overhanging skin due to brow ptosis is sufficiently low to produce a visually significant field restriction of approximately 30 degrees or less from fixation or a central "pseudo- margin to reflex distance" of 2.0 mm or less, and
- 4) The visual field impairment cannot be corrected by an upper lid blepharoplasty alone.

Otherwise, brow ptosis repair is included on line 652.

Brow Ptosis
2019 ICD-10 Code Placement Issues

OPTION 2: suggested by medical directors with simplified language

GUIDELINE NOTE XXX BROW PTOSIS

Lines 393,469,652

Brow ptosis repair is included on line 393 for congenital brow ptosis in children only when ALL the following criteria are met:

- 1) The condition developed within the first year of life, and
- 2) Ptosis interferes with field of vision, and
- 3) The child has abnormal head posture (e.g., head tilt or turn, chin up or chin down), amblyopia or strabismus or is at high risk for development of amblyopia.

Brow ptosis repair is included on line 469 for acquired brow ptosis only when ALL the following criteria are present:

- 1) Brow ptosis is causing a functional impairment of upper/outer visual fields with documented complaints of interference with vision or visual field related activities such as difficulty reading or driving due to upper brow drooping, looking through eyelashes, or seeing the upper eyelid skin, and
- 2) Photographs show the eyebrow below the supraorbital rim, and
- 3) The visual field impairment cannot be corrected by an upper lid blepharoplasty alone.

Otherwise, brow ptosis repair is included on line 652.

Blepharoplasty

Question: Should the blepharoplasty guideline be clarified and brought into alignment with the CMS coverage criteria?

Question source: Holly Jo Hodges, CCO medical director

Issue: Recently, dermatochalasis was added to a covered line to pair with blepharoplasty. The blepharoplasty guideline was written by the ophthalmology ICD-10 reviewers, but never utilized as the diagnosis code needed for pairing with blepharoplasty was not added to the line in error. In May 2018, the HERC added the dermatochalasis diagnosis code to the blepharoplasty line. Dr. Hodges requested that the blepharoplasty guideline be reviewed. In particular, the first clause of the guideline was found to be confusing. CMS national coverage determination language has been updated since the ICD-10 ophthalmology review and Dr. Hodges suggested substituting in the current LCD language. The new language requires that the eyelid droop is “sufficiently low to produce a visually significant field restriction considered by this policy to be approximately 30 degrees or less from fixation.” Changing the current language requiring “visual fields demonstrate an absolute superior defect to within 15 degrees of fixation” to language requiring “30 degree loss of visual field” will allow ease of reviewing and reduce confusion among ophthalmologists.

This change was discussed at the August, 2018 VBBS meeting. HERC staff were directed to clarify the wording in the guideline with ophthalmology to allow non-ophthalmologists to better understand what the guideline is requiring. HERC staff consulted with ophthalmologists, who noted that the current wording is what CMS requires and what they are used to documenting. The ophthalmologists could not come up with different wording for item #1. Ophthalmology and CCO medical directors agreed that item #4 in the guideline should be removed.

HERC staff recommendation:

- 1) Modify GN130 as shown below

GUIDELINE NOTE 130, BLEPHAROPLASTY

Line 469

Blepharoplasty is covered when 1) ~~visual fields demonstrate an absolute superior defect to within 15 degrees of fixation~~ a minimum of 30 degrees of visual field loss exists with upper lid skin/margin in repose, 2) upper eyelid position contributes to difficulty tolerating a prosthesis in an anophthalmic socket, OR 3) essential blepharospasm or hemifacial spasm is present, ~~OR 4) when there is significant ptosis in the downgaze reading position.~~

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Question: Should elective newborn circumcision be moved to a higher priority position on the Prioritized List?

Question sources: Dr Rick Wopat, family physician; Dr. Steven Skoog, OHSU Pediatric Urology; Dr. Kim Wentz and Dr. Allan Merritt, HSD; various CCO medical directors

Issue: Newborn elective circumcision is currently prioritized to line 623 REDUNDANT PREPUCE Treatment ELECTIVE CIRCUMCISION. Medically indicated circumcision is found on several higher priority lines, 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION, 412 BALANOPOSTHITIS AND OTHER DISORDERS OF PENIS, and 496 PHIMOSIS. Medical conditions of the foreskin are also on higher priority lines without pairing with circumcision, such as balanitis on line 412 BALANOPOSTHITIS AND OTHER DISORDERS OF PENIS.

Historically, the OHP has never covered elective newborn circumcision. Review of minutes finds no discussion in the past 20 years on coverage of routine circumcision in newborns. When the Prioritized List was created, the American Academy of Pediatrics had a policy statement that routine newborn circumcision was not medically justified. The AAP has since changed this policy to a more pro newborn circumcision stance.

Recently, HERC staff undertook a review of medical indications for circumcision. As part of that review, HERC staff received considerable feedback regarding the need to review evidence published in the past 10 years regarding the benefits of newborn circumcision and the need to reconsider OHP policy to not cover routine newborn circumcision. As a result of this feedback, HERC staff has conducted an evidence review of the health benefits of circumcision and a policy review of expert groups regarding newborn circumcision.

Evidence

General

- 1) **Friedman 2016**, evidence-based review of circumcision
 - a. Lowered risk of HIV infection, based on 3 large RCTs conducted in Africa in areas of high HIV endemicity. Lowered risk of STI infection in males in settings of high STI endemicity
 - i. These conclusions are limited by the lack of high-quality data from areas outside of Africa.
 - ii. Evidence outside of Africa comes mostly from observational studies. Such studies were conducted in the USA and Israel, where circumcision rates are high and HIV burden is relatively low, and similarly showed an inverse association between circumcision and HIV acquisition
 - b. When the effects of adult circumcision on sexual function and satisfaction of men are examined, high-quality evidence strongly supports lack of harm.
 - c. Circumcision rarely causes serious complications if practiced by trained practitioners, in a sterile setting, and with a proper follow-up.
 - d. Conclusion: a definite pro or con recommendation, based on a risk-benefit ratio, cannot be made

Reduction in HIV acquisition

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- 1) **Sigfried 2013**, Cochrane review on male circumcision and reduction in HIV acquisition
 - a. N=3 RCT
 - i. Conducted in South Africa (N = 3 274), Uganda (N = 4 996) and Kenya (N = 2 784) between 2002 and 2006. All three trials were stopped early due to significant findings at interim analyses.
 - b. The incidence risk ratio (IRR) was 0.50 at 12 months with a 95% confidence interval (CI) of 0.34 to 0.72; and 0.46 at 21 or 24 months (95% CI: 0.34 to 0.62). These IRRs can be interpreted as a relative risk reduction of acquiring HIV of 50% at 12 months and 54% at 21 or 24 months following circumcision.
 - c. We conducted a meta-analysis of the secondary outcomes measuring sexual behaviour for the Kenyan and Ugandan trials and found no significant differences between circumcised and uncircumcised men. For the South African trial the mean number of sexual contacts at the 12-month visit was 5.9 in the circumcision group versus 5 in the control group, which was a statistically significant difference ($p < 0.001$). This difference remained statistically significant at the 21-month visit (7.5 versus 6.4; $p = 0.0015$). No other significant differences were observed.
 - d. Incidence of adverse events following the surgical circumcision procedure was low in all three trials.
 - e. the potential for significant biases affecting the trial results was judged to be low to moderate given the large sample sizes of the trials, the balance of possible confounding variables across randomised groups at baseline in all three trials, and the employment of acceptable statistical early stopping rules.
 - f. The quality of the evidence was moderate to high, downgraded for unreliable randomization methods in two of the trials and early discontinuation in all three trials
- a. **Authors' conclusions** There is strong evidence that medical male circumcision reduces the acquisition of HIV by heterosexual men by between 38% and 66% over 24 months. Incidence of adverse events is very low, indicating that male circumcision, when conducted under these conditions, is a safe procedure. Inclusion of male circumcision into current HIV prevention measures guidelines is warranted, with further research required to assess the feasibility, desirability, and cost-effectiveness of implementing the procedure within local contexts.

Reduction in UTI

- 1) **Jagannath 2012**, Cochrane review of circumcision for prevention of UTI
 - a. **Authors' conclusions** We were unable to identify any randomised controlled trials on the use of routine neonatal circumcision for prevention of UTI in male infants. Until further evidence becomes available, clinicians should continue to base their decisions on position statements and recommendations and in conjunction with the opinions of the children's parents
- 2) **Morris 2013**, systematic review and meta-analysis of circumcision for the prevention of UTI
 - a. N=22 studies, 250,000+ patients
 - i. 1 RCT (Turkey), 4 cohort studies (not specified prospective or retrospective), 2 prospective cohort studies, 1 retrospective cohort study, 11 case-control studies, 1 cross sectional study, 2 "retrospective analysis" studies
 - ii. UTI definition varied across studies

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- b. For age 0 to 1 year the relative risk of UTI was 9.91 (95% CI 7.49–13.1), for age 1 to 16 years RR was 6.56 (95% CI 3.26–13.2) and for older than 16 years it was 3.41-fold (95% CI 0.916–12.7) higher in uncircumcised males.
 - c. 32.1% (95% CI 15.6–49.8) of uncircumcised males experience a urinary tract infection in their lifetime compared with 8.8% (95% CI 4.15–13.2) of circumcised males (RR 3.65, 95% CI 1.15–11.8).
 - d. The number needed to treat was 4.29 (95% CI 2.20–27.2).
 - e. **Conclusions:** The single risk factor of lack of circumcision confers a 23.3% chance of urinary tract infection during the lifetime. This greatly exceeds the prevalence of circumcision complications (1.5%), which are mostly minor. The potential seriousness of urinary tract infection supports circumcision as a desirable preventive health intervention in infant males.
- 3) **Singh-Grewal D 2005**, Systematic review of circumcision for the prevention of UTI
- a. N=402,908 children from 12 studies (1 RCT, 4 cohort studies, 7 case-control studies)
 - b. Circumcision was associated with a significantly reduced risk of UTI (OR = 0.13; 95% CI, 0.08 to 0.20; p,0.001) with the same odds ratio (0.13) for all three types of study design.
 - c. **Conclusions:** Circumcision reduces the risk of UTI. Given a risk in normal boys of about 1%, the number needed-to-treat to prevent one UTI is 111. In boys with recurrent UTI or high grade vesicoureteric reflux, the risk of UTI recurrence is 10% and 30% and the numbers-needed-to-treat are 11 and 4, respectively. Haemorrhage and infection are the commonest complications of circumcision, occurring at rate of about 2%. Assuming equal utility of benefits and harms, net clinical benefit is likely only in boys at high risk of UTI.

Complications

- 1) **Weiss 2010**, systematic review of complications of elective circumcision
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2835667/pdf/1471-2490-10-2.pdf>
 - a. N=16 studies of neonatal or infant circumcision
 - i. 12 countries, variety of circumcision methods
 - b. The median frequency of any adverse event was 1.5% (range 0-16%), and median frequency of any serious adverse event was 0% (range 0-2%). Nine studies reported no serious adverse events, but three studies reported that 1-2% of boys had a serious complication
 - c. Complications included infection, ulceration, urethral laceration, amputation of the glans penis, bleeding, excess residual foreskin, hematoma, and meatal stenosis

Expert recommendations

- 1) **CDC 2017**, Male Circumcision and the Prevention of HIV Infection, Sexually Transmitted Infections, and other Health Outcomes <https://stacks.cdc.gov/view/cdc/58456>
 - a. Expert symposium, evidence review, and review of public comments
 - b. Health benefits
 - i. During infancy, circumcised infants are less likely than uncircumcised infants to experience urinary tract infections (UTIs); an estimated 7% of infant males presenting with fever in outpatient clinics and emergency rooms had UTIs, including 20% of uncircumcised febrile infants and 2% of circumcised febrile infants aged younger than 3 months of age.

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- ii. An estimated 32% of uncircumcised males compared with 9% of circumcised males will experience a UTI in their lifetime, suggesting that circumcision is associated with a 23% absolute decreased lifetime risk of UTI.
 - iii. Although most UTIs are treatable, serious complications may occur when UTIs are not diagnosed, recurrent, difficult to treat, or left untreated. Such complications may include sepsis, pyelonephritis, and renal scarring and have been associated with an increased risk for long-term consequences, including hypertension, build-up of kidney waste products (uremia), and end-stage renal disease.
 - iv. An estimated 14% of uncircumcised boys compared with 6% of circumcised boys experienced balanitis, irritation, adhesions, phimosis or paraphimosis, suggesting that circumcision is associated with an 8% absolute decreased risk of these conditions
 - v. During adulthood, circumcised males were less likely than uncircumcised males to experience penile cancer.
 - vi. Other anticipated health benefits derive in part from future prevention of HIV and some STIs acquired through heterosexual sex. Eight percent of annual HIV diagnoses in the United States are among persons with infection attributed to heterosexual contact. STIs are very common, with human papilloma virus (HPV) infection of the anus or genitals occurring in many sexually active persons, although HPV vaccination is highly effective against many serotypes. Current risks for either HIV or other non-HIV STIs may not remain constant in the future and the future risk for any individual neonate, child, or adolescent cannot be definitively defined at the time that a circumcision decision is made.
- c. Complications
- i. Complications of medically performed male circumcision in the United States are typically uncommon and easily managed. Severe complications are rare in all age groups and occur in 0.23% of all circumcised males overall.
 - ii. Among newborns and children aged 1–9 years, most frequently reported complications include bleeding and inflammation of the penis or incomplete wound healing or adhesions requiring corrective procedures.
 - iii. Complications occur (according to age at circumcision) in 0.2% of infants aged ≤ 1 month, 0.4% of infants aged <1 year, and approximately 9% in children aged 1–9 years.

2) American Academy of Pediatrics 2012 www.pediatrics.org/cgi/doi/10.1542/peds.2012-1990

- a. Systematic evaluation of English-language peer-reviewed literature from 1995 through 2010 indicates that preventive health benefits of elective circumcision of male newborns outweigh the risks of the procedure. Benefits include significant reductions in the risk of urinary tract infection in the first year of life and, subsequently, in the risk of heterosexual acquisition of HIV and the transmission of other sexually transmitted infections.
- b. The procedure is well tolerated when performed by trained professionals under sterile conditions with appropriate pain management. Complications are infrequent; most are minor, and severe complications are rare. Male circumcision performed during the newborn period has considerably lower complication rates than when performed later in life.

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- c. Although health benefits are not great enough to recommend routine circumcision for all male newborns, the benefits of circumcision are sufficient to justify access to this procedure for families choosing it and to warrant third-party payment for circumcision of male newborns. It is important that clinicians routinely inform parents of the health benefits and risks of male newborn circumcision in an unbiased and accurate manner. Parents ultimately should decide whether circumcision is in the best interests of their male child. They will need to weigh medical information in the context of their own religious, ethical, and cultural beliefs and practices. The medical benefits alone may not outweigh these other considerations for individual families.

3) American Academy of Family Practice 2018

- a. There are potential health benefits from neonatal circumcision. The evidence is strongest for the prevention of UTI in newborn males. The number needed to treat to prevent one UTI is about 140 and to prevent one hospitalization for UTI is 195. Circumcision also prevents penile cancer, but this is a rare disease (0.6/100,000), and the number needed to treat to prevent one case is approximately 300,000. In addition, about 1/3 of penile cancers are caused by human papilloma virus and may be prevented by HPV vaccine. There is also evidence that circumcision can prevent some other STDs, including the acquisition of HIV, but the evidence for this comes from studies of adult circumcision in Africa and may not be generalizable to neonatal circumcision in the U.S.
- b. Circumcision can also result in complications. Acute complications can include bleeding (0.8-1.8/1,000), infection (6/10,000), and injury to the penis (4/10,000). Late complications can include incomplete circumcision, excessive skin removal, adhesions, meatal stenosis, phimosis, inclusion cysts. The rate at which these late complications occur is not well defined.
- c. The potential health benefits from circumcision justify it being a covered medical service by third-party payers, and it should be an available service for those who desire it.

4) American Urologic Association 2017

- a. The risks and disadvantages of circumcision are encountered early whereas the advantages and benefits are prospective. When circumcision is being discussed with parents and informed consent obtained, medical benefits and risks, and ethnic, cultural, religious and individual preferences should be considered

5) Canadian Paediatric Society 2018

- a. While there may be a benefit for some boys in high-risk populations and circumstances where the procedure could be considered for disease reduction or treatment, the Canadian Paediatric Society does not recommend the routine circumcision of every newborn male.

6) Royal Australasian Society of Physicians 2010 <https://www.racp.edu.au/docs/default-source/advocacy-library/circumcision-of-infant-males.pdf>

- a. Circumcision is generally a safe procedure but there are risks of minor complications and some rare but serious complications
- b. The most important conditions where benefits may result from circumcision are recurrent urinary tract infections in children; and Human Immunodeficiency Virus (HIV) plus some other sexually transmitted infections in adults from populations with a high prevalence of these conditions; cancer of the penis in men with a history of phimosis, and cancer of the cervix in women whose partners engage in sexual practices known to increase the risk of Human Papilloma Virus (HPV) infection. The protection against

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Sexually Transmitted Infections (STIs) and HIV is less clear-cut in Australia and New Zealand than in high prevalence countries.

- c. Ethical and human rights concerns have been raised regarding elective infant male circumcision because it is recognised that the foreskin has a functional role, the operation is non-therapeutic and the infant is unable to consent.
- d. After reviewing the currently available evidence, the RACP believes that the frequency of diseases modifiable by circumcision, the level of protection offered by circumcision and the complication rates of circumcision do not warrant routine infant circumcision in Australia and New Zealand.

Other Medicaid coverage:

There are several CCOs in Oregon that are currently covering newborn circumcision due to patient and provider demand.

As of 2009 (**Clark 2011**) newborn male circumcision was not covered for Medicaid enrollees in fifteen states: Arizona, California, Florida, Idaho, Louisiana, Maine, Minnesota, Mississippi, Missouri, Montana, North Carolina, North Dakota, Oregon, Utah, and Washington. Two states had variable policies. In Nevada, Medicaid managed care plans in two urban areas covered routine newborn male circumcision, while fee-for-service elsewhere in the state covered male circumcision only if medically necessary. In Tennessee, one of two Medicaid managed care plans covered routine newborn male circumcision, while the other covered male circumcision only when medically necessary. The remaining thirty-three states covered newborn circumcision for all Medicaid enrollees.

State coverage for adult male circumcision is variable.

Current line prioritization scoring

Line 623 REDUNDANT PREPUCE

Category: 9

HL: 0

Suffering: 0

Population effects: 0

Vulnerable population: 0

Tertiary prevention: 0

Effectiveness: 5

Need for service: 0

Net cost: 2

Score: 0

Approximate line placement: 623

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HERC staff summary

Neonatal circumcision remains a controversial topic. Studies have found that neonatal circumcision reduces the rate of HIV and other STI acquisition; however, this conclusion is based on data from high prevalence countries, is limited to heterosexual patients, and it is not clear how it translates to areas of lower HIV/STI prevalence. Neonatal circumcision reduces the risk of UTI in infants and young boys, with a NNT of between 4 and 111 (the literature is highly variable on this estimate). The reason for the variation in NNT for prevention of UTI may be in the study methods (higher NNT came from a review that specifically excluded high risk boys). Boys with vesicoureteral reflux appear to have greater benefit in UTI prevention with circumcision given their higher prevalence of UTI. The complications of circumcision are generally minor, but can include rare serious adverse events. The rate of complications is estimated to be 1.5% overall, with 0.23% rate of serious complications. The risks of circumcision are much higher when done outside of the neonatal period, due to need for general anesthesia, etc. There appears to be no impact on sexual satisfaction with circumcision. Coverage for routine neonatal circumcision is highly variable among Medicaid programs. Desire for circumcision varies widely among families, depending on religious and cultural norms and other factors.

HERC staff recommendation:

- 1) Rescore line 623 as shown below
 - a. Change category from 9 (Inconsequential care) to 7 (non-fatal condition with treatment aimed at disease modification or cure)
 - b. Change population effects from 0 to 1 (possible prevention of HIV/STIs in low prevalence setting; scale 0 to 5)
 - c. Change tertiary prevention from 0 to 2 (prevention of UTI and penile cancer; possible prevention of HIV/STIs in low prevalence setting; scale 0 to 5)
 - d. Change need for service from 0 to 0.1 (scale 0 to 1)

Recommended line prioritization scoring (current scores in parentheses)

Line 623 REDUNDANT PREPUCE

Category: 7 (9)

HL: 0

Suffering: 0

Population effects: 1 (0)

Vulnerable population: 0

Tertiary prevention: 2 (0)

Effectiveness: 5

Need for service: 0.1 (0)

Net cost: 4 (2)

Score: 30

Approximate line placement: 569

Neonatal Circumcision

There are potential health benefits from neonatal circumcision. The evidence is strongest for the prevention of UTI in newborn males. The number needed to treat to prevent one UTI is about 140 and to prevent one hospitalization for UTI is 195. Circumcision also prevents penile cancer, but this is a rare disease (0.6/100,000), and the number needed to treat to prevent one case is approximately 300,000. In addition, about 1/3 of penile cancers are caused by human papilloma virus and may be prevented by HPV vaccine. There is also evidence that circumcision can prevent some other STDs, including the acquisition of HIV, but the evidence for this comes from studies of adult circumcision in Africa and may not be generalizable to neonatal circumcision in the U.S.

Circumcision can also result in complications. Acute complications can include bleeding (0.8-1.8/1,000), infection (6/10,000), and injury to the penis (4/10,000). Late complications can include incomplete circumcision, excessive skin removal, adhesions, meatal stenosis, phimosis, inclusion cysts. The rate at which these late complications occur is not well defined.

The potential health benefits from circumcision justify it being a covered medical service by third-party payers, and it should be an available service for those who desire it.

The decision whether to circumcise a newborn male is affected by parents' values and beliefs and should be made by parents after a discussion of the benefits and harms. Family physicians should provide this information in an unbiased manner, and the parents' decision should be respected.

Circumcision is preferably performed in the newborn period. When circumcision is performed, topical or local anesthesia techniques should be used to minimize newborn discomfort. (2013 COD) (April 2018 BOD)

Circumcision

The American Urological Association, Inc.® (AUA) believes that neonatal circumcision has potential medical benefits and advantages as well as disadvantages and risks. Neonatal circumcision is generally a safe procedure when performed by an experienced operator. There are immediate risks to circumcision such as bleeding, infection and penile injury, as well as complications recognized later that may include buried penis, meatal stenosis, skin bridges, chordee and poor cosmetic appearance. Some of these complications may require surgical correction. Nevertheless, when performed on healthy newborn infants as an elective procedure, the incidence of serious complications is extremely low. The minor complications are reported to be three percent.

Properly performed neonatal circumcision prevents phimosis, paraphimosis and balanoposthitis, and is associated with a markedly decreased incidence of cancer of the penis among U.S. males. In addition, there is a connection between the foreskin and urinary tract infections in the neonate. For the first three to six months of life, the incidence of urinary tract infections is at least ten times higher in uncircumcised than circumcised boys. Evidence associating neonatal circumcision with reduced incidence of sexually transmitted diseases is conflicting depending on the disease. While there is no effect on the rates of syphilis or gonorrhea, studies performed in African nations provide convincing evidence that circumcision reduces, by 50-60 percent, the risk of transmitting the Human Immunodeficiency Virus (HIV) to HIV negative men through sexual contact with HIV positive females. There are also reports that circumcision may reduce the risk of Human Papilloma Virus (HPV) infection. While the results of studies in other cultures may not necessarily be extrapolated to men in the United States at risk for HIV infection, the AUA recommends that circumcision should be presented as an option for health benefits. Circumcision should not be offered as the only strategy for HIV and/or HPV risk reduction. Other methods of HIV and/or HPV risk reduction, including safe sexual practices, should be emphasized. Circumcision may be required in a small number of uncircumcised boys when phimosis, paraphimosis or recurrent balanoposthitis occur and may be requested for ethnic and cultural reasons after the newborn period. Circumcision in these children usually requires general anesthesia.

The risks and disadvantages of circumcision are encountered early whereas the advantages and benefits are prospective. When circumcision is being discussed with parents and informed consent obtained, medical benefits and risks, and ethnic, cultural, religious and individual preferences should be considered.

Board of Directors, May 1989
Board of Directors, October 1996 (Revised)
Board of Directors, February 1998 (Revised)
Board of Directors, February 2003 (Revised)
Board of Directors, May 2007 (Revised)
Board of Directors, May 2012 (Reaffirmed)
Board of Directors, May 2017 (Revised)

Position statement

Newborn male circumcision

Posted: Sep 8 2015 | **Reaffirmed:** Feb 28 2018

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Abstract

The circumcision of newborn males in Canada has become a less frequent practice over the past few decades. This change has been significantly influenced by past recommendations from the Canadian Paediatric Society and the American Academy of Pediatrics, who both affirmed that the procedure was not medically indicated. Recent evidence suggesting the potential benefit of circumcision in preventing urinary tract infection and some sexually transmitted infections, including HIV, has prompted the Canadian Paediatric Society to review the current medical literature in this regard. While there may be a benefit for some boys in high-risk populations and circumstances where the procedure could be considered for disease reduction or treatment, the Canadian Paediatric Society does not recommend the routine circumcision of every newborn male.

Key Words: *Circumcision; HIV; HPV; HSV; Infant; STI; UTI*

The cultural and religious ritual of male circumcision has been practiced for thousands of years. Circumcision as a medical procedure arose in Britain and the United States in the late 19th century. The historical medical benefits of neonatal circumcision have included ease of genital hygiene, diminished risk of disease and avoidance of circumcision later in life. In the middle of the last century, most Canadian boys were circumcised. However, the rate of neonatal circumcision has declined over time to the current Canadian average of 32%, with significant regional variability.[1] The Canadian Paediatric Society (CPS) published a position statement in 1996 stating that circumcision was not recommended as a routine procedure for male newborns because the benefits and harms were evenly balanced. A similar viewpoint was expressed by the American Academy of Pediatrics (AAP) in 1999 and reaffirmed in 2005.[2] More recent evidence regarding the beneficial role of male circumcision in preventing urinary tract infection (UTI) in infancy and some sexually transmitted diseases (STIs) in adult life has prompted the CPS to review the current medical information on the circumcision of newborn males. The AAP updated its own policy statement in 2012.[3] The goal of the present statement is to provide guidance to health care providers and up-to-date information for the parents of newborn boys, to enable them to make informed decisions regarding circumcision.

Methods

A Medline search using the MESH heading "circumcision, male" was initially performed, which yielded 1596 articles. These articles were subsequently reviewed, as were their references when appropriate. The focus was on neonatal and infant male circumcision and its outcomes.

The hierarchy of evidence from the Centre for Evidence-Based Medicine was applied, using levels of evidence for therapy and prognosis.[4]

The foreskin and circumcision

In the male newborn, the mucosal surfaces of the inner foreskin and glans penis adhere to one another; the foreskin is not redundant skin. The foreskin gradually separates from the glans during childhood. By six years of age, 50% of boys can retract their foreskins, although the process of separation may not be complete until puberty: 95% of boys have retractile foreskin by 17 years of age.[5] Parents may be reassured by their observation of an unimpaired urinary stream in a boy with a nonretracted foreskin. Until this developmental process is complete, the best descriptor to use is 'nonretractile foreskin' rather than the confusing and perhaps erroneous term 'physiologic phimosis'. Appropriate care for the uncircumcised penis has been well reviewed[6] and should include anticipatory guidance on hygiene and an understanding of the normal nonretractile foreskin.

Circumcision involves the partial or complete removal of the foreskin (prepuce); a number of methods are used.[6] In Canada, the majority of newborn male circumcisions are performed by medical practitioners and most of the remainder by skilled traditional providers. Whatever method is used, strict adherence to hygienic principles and the use of effective analgesia are essential.

Potential benefits of circumcision

Phimosis treatment

Phimosis is defined as a scarring and thickening of the foreskin that prevents retraction back over the glans.[7] Phimosis may occur secondary to recurrent infections, inflammation or lichen sclerosis. Phimosis needs to be differentiated from the normal nonretractile foreskin.

The foreskin can become inflamed or infected (posthitis), often in association with the glans (balanoposthitis) in 1% to 4% of uncircumcised boys.[8][9] The foreskin can also become entrapped behind the glans (paraphimosis) in 0.5% of cases. Both conditions usually resolve with medical therapy but, if recurrent, can cause phimosis.[7][10] An estimated 0.8% to 1.6% of boys will require circumcision before puberty, most commonly to treat phimosis.[7] The first-line medical treatment of phimosis involves applying a topical steroid twice a day to the foreskin, accompanied by gentle traction. This therapy serves to thin the tissue and release adhesions, allowing the foreskin to become retractable in 80% of treated cases, thus usually avoiding the need for circumcision.[11][12] Topical steroid treatment is also useful to hasten foreskin retraction in boys with nonretractile foreskins.[12] A number of steroid preparations have been used, including betamethasone 0.05% to 0.1%, triamcinolone 0.1% and mometasone furoate 0.1%.

Other dermatoses of the penis can occur in childhood and should be considered if the skin over the penile shaft, foreskin or glans is abnormal.[10][13] Such presentations may necessitate referral to a urologist or dermatologist for diagnosis and treatment, which may include circumcision.

UTI reduction

The preputial sac provides an environment for colonization of the urethra with uropathogenic organisms that can cause UTI in infant boys.[14] UTI occurs in approximately one in 100 boys in the first month of life. A meta-analysis that included one randomized trial and 11 observational studies found that UTI was decreased by 90% in circumcised infants, with a significant OR of 0.13 (95% CI 0.08 to 0.20).[15] In a more recent meta-analysis that included 14 studies, the pooled prevalence of UTI in febrile infants <3 months of age was 7.5% for females, 2.4% for circumcised males and 20.1% for uncircumcised males. The prevalence rate of UTI in febrile males (circumcised and uncircumcised) decreased to 1.7% by six to 12 months of age, but the 10-fold difference related to circumcision status was maintained.[16] Since the publication of this meta-analysis, a further prospective cohort study, in which a series of urine cultures were obtained in boys up to 15 months of age, also found a lower incidence of UTI in individuals who had undergone newborn circumcision (0% versus 2%, $P < 0.001$).[17] The risk of UTI declines rapidly in males after the first few months of life to an incidence of one in 1000 by one year of age.[16] Using estimates of lifetime risk for male UTI, a recent meta-analysis calculated that, over a lifetime, the RR for UTI was 3.65 for uncircumcised versus circumcised males, with 23% of all UTIs attributed to lack of circumcision.[18] However, this conclusion should be questioned because the adult data were limited to a single study of only 78 men.

It has been estimated that 111 to 125 normal infant boys (for whom the risk of UTI is 1% to 2%) would need to be circumcised at birth to prevent one UTI.[15][16] In boys at higher risk for UTI, such as those with recurrent UTI or an underlying urinary tract anomaly (eg, high-grade vesico-ureteric reflux or obstructive uropathy), circumcision may be of greater benefit. In these cases, it is estimated that only four boys would need to be circumcised to prevent one UTI.[15] However, it should be noted that contaminated urines are more common in uncircumcised males, potentially leading to overdiagnosis of UTI; thus, the number needed to treat may be considerably higher than that found in these studies. Childhood UTI leads to dimercaptosuccinic acid (DMSA)-detectable renal scarring in 15% of cases.[19] Although these scars could theoretically have an impact on long-term renal function and hypertension, there is no evidence for this effect, and most experts believe that UTIs in children with normal kidneys do not result in long-term sequelae.

STI reduction

Observational studies performed in Africa and in developed countries since the emergence of HIV/AIDS have suggested that uncircumcised men are at higher risk for HIV infection.[20][21] The inner surface of the foreskin is rich in Langerhans and other HIV target cells that are exposed to infection during sexual intercourse, which is speculated to be one mechanism leading to HIV acquisition.[22] If true, then removing the foreskin could theoretically have a protective effect against HIV acquisition.

Conclusive evidence that circumcision is partially effective in decreasing the risk for heterosexually-acquired HIV infection among men in sub-Saharan Africa has been provided by three large randomized controlled trials involving men and adolescent boys in Uganda,[23] South Africa[24] and Kenya.[25] Compared with uncircumcised controls, there was a decrease in new HIV infection by 50% to 60% in the circumcised male participants. In the Kenyan study, this protective effect was sustained for at least 42 months[25] (Level of Evidence 1). Observational studies undertaken in sub-Saharan Africa have also suggested that there is a similar degree of protection when circumcision is performed in the neonatal period[20][26] (Level of Evidence 4). It remains unclear, however, whether these conclusions can be applied to populations in developed countries, where the HIV seroprevalence rates are lower and common routes of HIV transmission include injection drug use (IDU) and men who have sex with men (MSM).[27]

The Centers for Disease Control and Prevention (CDC, Georgia, USA) recently published an analysis of the cost-effectiveness of newborn circumcision in reducing the lifetime risk of HIV acquisition in American males, assuming 60% efficacy over a lifetime and a risk of HIV acquisition varying from 0.94% for white males to 6.22% for black males.[28] The CDC estimated that the risk of lifetime acquisition through heterosexual transmission was reduced by 16% overall, ranging from 8% in white males to nearly 21% for black males. The analysis, based on a cost of USD\$257 for the procedure, demonstrated cost savings in both Hispanic and black males. The number needed to treat to prevent one HIV infection varied from 1231 in white males to 65 in black males, with an average in all males of 298. The model did not account for the cost of complications of circumcision. In addition, there is a risk that men may overestimate the protective effect of being circumcised and be less likely to adopt safe sex practices. In 2011, the Public Health Agency of Canada reported that 46.6% of new cases of HIV in Canada for which an exposure category was reported were attributed to MSM and 13.7% to IDU.[29] The proportion of new cases attributed to heterosexual transmission involving individuals not originally from a country where HIV is endemic was 20.3%, while 16.9% of new cases were in individuals originally from HIV-endemic countries. The report noted that the estimated rate of new infection in the latter group was nine times higher than in the general Canadian population. A disproportionate number of new cases occurred in Aboriginal people (12.2%), a rate estimated to be 3.5 times higher than in the non-Aboriginal population. IDU was the main reported source of exposure (58.1%), followed by heterosexual exposure (30.2%).[29]

It is presumed that male circumcision, by reducing the burden of HIV in men, will indirectly protect women. There does not appear to be a significant role in decreasing male-to-female transmission in HIV-discordant couples.[30][31]

Evidence obtained from observational studies that male circumcision can decrease the risk of other STIs has been conflicting. Analysis of data regarding subjects enrolled in the randomized sub-Saharan African studies revealed lower rates of herpes simplex virus-2 (HSV-2) seroconversion (adjusted HR = 0.72) and acquisition of high-risk human papillomavirus (HPV) genotypes (adjusted RR = 0.65) in circumcised men during the two-year follow-up postcircumcision.[32] The rate of HPV infection was also

lower in circumcised men in many other countries (OR = 0.37)[32] (Level of Evidence 2). Circumcision was not found to be protective against gonorrhoea or chlamydia.[33] No studies have examined the impact of routine neonatal circumcision on STIs other than HIV.

The female partners of men circumcised in the same African studies had a lower adjusted prevalence rate of 0.52 for *Trichomonas vaginalis* infection, 0.60 for bacterial vaginosis and 0.78 for genital ulcer disease.[34]

Although circumcision can decrease the risk of acquiring and transmitting STIs, it should be emphasized that other preventative measures, including abstinence, use of condoms and other safe sex practices, must continue to be taught and practiced.

Cancer reduction

Female partners of circumcised men have a reduced cervical cancer risk, with ORs ranging from 0.18 to 1.61 depending on the sexual-behavioural risk level of their partner[35] (Level of Evidence 3). The incidence of cervical cancer in Canada ranges from nine to 17/100,000.

Penile cancer is rare in developed countries (one in 100,000 men). Squamous cell carcinoma of the penis occurs almost exclusively in uncircumcised men, with phimosis being the strongest associated risk factor (OR 11.4 [95% CI 5.0 to 25.9]).[36] This finding underscores the importance of genital hygiene and of identifying and treating cases of phimosis and residual nonretractile foreskin in all males.

There is a strong association between HPV infection and penile cancer regardless of circumcision status, with 80% of tumour specimens being HPV DNA-positive.[37] It is expected that routine HPV vaccination for girls will dramatically decrease the incidence rate of cervical cancer. The benefit may also extend to penile cancer, especially as the program is broadened to include young men.

Potential risks of circumcision

Surgical procedures, including circumcision, are painful. Even with procedural analgesia, individuals experience postprocedural pain that must be treated. Newborns who experience procedural pain have altered response to later vaccinations, with demonstrated higher pain scores.[38]

Acute complications of neonatal circumcision include minor bleeding, local infection and an unsatisfactory cosmetic result. Severe complications, such as partial amputation of the penis and death from hemorrhage or sepsis, are rare occurrences. A recent meta-analysis reporting on prospective and retrospective studies investigating circumcision found a median complication rate of 1.5% in neonates or infants. When circumcision was performed during childhood, the complication rate increased to 6%, a rate similar to that reported in studies of circumcised adolescents and adults.[39]

The most common late complication of circumcision is meatal stenosis (2% to 10%), which may require surgical dilation.[40] This condition can be prevented almost completely by applying petroleum jelly to the glans for up to six months following circumcision.[41] Partial re-adherence of the penile skin to the glans is not uncommon. Such adhesions often resolve spontaneously by puberty but, when they are extensive, may also benefit from treatment with a topical steroid preparation. Surgical lysis is rarely required.[42]

The foreskin serves to cover the glans penis and has an abundance of sensory nerves,[5] but medical studies do not support circumcision as having a negative impact on sexual function or satisfaction in males or their partners.[43]-[45] It has been reported that some parents or older boys are not happy with the cosmetic result, but no specific data from the literature to quantify this outcome could be found. Health care providers should be aware of potential contraindications to neonatal circumcision. Hypospadias requires an assessment by a urologist before circumcision is considered. Any risk of bleeding diathesis requires further investigation and discussion with appropriate professionals and decision makers before proceeding with circumcision.

Ethics and legalities of circumcision

Neonatal circumcision is a contentious issue in Canada. The procedure often raises ethical and legal considerations, in part because it has lifelong consequences and is performed on a child who cannot give consent. Infants need a substitute decision maker – usually their parents – to act in their best interests. Yet the authority of substitute decision makers is not absolute. In most jurisdictions, authority is limited only to interventions deemed to be medically necessary. In cases in which medical necessity is not established or a proposed treatment is based on personal preference, interventions should be deferred until the individual concerned is able to make their own choices.[46]

With newborn circumcision, medical necessity has not been clearly established. However, there are some health benefits, especially in certain populations. Furthermore, performing circumcision in older boys, who are able to provide consent, can also increase risk and costs to the individual.[39] Therefore, some parents view circumcision as being in their child's best interest. A complete discussion of ethical and legal issues associated with newborn male circumcision is beyond the scope of this statement. Readers are referred to the July 2013 issue of the *Journal of Medical Ethics*, which is devoted to the topic.[47] Both parents and health care providers should be familiar with the legal issues related to consent.

Summary

Current evidence indicates that there are potential health benefits associated with male circumcision, particularly in high-risk populations. Infant circumcision reduces the incidence of UTI in young boys and eliminates the need for medical circumcision in later childhood to treat recurrent balanoposthitis, paraphimosis and phimosis. Circumcised men have a lower risk of developing penile cancer, while the incidence of trichomonas, bacterial vaginosis and cervical cancer in the female partners of circumcised men is also reduced. Circumcision in adult men can reduce the risk of acquiring an STI (specifically HIV, HSV and HPV). Minor complications of circumcision can occur, although severe complications are rare. The risk of complications is lower in infants than in older children. The complication rate decreases significantly when the procedure is performed by experienced health care professionals, with close follow-up in the days postprocedure to ensure that bleeding does not increase. It is important to remember that most data regarding the benefits and outcomes following circumcision come from countries other than Canada, which can make application to our population difficult.

Because the medical risk:benefit ratio of routine newborn male circumcision is closely balanced when current research is reviewed (Table 1), it is challenging to make definitive recommendations for the entire male newborn population in Canada. For some boys, the likelihood of benefit is higher and circumcision could be considered for disease reduction or treatment. Health care professionals should provide parents with the most up-to-date, unbiased and personalized medical information available so that they can weigh the specific risks and benefits of circumcising their son in the context of familial, religious and cultural beliefs. Having the right information will enable them to make the best decision for their boys. Decision aids based on current medical information can be helpful.

Recommendations

- The CPS does not recommend the routine circumcision of every newborn male.
- Physicians and other health care professionals caring for newborns must stay informed about circumcision and assist parents in understanding potential risks and benefits of the procedure.
- The parents of male newborns must receive the most up-to-date, unbiased and personalized medical information available about neonatal circumcision, so that they can weigh specific risks and benefits of circumcision in the context of their own familial, religious and cultural beliefs.
- Parents who choose to have their sons circumcised should be referred to a practitioner who is trained in the procedure.
- Neonatal male circumcisions must be performed by trained practitioners whose skills are up-to-date and strictly adhere to hygienic and analgesic best practices.
- Close follow-up in the early postcircumcision time period is critical. The parents of circumcised boys must be thoroughly and accurately informed about postprocedural care and possible complications.
- At the time of hospital discharge, health professionals should ensure that the parents of uncircumcised newborn boys know how to appropriately care for their son's penis and are aware that the normal foreskin can remain nonretractile until puberty.
- Quality Canadian data are required to understand the clinical and economic issues involved with neonatal male circumcision, including its potential risks, benefits and costs, in the Canadian context.

TABLE 1

Potential risks and benefits of neonatal circumcision

Outcome	Effect size (reference)
Potential risks	
Minor bleeding	1.5% (combined)
Local infection (minor)	NNH = 67 [39]
Severe infection	Extremely rare
Death from unrecognized bleeding	Extremely rare
Unsatisfactory cosmetic results	
Meatal stenosis	NNH 10–50 (<1% when petroleum jelly is used)

Potential benefits

Prevention of phimosis	NNT = 67 [7]
Decrease in early UTI	NNT = 111 – 125 [16]
Decrease in UTI in males with risk factors (anomaly or recurrent infection)	NNT = 4 – 6 [15]
Decreased acquisition of HIV	NNT = 298 (65 – 1231 depending on population) [28]
Decreased acquisition of HSV	NNT = 16 [32]
Decreased acquisition of HPV	NNT = 5 [32][35]
Decreased penile cancer risk	NNT = 900 – 322,000 [36][37]
Decreased cervical cancer risk in female partners	NNT = 90 – 140 [35]

HPV Human papillomavirus; HSV Herpes simplex virus; NNH Number needed to harm; NNT Number needed to treat; UTI Urinary tract infection

Selected resources

- Canadian Paediatric Society. Circumcision of baby boys: Information for parents <www.caringforkids.cps.ca/handouts/circumcision>
- American Academy of Pediatrics. Circumcision <www.healthychildren.org/English/ages-stages/prenatal/decisions-to-make/Pages/Circumcision.aspx>

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Medically Indicated Circumcision

Questions:

- 1) Should circumcision be paired with balanitis xerotica obliterans (BXO)?
- 2) Should circumcision be paired with balanitis?
- 3) What other medical indications need to be paired with circumcision on the Prioritized List?

Question sources:

- 1) HSD appeals
- 2) Holly Jo Hodges, CCO medical directors
- 3) HERC staff, various urology providers

Issues: Balanitis xerotica obliterans (BXO) is also known as penile lichen sclerosis. It is coded with ICD-10 N48.0 (Leukoplakia of penis). It is an atrophic and sclerotic condition of the head of the penis (glans penis). Sometimes it leads to stenosis and occasionally obliteration of the external meatal orifice. It can also lead to the inability to fully pull back the foreskin over the glans or the inability to return the pulled-back foreskin back over the glans (paraphimosis). Currently N48.0 is on line 243 DERMATOLOGICAL PREMALIGNANT LESIONS AND CARCINOMA IN SITU and not paired with circumcision, which is a standard treatment if the foreskin is involved. Other treatments for this condition include topical steroids and topical tacrolimus, which are covered. The surgical treatments for this condition include urethral surgery if the urethra becomes stenotic and circumcision if the foreskin becomes involved; neither of these surgeries currently pair. Experts (see **Clouston 2011**) indicate that circumcision is required in most cases.

Balanitis is an inflammation of the glans penis. When the foreskin is also affected, it is termed balanoposthitis. The condition causes rashes and pain in the penis. Recurrent bouts of balanitis may cause scarring of the preputial orifice; the reduced elasticity may lead to pathologic phimosis. Balanitis is a common condition affecting 11% of adult men seen in urology clinics and 3% of children in the United States; globally, balanitis may occur in up to 3% of uncircumcised males. Initial treatment in adults often involves simply pulling back the foreskin and cleaning the penis. If cleaning is not effective, then topical steroids or other topical medications may be required. Circumcision is only indicated when the patient has recurrent bouts of balanitis. Balanitis is coded with ICD-10 N48.1 and is currently on line 412 BALANOPOSTHITIS AND OTHER DISORDERS OF PENIS.

Phimosis was reviewed in 2007, and felt that it should be paired with circumcision when medically indicated, such as when it caused ischemia. Further research was suggested to identify the medical indications for circumcision and ensure they were included on a covered line with a guideline. This later review did not appear to have been completed. HERC staff have determined that a complete review of medical indications for circumcision should be undertaken.

Evidence

- 1) **Malone 2007**, review of medical indications for circumcisions
 - a. Preputial adhesions and physiological phimosis
 - i. No: Resolve with puberty
 - b. Paraphimosis
 - i. No. Reduction under local or general anaesthesia is nearly always possible with several minimally invasive methods; a literature review that included the Cochrane database and Medline searches failed to show that any one was

Medically Indicated Circumcision

better than the others. There is no evidence that circumcision is subsequently necessary.

- c. Balanoposthitis
 - i. Antibiotic treatment is the first line treatment,
 - ii. Circumcision should be reserved for those with recurrent balanoposthitis, although alternative methods, such as preputioplasty (an operative technique to widen the preputial ring), may achieve the same effect in preventing further episodes of balanoposthitis and leaving a retractile foreskin.
 - d. Preputial pearls
 - i. No. Always resolve spontaneously.
 - e. redundant foreskin
 - i. No medical need for circumcision
 - f. Physiological phimosis
 - i. No. Self resolves with age
 - g. Pathological phimosis
 - i. Almost always associated with balanitis xerotica obliterans, requires circumcision
 - h. Prevention of UTI in boys with urologic abnormalities
 - i. A metaanalysis of the effect of circumcision in boys suggested that only those at high risk of urinary tract infection—that is, those with recurrent infections or with abnormal urinary tracts such as high grade vesicoureteric reflux— would benefit from circumcision. However, a note of caution must be struck on the benefit of circumcision, even in the presence of an underlying abnormality of the urinary tract, as shown in a controlled trial published a few years ago. No benefit was found for circumcision when it was performed at the same time as antireflux surgery for severe vesicoureteric reflux irrespective of the age of the patient.
 - a. Hypospadias repair
 - ii. Circumcision may be required to provide tissue for reconstruction
 - b. Medical indications for circumcision are generally accepted as phimosis secondary to balanitis xerotica obliterans and recurrent balanoposthitis, which occur in 1.5% and 1% of boys respectively
 - c. Summary: The only absolute medical indications for circumcision are balanitis xerotica obliterans and a scarred foreskin. Firm evidence for relative indications is limited to recurrent balanitis and to the prevention of urinary tract infection in boys with vesicoureteric reflux or other urological abnormalities. Many other “medical indications” have little or no evidence base, including a long foreskin, balanoposthitis, preputial concretions, physiological phimosis, and preputial adhesion
- 2) **Singh-Grewal D 2005**, Systematic review of circumcision for the prevention of UTI
- a. N=402,908 children from 12 studies (1 RCT, 4 cohort studies, 7 case-control studies)
 - b. Conclusions: In boys with recurrent UTI or high grade vesicoureteric reflux, the risk of UTI recurrence is 10% and 30% and the numbers-needed-to-treat are 11 and 4, respectively.

Medically Indicated Circumcision

Expert input

Dr. Steven Skoog, OHSU pediatric urology

He agreed with the staff proposed indications (Balanitis xerotica obliterans, recurrent balanoposthitis, severe foreskin scarring causing physiologic complications, or vesicoureteric reflux or other urological abnormalities). In addition, he proposed a few additional indications: “we will at times call severe scarring, cicatrix formation, also boys with severe dysuria and alteration of urinary stream deserve a circumcision. Boys with recurrent urinary infection and ballooning of the prepuce with voiding need circumcision. Older pre-adolescent boys with painful erections and persistent adhesions need circumcision. Boys with prenatally diagnosed moderate to severe hydronephrosis benefit from circumcision to prevent UTI.”

Dr. Skoog recommended defining recurrent balanoposthitis as 2 or more bouts.

CCO medical directors

The CCO medical directors objected to the addition of circumcision for prevention of UTI even in high risk patients, including patients with vesicoureteric reflux. The evidence of benefit is not strong, and these cases can be approved through the exceptions process.

Medically Indicated Circumcision

Diagnoses for possible consideration for pairing with medical circumcision

Code	Code description	Current line(s)
N13.7	Vesicoureteral-reflux	21 VESICoureTERAL REFLUX
N47.5	Adhesions of prepuce and glans penis	496 PHIMOSIS
N47.6	Balanoposthitis	412 BALANOPOSTHITIS AND OTHER DISORDERS OF PENIS
N47.8	Other disorders of prepuce (includes ballooning of the prepuce)	623 REDUNDANT PREPUCE
N48.0	Leukoplakia of penis [includes balanitis xerotica obliterans]	243 DERMATOLOGICAL PREMALIGNANT LESIONS AND CARCINOMA IN SITU
N48.1	Balanitis	412
Z87.440	Personal history of urinary (tract) infections	Informational File

Circumcision is currently found on the following lines:

Code	Code description	Lines
54150	Circumcision, using clamp or other device with regional dorsal penile or ring block	496 PHIMOSIS 623 REDUNDANT PREPUCE
54160	Circumcision, surgical excision other than clamp, device, or dorsal slit; neonate (28 days of age or less)	496,623
54161	Circumcision, surgical excision other than clamp, device, or dorsal slit; older than 28 days of age	327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION 496,623

Medically Indicated Circumcision

HERC staff summary

Circumcision is medically necessary for balanitis xerotica obliterans causing phimosis and for recurrent balanoposthitis, and severe foreskin scarring causing medical issues (not simply cosmetic issues). There also appears to be benefit in the prevention of urinary tract infection in boys with abnormal urinary tracts, such as high grade vesicoureteric reflux.

HERC staff recommendations:

- 1) Add CPT 54150 (Circumcision, using clamp or other device with regional dorsal penile or ring block), 54160 (Circumcision, surgical excision other than clamp, device, or dorsal slit; neonate (28 days of age or less)) and 54161 (Circumcision, surgical excision other than clamp, device, or dorsal slit; older than 28 days of age) to lines 21 VESICoureTERAL REFLUX and 412 BALANOPOSTHITIS AND OTHER DISORDERS OF PENIS
- 2) Add CPT 54150 (Circumcision, using clamp or other device with regional dorsal penile or ring block) and 54160 (Circumcision, surgical excision other than clamp, device, or dorsal slit; neonate (28 days of age or less)) to line 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
 - a. CPT 54161 is already on this line
- 3) Remove ICD-10 N48.0 (Leukoplakia of penis) from line 243 DERMATOLOGICAL PREMALIGNANT LESIONS AND CARCINOMA IN SITU and add to line 412 BALANOPOSTHITIS AND OTHER DISORDERS OF PENIS
- 4) Add ICD-10 Z87.440 (Personal history of urinary (tract) infections) to line 327 FUNCTIONAL AND MECHANICAL DISORDERS OF THE GENITOURINARY SYSTEM INCLUDING BLADDER OUTLET OBSTRUCTION
 - a. Advise HSD to remove ICD-10 Z87.440 from the Informational File
- 5) Keep circumcision CPT codes on line 496 PHIMOSIS and on line 623 REDUNDANT PREPUCE; however, these lines should remain below the funding line as circumcision is elective for these conditions
 - a. See separate evidence review for redundant prepuce
- 6) Add a new guideline note regarding circumcision as shown below

GUIDELINE NOTE XXX MEDICALLY INDICATED CIRCUMCISION

Lines 327, 412

Circumcision (CPT 54150, 54161) is included on these lines only for patients with

- 1) Balanitis xerotica obliterans, or
- 2) Recurrent balanoposthitis (2 or more bouts), or
- 3) Severe foreskin scarring causing physiologic complications, or
- 4) Vesicoureteric reflux or other urologic abnormalities, or
- 5) Recurrent urinary tract infections (2 or more with documented positive urine cultures).

Balanitis (ICD-10 N48.1) does not pair with circumcision.

Postpartum Depression Screening

Question: How should coverage of postpartum depression screening be clarified on the Prioritized List?

Question source: Dana Hargunani, CMO; HSD

Issue: Postpartum depression has major impacts on child and maternal health. Currently, it is not clear that postpartum depression screening is explicitly intended to be covered on the Prioritized List. Also, there is a lack of clarity about the coverage of this screening when provided during the child's appointment rather than during the mother's visit.

Perinatal depression (encompassing pregnancy and 12 months postpartum) or postpartum depression (typically up to 6 weeks postpartum) are both underassessed and treated.

The American Academy of Pediatrics (AAP) developed a new CPT code to allow reporting of the administration of a caregiver-focused health risk assessment (eg, maternal depression inventory) for the benefit of the patient.

Metrics and Scoring have approved a postpartum visit metric for 2019-2020 with a future plan to include quality measures such as postpartum depression screening in 2021.

Prioritized List Status

Code	Code Description	Current List Placement	Fee Schedule
Z13.32	Encounter for screening for maternal depression	New ICD 10 code, just reviewed by BHAP, recommended placement on Line 3	
96127	Brief emotional/behavioral assessment (eg, depression inventory, attention-deficit/hyperactivity disorder [ADHD] scale), with scoring and documentation, per standardized instrument	Diagnostic Procedures File	\$4.42
96150	Health and behavior assessment (eg, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; initial assessment	1,3,4,5,8,9,10,12 and 184 other lines.	\$15.04-17.23
96151	Health and behavior assessment (eg, health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; re-assessment	1,3,4,5,8,9,10,12 and 184 other lines.	\$14.53-16.68
96152	Health and behavior intervention, each 15 minutes, face-to-face; individual	1,3,4,5,8,9,10,12 and 184 other lines.	\$13.77-15.85
96153	Health and behavior intervention, each 15 minutes,	1,3,4,5,8,9,10,12 and 184	\$2.98-

Postpartum Depression Screening

Code	Code Description	Current List Placement	Fee Schedule
	face-to-face; group (2 or more patients)	other lines.	3.52
96154	Health and behavior intervention, each 15 minutes, face-to-face; family (with the patient present)	1,3,4,5,8,9,10,11 and 194 other lines.	\$13.27-15.81
96155	Health and behavior intervention, each 15 minutes, face-to-face; family (without the patient present)	1,3,4,5,8,9,10,11 and 194 other lines.	\$15.95-17.42
96160	Administration of patient-focused health risk assessment instrument (eg, health hazard appraisal) with scoring and documentation, per standardized instrument	Diagnostic Procedures File	\$3.23
96161	Administration of caregiver-focused health risk assessment instrument (eg, depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument	Diagnostic Procedures File	\$3.23
G8431	Screening for depression is documented as being positive and a follow-up plan is documented	Ancillary Procedures File	
G8432	Depression screening not documented, reason not given	Ancillary Procedures File	
G8433	Screening for depression not completed, documented reason	Ancillary Procedures File	
G8510	Screening for depression is documented as negative, a follow-up plan is not required	Ancillary Procedures File	
G8511	Screening for depression documented as positive, follow-up plan not documented, reason not given	Ancillary Procedures File	

Evidence Summary

USPSTF, 2016

<https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/depression-in-adults-screening1>

The USPSTF recommends screening for depression in the general adult population, including pregnant and postpartum women. Screening should be implemented with adequate systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up.

- “B” Recommendation

O’Connor, 2016

<https://jamanetwork.com/journals/jama/fullarticle/2484344>

- Systematic review for USPSTF
- Pregnant and postpartum women 18 years and older
- 6 trials (n = 11 869) showed 18% to 59% relative reductions with screening programs, or 2.1% to 9.1% absolute reductions, in the risk of depression at follow-up (3-5 months) after participation in programs involving depression screening, with or without additional treatment components, compared with usual care.
- Based on 23 studies (n = 5398), a cutoff of 13 on the English-language Edinburgh Postnatal Depression Scale demonstrated sensitivity ranging from 0.67 (95% CI, 0.18-

Postpartum Depression Screening

0.96) to 1.00 (95% CI, 0.67-1.00) and specificity consistently 0.87 or higher. Data were sparse for Patient Health Questionnaire instruments.

- Pooled results for the benefit of CBT for pregnant and postpartum women with screen-detected depression showed an increase in the likelihood of remission (pooled relative risk, 1.34 [95% CI, 1.19-1.50]; with absolute increases ranging from 6.2% to 34.6%.
- Author conclusions: Direct and indirect evidence suggested that screening pregnant and postpartum women for depression may reduce depressive symptoms in women with depression and reduce the prevalence of depression in a given population.

MED, 2016

- Policy brief on screening for postpartum depression and linkage to care
 - Some states allow only PHQ-9, EPDS, or Beck, and others allow any validated screen

Table 2. Test Characteristics of Postpartum Depression Screening Tools

Screening Test	Sensitivity (95% CI)	Specificity (95% CI)	Strength of Evidence ³
Antenatal Risk Questionnaire	78.1% (65.0 to 88.7%)	47.1% (40.3 to 59.9%)	Low
BDI	80% to 90% ¹	80% to 90% ¹	Low
BDI-II	75% to 90% ¹	80% to 90% ¹	Low
EPDS	80% to 90% ¹	80% to 90% ¹	Moderate
HRSD-17	80% to 85% ²	80% to 85% ²	Low
HRSD-21	80% to 85% ²	75% to 80% ²	Low
Leverton Questionnaire	95.2% (90.4 to 98.1%)	91.3% (88.4 to 93.7%)	Low
PDSS	80% to 90% ¹	80% to 90% ¹	Moderate
PHQ-9	75% to 89% ²	83% to 91% ²	Low
Two-Question Screen	100% (2 studies; sensitivity 100% in both)	44.3% and 65.7%	Moderate

BDI = Beck Depression Inventory, EPDS= Edinburgh Postpartum Severity Score, HRSD = Hamilton Rating Scale for Depression, PDSS = Postpartum Depression Screening Scale, PHQ = Patient Health Questionnaire

Source: AHRQ (Myers et al., 2013)

¹ Approximate range at most commonly used thresholds

² Approximate range at varying thresholds

³ Based on four domains: risk of bias, consistency, directness, and precision

- - Some allow for billing on mom's or child's Medicaid ID (Colorado, Illinois), others only on mom (New York) or only child (Minnesota)
 - Several states used 99420 which has been replaced with 96160
 - Key issues identified in the MED report – resources need to be available for screening tools, referral pathways need to be in place, provider and telephonic support can be important.

Other state strategies

Minnesota

- Developed clinical pathways for postpartum depression screening and follow up
- Postpartum depression screening is covered in well child checks, up to 3 times in the first 12 months of life
- Recommended 99420 which was reimbursed in 2015 at \$8.67

Postpartum Depression Screening

New York

- Reimburses for screening for postpartum depression
- When done during the infant visit, it is billed to the mother's Medicaid number
- Up to 3 screens in the 12 months postpartum are covered
- Providers are instructed to have a plan in place to address positive screens
- 99420 is to be used, reimbursement \$15.60

Illinois

- Created metrics around prenatal and postpartum depression screening
- 96127, with the HD modifier (96127 HD) for postpartum depression screening, up to a year after the infant's birth; may be billed on the infant's recipient number, if infant is the patient.
- The University created a phone consultation service to connect providers to psychiatrists for advice about diagnosis, management, and medications
- The creation of a hotline, staffed by mental health experts, for women to call for advice or resources
- Provider education efforts across the state

Colorado

- Any screen is acceptable but encourage PHQ9 and EPDS
- Recently replaced 99420 with G8431- positive screen, G8510- negative screen
- Reimbursement \$10.28, yearly

National Guidance

CMS, 2015

CMS Core Set of Children's Health Care Quality Measures includes a maternity care behavioral risk assessment at the initial prenatal visit with depression screening listed along with alcohol, tobacco, drug use, and intimate partner violence screening

CMS, 2016 Informational Bulletin on Postpartum Depression

- Maternal depression screening during the well-child visit is considered a pediatric best practice and is a simple way to identify mothers who may be suffering from depression and may lead to treatment for the child or referral for mothers to other appropriate treatment.
- States and managed care plans can promote uptake by:
 - Posting information about maternal depression screening on provider websites and publishing information in provider newsletters.
 - Delivering provider trainings to promote the use of maternal depression screening tools and proper billing codes.
 - Conducting in-person visits to clinics to train providers on how to implement screenings, help practices modify clinic flow, and discuss referral strategies.
 - Offering practitioners continuing medical education (CME) credits for participation.
- States may cover maternal depression screening for non-Medicaid eligible mothers during the well-child visit. States may also cover treatment for the mother when both

Postpartum Depression Screening

the child and the mother are present, treatment focuses on the effects of the mother's condition on the child, and services are for the direct benefit of the child.

Recommendations from professional associations

AAP Bright Futures https://www.aap.org/en-us/Documents/periodicity_schedule.pdf

- Maternal depression screening is recommended during well child checks by 1 month, 2 months, 4 months, and 6 months

ACOG, 2015 <https://www.acog.org/-/media/Committee-Opinions/Committee-on-Obstetric-Practice/co630.pdf?dmc=1&ts=20180710T0405387857>

- ACOG recommends screening at least once during the perinatal period for depression and anxiety symptoms using a standardized, validated tool
- Screening by itself is insufficient. It must be coupled with appropriate follow up and treatment
- Systems should be in place to ensure follow up for diagnosis and treatment

Postpartum Depression Screening

HERC Staff Summary

Screening for postpartum depression is recommended by the USPSTF and is intended to be covered on the Prioritized List, during mom's or a child's visit, and clarity is needed.

The American Academy of Pediatrics has specifically been advocating for the use of the 96161 to be used during the child's visit for maternal depression screening so clarifying this code is appropriate would be in alignment with national efforts.

The claim for maternal depression screening can be appropriately billed to mom when she is the patient, or to the infant when they are the patient.

HERC Staff Recommendations:

1. Add Z13.32 Encounter for screening for maternal depression to Line 3 (per BHAP recommendations), although pairing with this would not be necessary, any well child or postpartum visit would be appropriate pairing.
2. Add 96160, 96161, and 96127 to Line 3 (and continue to have them be Diagnostic as well)
3. Add a Guideline

GUIDELINE NOTE XXX POSTPARTUM DEPRESSION SCREENING

Line 3

Postpartum depression screening using a validated instrument (e.g. Edinburgh Postpartum Severity Score, PHQ-9) is included on this line during the child's visit (CPT 96161) or during the mother's visit (CPT 96160, 96127) when there is a plan in place to address positive depression screens.

4. HSD may need to clarify that this code can be billed in addition to other screens such as developmental screening
5. Recommend to HSD to review the reimbursement rate for these codes. Other states are reimbursing between \$8.67 and \$15.60. The current reimbursement rates for FFS are \$3.23.
6. Other parts of OHA will need to work with partners on promoting the uptake of postpartum depression screening and additional resources to ensure adequacy of follow-up and access to appropriate treatment. There are excellent examples from other states.

Cardiac MRI for Indications other than Congenital Heart Disease

Question: Should cardiac MRI be included for indications other than evaluation of congenital cardiac disease?

Question source: Primary Health; HERC staff

Issue: Cardiac MRI CPT codes were new codes in 2007. Placement was debated over several meetings in 2007 and 2008. Ultimately, it was decided to put cardiac MRI codes only on the congenital heart disease lines. It was felt that other indications had less expensive imaging modalities available, such as ECHO. There was also concern that the test had not been proven as a valuable test in many areas.

Cardiac MRI has become a more common and accepted test over the past decade. CMS recently changed their guidelines regarding determination of ejection fraction (EF) for qualifying for an implantable cardiac defibrillator and included cardiac MRI as one modality for determining EF. Most private insurers cover cardiac MRI for evaluation of cardiomyopathy, and for determination of EF, although some restrict to when ECHO is non-diagnostic. CCO's are increasingly getting requests for cardiac MRIs for evaluation of cardiomyopathy. Echocardiography, in particular trans-esophageal echocardiogram (TEE), remains the generally accepted modality for the evaluation of cardiac anatomy and function most of the time by most practitioners. However, there are patients who cannot be adequately imaged with ECHO.

Expert Guidelines

THE NICE 2015 (<https://www.nice.org.uk/guidance/qs99/resources/secondary-prevention-after-a-myocardial-infarction-pdf-2098977438661>) guideline on Secondary Prevention after MI states that "Left ventricular function can be assessed using a variety of methods, including echocardiography, cardiac magnetic resonance imaging (MRI), angiography and nuclear imaging. [Expert opinion]." The NICE 2010 (<https://www.nice.org.uk/guidance/cg108/resources/chronic-heart-failure-in-adults-management-pdf-35109335688901>) guideline on management of congestive heart failure states "Consider alternative methods of imaging the heart (for example, radionuclide angiography, cardiac magnetic resonance imaging or transoesophageal Doppler 2D echocardiography) when a poor image is produced by transthoracic Doppler 2D echocardiography. [2003]."

The ACCF/ACR/AHA/NASCI/SCMR 2010 Expert Consensus Document on Cardiovascular Magnetic Resonance (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3042771/pdf/nihms268875.pdf>) stated that "CMR may be used for assessment of LV and RV size and morphology, systolic and diastolic function, and for characterizing myocardial tissue for the purpose of understanding the etiology of LV systolic or diastolic dysfunction." Additionally, "CMR may be useful for identifying coronary artery anomalies and aneurysms, and for determining coronary artery patency."

Expert input

Dr. Eric Stecker:

My feeling is CMR is unlikely to be abused or overused since it is probably a money loser for cardiologists and health systems. Labor intensive by tech's and cardiologists to protocol and conduct it. It is not used as first line for EF assessment – echo is. Rarely it's used when echo images or precision of estimate of EF are insufficient. CMR is essential to evaluate for a non-ischemic etiology of cardiomyopathies, myocardial viability when needed to guide whether to

Cardiac MRI for Indications other than Congenital Heart Disease

revascularize or not, and evaluating for risk of sudden cardiac death among patients with unexplained arrhythmias (heart block, VT, VF) or family history of a genetic disorder predisposing to hypertrophic cardiomyopathy, fibrosis or cardiomyopathy. So I think it should just be covered as a standard diagnostic test and encourage echo first line when possible. Can look later to see if people are overusing it.

Current Prioritized List Placement

CPT	Code Description	Current Lines
75557	Cardiac magnetic resonance imaging for morphology and function without contrast material;	Congenital heart disease lines: 44,67,70,85,86,89,90,105,106, 111, 128, 130, 138, 176, 186, 188, 224, 233,258, 264, 651
75559	With stress imaging	Same as above
75561	Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences;	Same as above
75563	with stress imaging	Same as above
75565	Cardiac magnetic resonance imaging for velocity flow mapping	Same as above

HERC staff summary

Cardiac MRI (CMR) has become a standard imaging modality for a variety of cardiac indications. It does not appear to have potential for overuse according to our cardiology expert.

HERC staff recommendations:

- 1) Remove CMR from all current lines on the Prioritized List and add to the Diagnostic Procedures File
 - a. CPT 75557-75565 (Cardiac magnetic resonance imaging)
- 2) Consider adopting a new diagnostic guideline as shown below

DIAGNOSTIC GUIDELINE DX CARDIAC MAGNETIC RESONANCE IMAGING

Cardiac magnetic resonance imaging (CMR) is covered only after it has been determined that echocardiogram and Doppler studies are inconclusive or expected to be nondiagnostic.

Allergy Testing for Eczema

Questions:

- 1) Should specific IgE testing and skin allergy testing be paired with severe eczema?
- 2) Should specific IgE testing and skin allergy testing continue to be paired with mild eczema?

Question sources:

- 1) Thermo Fisher Scientific
- 2) HERC staff

Issue: IgE allergy testing (a blood test to see if there are antibodies to a specific protein) and skin patch testing are currently not paired with severe eczema (also known as atopic dermatitis) on line 424 SEVERE INFLAMMATORY SKIN DISEASE. However, various types of allergy testing are paired with mild/moderate eczema on line 530 MILD ECZEMA.

Thermo Fisher Scientific contacted the HERC requesting a review of IgE testing for allergic rhinitis (currently paired but below the funding line) and for children with severe eczema. They provided guidelines from the American Academy of Dermatology indicating the children with severe eczema who are not responding to optimal medical therapy should have allergy testing. They also provided information from the National Institute of Allergy and Infectious Diseases indicating that children with severe eczema should receive IgE allergy testing for peanuts prior to introducing peanuts into their diet; similarly, children with egg allergy should have IgE testing for peanuts prior to introduction. The ICD-10 code for egg allergy (Z91.012 Allergy to eggs) is currently informational.

IgE blood tests were restricted to various lines based on the 2018 CPT code review; the lines included only those that included skin allergy testing. Previously, these tests were diagnostic, were widely used and paired with a variety of diagnoses. The other diagnoses on line 424, such as psoriasis, are not generally recommended for evaluation by allergy testing.

Expert guidelines

- 1) American Academy of Dermatology 2014, guideline for management of atopic dermatitis**
 - a. The role of allergens in eliciting and maintaining atopic dermatitis (AD) skin lesions is complex, further complicated by challenges in determining clinical relevance and their importance relative to other factors.
 - b. In summary, allergens may be pertinent to some AD patients but require a detailed history, careful evaluation, and correlation of allergy test results to determine clinical relevance. It is extremely rare to find 1 allergen responsible for AD, which is a complex multifactorial disease in which nonallergic factors, such as climate and secondary infection, may also be implicated.
 - a. Recommendations:
 - a. Atopic dermatitis patients have an increased rate of environmental and food allergies, and physicians should assess for these conditions during history taking. If significant concerns for allergy are identified (hives, urticaria, etc) assessment can be undertaken. Allergy testing independent of history is not recommended.
 - b. Patch testing should be considered in patients with atopic dermatitis who have persistent/recalcitrant disease and/or a history or physical examination findings consistent with allergic contact dermatitis.
 - c. Level of Evidence: II; Strength of Recommendations: B

Allergy Testing for Eczema

- b. Children <5 years of age with moderate to severe AD should be considered for food allergy evaluation for milk, egg, peanut, wheat, and soy if at least 1 of the following is met: (A) persistent AD in spite of optimized treatment or (B) having a reliable history of immediate reaction after ingestion of a specific food. (no level of evidence specified)
- 2) **NICE 2007**, guideline for diagnosis and treatment of eczema in children under 12
<https://www.nice.org.uk/guidance/cg57/resources/atopic-eczema-in-under-12s-diagnosis-and-management-pdf-975512529349>
- a. Healthcare professionals should consider a diagnosis of food allergy in children with atopic eczema who have reacted previously to a food with immediate symptoms, or in infants and young children with moderate or severe atopic eczema that has not been controlled by optimum management, particularly if associated with gut dysmotility (colic, vomiting, altered bowel habit) or failure to thrive.
 - b. Healthcare professionals should consider a diagnosis of inhalant allergy in children with seasonal flares of atopic eczema, children with atopic eczema associated with asthma or allergic rhinitis, and children aged 3 years or over with atopic eczema on the face, particularly around the eyes.
 - c. Healthcare professionals should consider a diagnosis of allergic contact dermatitis in children with an exacerbation of previously controlled atopic eczema or with reactions to topical treatments.
 - d. Healthcare professionals should reassure children with mild atopic eczema and their parents or carers that most children with mild atopic eczema do not need to have testing
- 3) **NIAID 2017**, guidelines for the prevention of peanut allergy
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5217343/>
- a. Expert consensus guideline
 - i. Infants with severe eczema, egg allergy, or both: Strongly consider evaluation by IgE measurement of peanut antibody and/or skin prick test and, if necessary, an oral food challenge. Based on test results, introduce peanut-containing foods.
 - ii. Quality of evidence noted to be moderate, with significant contribution of expert input

Expert Input

Dr. Tracy Funke, OHSU Dermatology

Allergy testing is not a routine part of eczema work-up or management. Allergy testing is unreliable in infants and can lead to food restriction based on false positives. It is also now recommended that infants with mild-moderate atopic dermatitis introduce peanut and egg into their diet between 4-6 months of age and that is where I focus my efforts in an attempt to reduce food allergy development. I find that the vast majority of infants fall into the mild-moderate eczema category and that very few really have severe atopic dermatitis by 6 months of age. I do not think that allergy testing should be a routine part of atopic dermatitis work-up or management and should be used only in select patients with allergy-specific symptoms (hives, etc).

Allergy Testing for Eczema

Dr Julie Dhossche, OHSU Dermatology

...we do not routinely do any kind of allergy testing (blood, prick or patch) in patients with eczema/atopic dermatitis. I would say in adults more often than kids we do consider patch testing (which we do in dermatology clinic) in those with persistent/worsening/changing disease to tease out any component of allergic contact dermatitis which may be contributing to their rash.

HERC staff summary

Allergy testing (either IgE blood testing or skin patch testing) is recommended by expert groups for patients with severe eczema with no or minimal improvement with optimal medical therapy or with concurrent hives or urticaria, or for infants with severe eczema prior to introducing peanuts. However, it does not appear to be common practice in Oregon and is not recommended by local dermatology experts except in situations where a patient has other signs of allergy (hives, etc.). It does not appear to have strong support for use in evaluation of patients with mild eczema, and NICE recommends against such testing for mild eczema.

Currently, allergy testing is paired with mild eczema but not severe eczema. There are multiple diagnoses on the line with severe eczema that are not appropriate for pairing; therefore, if allergy testing is added to this covered line then a guideline would need to be added to limit use to appropriate diagnoses.

HERC staff recommendations:

- 1) Remove allergy testing from line 530 MILD ECZEMA as NICE and expert groups do not recommend such testing for mild eczema
 - a. CPT 86003 AND 86008 (Allergen specific IgE)
 - b. CPT 86486, 95004, 95018, 95024-95028, 95044, 95052, 95056, 95060, 95065, 95070-95071, 95076, 95079 (Allergy testing, skin, mucous membrane, inhalation)
 - c. CPT 95115-95134 (Professional services for allergen immunotherapy)
 - d. CPT 95144-95170 (Professional services for the supervision of preparation and provision of antigen)
 - e. CPT 95180 (Rapid desensitization procedure)
- 2) Do not add IgE and skin patch testing for allergens to line 424 SEVERE INFLAMMATORY SKIN DISEASE
 - a. Not recommended by local experts
 - b. If patients have severe eczema that is affected by hives or another below the line diagnoses, the allergy testing can be done via pairing the allergy testing with the diagnoses of hives and using the comorbidity rule

MRI Guided Focused Ultrasound for Treatment of Essential Tremor

Question: Should MRI guided focused ultrasound (MRgFUS) be paired with essential tremor?

Question source: Insightec

Issue: MRgFUS (CPT 0398T) is a non-invasive treatment alternative to deep brain stimulation for treatment of essential tremor that does not respond to medical therapy. Of note, deep brain stimulation is currently not paired with essential tremor on the Prioritized List.

Essential tremor is the most common cause of disabling tremor and is distinct from Parkinson's disease. It typically affects the arms and hands, although it may also involve the head, jaw, tongue and legs. Treatment for essential tremor includes medications such as beta blockers (for example, propranolol), anti-epileptics (for example, primidone) or sedatives (for example, clonazepam). Rarely, injections of botulinum toxin may be used. Surgery may be considered in people whose condition has not responded adequately to best medical therapy. Surgical treatments include deep brain stimulation and radiofrequency thalamotomy.

MRgFUS uses high-power focused ultrasound to irreversibly ablate target tissue that is causing the tremor. The potential benefits of unilateral MRI-guided focused ultrasound thalamotomy are that it: is less invasive than the other existing procedures; results in a faster recovery time; and allows for testing of the effects of sublethal doses before ablation. However, it is only done on 1 side.

Current Prioritized List status:

ICD-10 G25.0 (Essential tremor) is on line 362 DYSTONIA (UNCONTROLLABLE); LARYNGEAL SPASM
CPT 0398T is not currently in the HERC database as this type of code is generally not reviewed

From Insightec:

National Government Services, the Medicare Administrative Contractor covering the States of NY, CT, RI, MA, ME, WI, IL, NH, VT, and MN has deemed MRI Guided Focused Ultrasound (CPT 0398T) to be medically reasonable and necessary to treat patients suffering from essential tremor (ICD-10: G25.0), and is a covered benefit for Medicare beneficiaries as of 4/1/2018...The Medicare Administrative Contractors for the States of **OR**, KT, OH, AL, GA, TN, NC, SC, VA, WV, CA, HI, NV, AK, AZ, ID, MT, ND, SD, UT, WA, WY, and US Commonwealth and Territories of American Samoa, Guam, Northern Mariana Islands also approved MRI Guided Focused Ultrasound for essential tremor as medically reasonable and necessary, currently in draft phase with an anticipated effective date for coverage of 11/2018...The covered treatment for individuals with essential tremor who are also non-responsive to medication therapy is Deep Brain Stimulation. This treatment is effective and appropriate in certain situations, however it is extremely invasive with a lower safety profile, requires follow up surgeries every few years to replace the batteries and/or to move the wiring, is expensive due to the hardware and inpatient hospital stay, recovery can be lengthy, and puts the patient at risk for infection, stroke and other complications. Alternatively, MRI Guided Focused Ultrasound is an outpatient procedure and the patient is in-and-out on the same day and this should be at minimum, an option for a physician and patient to choose if they feel that is the most patient centered, individualized and preferred course of treatment.

MRI Guided Focused Ultrasound for Treatment of Essential Tremor

Evidence

- 1) **NICE 2018:** Unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor
 - a. The evidence on the safety of unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor raises no major safety concerns. However, current evidence on its efficacy is limited in quantity. Therefore, this procedure should not be used unless there are special arrangements for clinical governance, consent, and audit or research.
 - b. The NICE evidence review found 11 articles on MRgUS for essential tremor: 1 systematic review, 1 randomised controlled trial (2 publications providing 1- and 2-year follow-up data), 2 non-randomised comparative studies and 6 case series
- 2) **Ravikumar 2017,** systematic review of MRgUS for essential tremor
 - a. Data was obtained on 83 magnetic resonance-guided focused ultrasound thalamotomies
 - b. Magnetic resonance-guided focused ultrasound thalamotomy resulted in significantly higher utility scores compared with deep brain stimulation (DBS; $P < 0.001$) or stereotactic radiosurgery ($P < 0.001$). Projected costs of magnetic resonance-guided focused ultrasound thalamotomy were significantly less than DBS ($P < 0.001$), but not significantly different from radiosurgery.
 - c. Conclusions: Magnetic resonance-guided focused ultrasound thalamotomy is cost-effective for tremor compared with DBS and stereotactic radiosurgery and more effective than both.
- 3) **Elias 2016,** RCT of MRgUS for essential tremor
 - a. N=76 patients
 - b. Randomized to MRgUS vs sham procedure
 - c. Hand-tremor scores improved more after focused ultrasound thalamotomy (from 18.1 points at baseline to 9.6 at 3 months) than after the sham procedure (from 16.0 to 15.8 points); the between group difference in the mean change was 8.3 points (95% confidence interval [CI], 5.9 to 10.7; $P < 0.001$). The improvement in the thalamotomy group was maintained at 12 months (change from baseline, 7.2 points; 95% CI, 6.1 to 8.3). Secondary outcome measures assessing disability and quality of life also improved with active treatment (the blinded thalamotomy cohort) as compared with the sham procedure ($P < 0.001$ for both comparisons). Adverse events in the thalamotomy group included gait disturbance in 36% of patients and paresthesias or numbness in 38%; these adverse events persisted at 12 months in 9% and 14% of patients, respectively.
 - d. **CONCLUSIONS** MRI-guided focused ultrasound thalamotomy reduced hand tremor in patients with essential tremor. Side effects included sensory and gait disturbances.

MRI Guided Focused Ultrasound for Treatment of Essential Tremor

HERC staff summary:

MRgUS is a promising but experimental procedure for treating essential tremor. To date, approximately 83 patients have had this procedure reported in the literature. NICE considers this procedure experimental. Alternative surgeries are currently not paired with essential tremor on the Prioritized List. Medications to treat essential tremor are available.

HERC staff recommendation:

- 1) Add CPT 0398T (MRgFUS) to line 660
- 2) Add the following entry to GN173

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

The following treatments are prioritized on Line 660, CONDITIONS FOR WHICH CERTAIN TREATMENTS HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS; UNPROVEN TREATMENTS, for the conditions listed here:

CPT/HCPCS Code	TREATMENT	Rational	Date of Last Review/Link to Meeting Minutes
O398T	MRI guided focused ultrasound for the treatment of essential tremor	Insufficient evidence of effectiveness	October, 2018

MRI Guided Focused Ultrasound for Treatment of Essential Tremor

Disposition of manufacturer provided literature

- 1) CMS and private insurer policies—not medical literature
- 2) Chang 2018—follow up of study included in systematic reviews
- 3) Kim 2017—retrospective cohort study; high quality studies available
- 4) Langford 2018—only included trial with MRgUS was the Elias trial, which was already included in the literature review
- 5) Fishman 2017—clinical review
- 6) Fishman 2018—safety data only

VbBS Issue Summaries 10-4-2018

Sacroiliac Joint Dysfunction Prioritization

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

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

Issue: Andy Kranenburg, MD from Medford, testified at the August 2018 VBBS meeting regarding the treatment of sacroiliac joint pain and dysfunction. Currently, there is a guideline on the Prioritized List regarding when treatment is appropriate, but the diagnosis is on an uncovered line. He requested reconsideration of the prioritization of sacroiliac joint dysfunction to a line above the funding level. He reviewed the HERC prioritization methodology, and SI joint dysfunction ended up with a very high score according to him and his colleagues, higher than many conditions that are currently covered. SI joint pain is a highly burdensome health state.

SI joint dysfunction and SI joint fusion were reviewed in August and November, 2016. ICD-10 M46.1 (Sacroiliitis, not elsewhere classified) and CPT 27279 (Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device) were added to 527 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS along with a guideline regarding when fusion should be covered. Sacroiliitis is also on line 401 CONDITIONS OF THE BACK AND SPINE (medical line). The VBBS and HERC felt that surgical treatment of this condition should be low priority. The guideline was adopted as the CCO medical directors thought it would be helpful to have when approving exceptions.

The manufacturer sent updated research synopses; however, the evidence regarding the effectiveness of SI joint fusion was reviewed in 2016. The current question is regarding the prioritization of sacroiliitis paired with surgical fusion.

Current Prioritized List placement:

Medical treatment of sacroiliitis is found on line 401 CONDITIONS OF THE BACK AND SPINE

SI joint fusion is found on line 527 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS and pairs with sacroiliitis.

Other back surgeries are found on line 346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS.

In order for a condition to be included on line 346, it must meet the criteria outlined in GN37, such as neurogenic claudication or evidence of nerve damage.

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:

Sacroiliac Joint Dysfunction Prioritization

- 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-Corticosteroid Percutaneous Interventions](#). See <https://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx>.

Sacroiliac Joint Dysfunction Prioritization

Current line prioritization scoring

527 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS

Category: 7

HL: 4

Suffering: 3

Population effects: 0

Vulnerable population: 0

Tertiary prevention: 0

Effectiveness: 1

Need for service: 0.8

Net cost: 2

Score: 112

Approximate line placement: 527

346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS

Category: 7

HL: 5

Suffering: 4

Population effects: 0

Vulnerable population: 0

Tertiary prevention: 4

Effectiveness: 3

Need for service: 1

Net cost: 2

Score: 780

Approximate line placement: 346

HERC staff recommendation:

- 1) Do not rescore line 527 or move surgical treatment of sacroiliitis to line 346 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS.
 - a. Sacroiliitis does not meet the criteria of GN47 regarding nerve damage or neurogenic complications

Human Donor Breast Milk

Question: Should human donor breast milk be included on the Prioritized List?

Question source: HSD

Issue: Breast milk is widely considered the healthiest food source for infants, particularly those who are premature. Breastfeeding is associated with multiple health benefits for infants (decreased risk of asthma, obesity, necrotizing enterocolitis, type 2 diabetes, ear infections, respiratory infections, sudden infant death syndrome, and gastrointestinal infections).

Oregon has one of the highest breastfeeding rates in the country, with a >90% initiation rate, 70% breastfeeding at 6 months, and 38% exclusively breastfeeding at 6 months. <https://www.oregon.gov/oha/PH/HEALTHYPEOPLEFAMILIES/BABIES/BREASTFEEDING/Documents/bf-whitepaper-2017.pdf>

Among Medicaid patients discharged from the NICU, 2017 data showed 66.7% were breastfeeding (Dr. Allen Merritt, personal communication).

When breast milk is not available through the mother, whether through medical contraindications or production challenges, donor breast milk is an option. However, it is quite expensive. Donor breast milk is currently paid for through OHP only in rare exceptions.

Clinical background

Ip, 2007 <https://www.ncbi.nlm.nih.gov/pubmed/17764214>

1. AHRQ systematic review of breastfeeding outcomes in developed countries
2. 29 systematic reviews or meta-analyses that covered approximately 400 individual studies were included in this review. 43 primary studies on infant health outcomes.
3. Results: We found that a history of breastfeeding was associated with a reduction in the risk of acute otitis media, non-specific gastroenteritis, severe lower respiratory tract infections, atopic dermatitis, asthma (young children), obesity, type 1 and 2 diabetes, childhood leukemia, sudden infant death syndrome (SIDS), and necrotizing enterocolitis. There was no relationship between breastfeeding in term infants and cognitive performance. The relationship between breastfeeding and cardiovascular diseases was unclear. Similarly, it was also unclear concerning the relationship between breastfeeding and infant mortality in developed countries.

Kramer, 2012 <https://www.ncbi.nlm.nih.gov/pubmed/22895934>

1. Cochrane systematic review on optimal duration of exclusive breastfeeding
2. 23 studies, 12 from developed countries, all observational studies
3. Results: Infants who are exclusively breastfed for six months experience less morbidity from gastrointestinal infection than those who are partially breastfed

Human Donor Breast Milk

as of three or four months, and no deficits have been demonstrated in growth among infants from either developing or developed countries who are exclusively breastfed for six months or longer.

CDC, 2018

<https://www.cdc.gov/breastfeeding/about-breastfeeding/why-it-matters.html>

Infants who are breastfed have reduced risks of:

- Asthma
- Obesity
- Type 2 diabetes
- Ear and respiratory infections
- Sudden infant death syndrome (SIDS)
- Gastrointestinal infections (diarrhea/vomiting)
- Necrotizing enterocolitis for preterm infants

Breastfeeding can help lower a mother's risk of:

- High blood pressure
- Type 2 diabetes
- Ovarian cancer
- Breast cancer

Current prioritized list status

Code	Description	Placement
T2102	Human breast milk processing, storage and distribution only	Ancillary File

Evidence summary

Quigley, 2018

<https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD002971.pub4/full>

1. Cochrane systematic review of formula versus donor breast milk in preterm or low birth weight infants
2. Randomized or quasi-randomized controlled trials

Human Donor Breast Milk

3. 11 trials, 1809 infants
 - a. 4 trials compared standard term formula versus donor breast milk
 - b. 7 trials compared nutrient-enriched preterm formula versus donor breast milk
4. Results:
 - a. Formula-fed infants had higher in-hospital rates of weight gain (mean difference (MD) 2.51, 95% confidence interval (CI) 1.93 to 3.08g/kg/day), linear growth (MD 1.21, 95% CI 0.77 to 1.65 mm/week) and head growth (MD 0.85, 95% CI 0.47 to 1.23 mm/week).
 - b. No evidence found of an effect on long-term growth or neurodevelopment.
 - c. Formula feeding increased the risk of necrotizing enterocolitis (typical risk ratio (RR) 1.87, 95% CI 1.23 to 2.85; risk difference (RD) 0.03, 95% CI 0.01 to 0.06). NNH is 33.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Formula (term or preterm) compared to donor breast milk (unfortified or fortified) for feeding preterm or low birth weight infants						
Patient or population: preterm or low birth weight infants Setting: neonatal unit Intervention: formula (term or preterm) Comparison: donor breast milk (unfortified or fortified)						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	# of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with DBM (unfortified)	Risk with Formula (term or preterm)				
Weight gain (g/ kg/ day)	-	MD 2.51 higher (1.93 higher to 3.08 higher)	-	1028 (9 studies)	Moderate ^a	I ² = 90%
Linear growth (crown-heel length mm/week)	-	MD 1.21 higher (0.77 higher to 1.65 higher)	-	820 (8 studies)	Moderate ^a	I ² = 68%
Head growth (mm/ week)	-	MD 0.85 higher (0.47 higher to 1.23 higher)	-	894 (8 studies)	Moderate ^a	I ² = 74%
Neurodevelopmental disability	Study population		RR 1.21 (0.62 to 2.35)	400 (2 studies)	Moderate ^b	
	73 per 1000	88 per 1000 (45 to 171)				
All-cause mortality	Study population		RR 1.11 (0.81 to 1.53)	1457 (6 studies)	Moderate ^b	
	88 per 1000	98 per 1000 (72 to 135)				
Necrotising enterocolitis	Study population		RR 1.87 (1.23 to 2.85)	1605 (8 studies)	Moderate ^b	
	37 per 1000	70 per 1000 (46 to 107)				

5. Limitations - Only the four most recent trials used nutrient-fortified donor breast milk. A number of the trials had limitations in terms of blinding and allocation concealment.
6. Author conclusions: Formula, compared to donor breast milk, results in increased growth parameters and an increased risk of necrotizing enterocolitis.

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Villamor-Martinez, 2018

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5852814/pdf/nutrients-10-00238.pdf>

1. Systematic review and meta-analysis of donor breast milk on bronchopulmonary dysplasia in preterm and very low birthweight infants
2. 18 studies, RCTs and observational studies
3. Results:
 - a. Meta-analysis of RCTs could not demonstrate that supplementation of mothers own milk (MOM) with pasteurized donor human milk reduced bronchopulmonary dysplasia (BPD) when compared to preterm formula (three studies, risk ratio (RR) 0.89, 95% confidence interval (CI) 0.60–1.32).
 - b. Meta-analysis of observational studies showed that pasteurized donor human milk supplementation reduced bronchopulmonary dysplasia (8 studies, RR 0.78, 95% CI 0.67–0.90).
 - c. An exclusive human milk diet reduced the risk of bronchopulmonary dysplasia, compared to a diet with preterm formula and/or bovine milk-based fortifier (three studies, RR 0.80, 95% CI 0.68–0.95).
 - d. Feeding raw MOM, compared to feeding pasteurized MOM, protected against BPD (two studies, RR 0.77, 95% CI 0.62–0.96).
 - e. Days of mechanical ventilation was less in those receiving pasteurized donor human milk (MD -5.73 days, 95% CI -10.68 to -0.77, $p = 0.023$) (3 RCTs)
 - a. Days on oxygen was not significantly different (MD -9.11 days, 95% CI -24.82 to 6.60, $p = 0.256$) (2 RCTs)
4. Authors conclusion: Pasteurized donor human milk protects against BPD in very preterm infants.

Miller, 2018 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6024377/pdf/nutrients-10-00707.pdf>

1. Systematic review and meta-analysis look at BW <1500g
2. Experimental and observational studies were pooled separately in meta-analyses. Risk of bias was assessed for each individual study and the GRADE system used to judge the certainty of the findings.
3. Forty-nine studies (with 56 reports) were included, of which 44 could be included in meta-analyses.
4. Results:
 - a. Human milk provided a clear protective effect against necrotizing enterocolitis (NEC), with an approximate 4% reduction in incidence.. Particularly for NEC, any volume of human milk is better than exclusive preterm formula, and the higher the dose the greater the protection.
 - b. Human milk provided a possible reduction in late onset sepsis, severe retinopathy of prematurity and severe NEC

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- c. Evidence regarding pasteurization is inconclusive, but it appears to have no effect on some outcomes
5. Author conclusions: Improving the intake of mother's own milk (MOM) and/or donor HM results in small improvements in morbidity in this population.

Abrams, 2014

1. Combination of 2 randomized trials, one including randomization to human milk fortification versus cow milk fortification and the other comparing donor human milk to cow-based formula.
2. Extremely preterm (EP) infants <1,250 g birth weight received a diet consisting of either human milk fortified with a human milk protein-based fortifier (HM) (n = 167) or a diet containing variable amounts of milk containing cow milk-based protein (CM) (n = 93).
3. Results: Mortality (2% versus 8%, p = 0.004) and NEC (5% versus 17%, p = 0.002) differed significantly between the HM and CM groups, respectively. For every 10% increase in the volume of milk containing CM, the risk of sepsis increased by 17.9% (p < 0.001). Growth rates were similar between groups. The duration of parenteral nutrition was 8 days less in the subgroup of infants receiving a diet containing <10% CM versus ≥10% CM (p < 0.02).
4. Author Conclusions: An exclusive human milk diet, devoid of CM-containing products, was associated with lower mortality and morbidity in EP infants without compromising growth and should be considered as an approach to nutritional care of these infants.
5. Note: The human milk based fortifier used in this study, Prolacta, is extremely expensive and this study is funded by Prolacta.

Recommendations from others

American Academy of Pediatrics, 2016

1. Policy statement about the use of donor human milk in high risk infants
2. Prioritization of donor human milk is for infants <1,500g
3. There are no clear guidelines for discontinuing the use of donor human milk in an infant <1500 g birth weight when the volume of mother's milk is not adequate. A range of postmenstrual ages from 32 to 36 weeks is commonly used in the United States, because this range covers the highest risk period for necrotizing enterocolitis. Further research is needed to clarify the optimal timing of discontinuing donor human milk.
4. Intestinal diseases - Fewer data are available regarding the use of donor human milk in other high-risk infants, including infants with abdominal wall defects, such as gastroschisis or omphalocele, and other conditions, such as congenital heart disease. Nonetheless, some infants with these conditions or other neonatal disorders may benefit from donor human milk either because of a direct effect on intestinal growth or improved feeding tolerance. In these cases,

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payers may expect documentation of intolerance to specialized infant formulas and the medical necessity for donor human milk before providing payment for human milk at home or in the hospital.

Other payers

Medi-Cal

<http://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPsandPolicyLetters/PL1998/MMCDPL98010.pdf>

Medi-Cal benefits include enteral nutritional supplemental or replacement formulas when medically diagnosed conditions preclude the full use of regular food (Title 22, California Code of Regulations, Section 5 13 13.3).

Plans must arrange for the provision of human milk for newborns in the following situation: mother is unable to breastfeed due to medical reasons, and the infant cannot tolerate or has medical contra-indications to the use of any formula, including elemental formulas. Plans must establish policies and procedures for ensuring the timely provision of human milk.

New York Medicaid <https://legislation.nysenate.gov/pdf/bills/2017/S4526>

New York Medicaid reimburses the cost for inpatient use when:

- A licensed medical practitioner has issued an order for an infant who is medically or physically unable to receive maternal breast milk or participate in breast feeding or whose mother is medically or physically unable to produce maternal breast milk or participate in breast feeding despite optimal lactation support.
- Such infants must: (I) have a documented birth weight of one thousand five hundred grams or less; or (II) have a congenital or acquired intestinal condition, and is therefore at a high risk for development of necrotizing enterocolitis and/or infection.
- Coverage for donor breast milk shall continue until the infant is at an age of medical adjustment of 34 weeks corrected gestational age and such coverage shall be not less than the reasonable cost of such milk procedure from a certified nonprofit milk bank, plus reasonable processing and handling fees.

Missouri <https://law.justia.com/codes/missouri/2015/title-xii/chapter-208/section-208.141/>

The department of social services shall reimburse a hospital for prescribed medically necessary donor human breast milk provided to a MO HealthNet participant if:

- (1) The participant is an infant under the age of three months;
- (2) The participant is critically ill;

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- (3) The participant is in the neonatal intensive care unit of the hospital;
 - (4) A physician orders the milk for the participant;
 - (5) The department determines that the milk is medically necessary for the participant;
 - (6) The parent or guardian signs and dates an informed consent form indicating the risks and benefits of using banked donor human milk; and
 - (7) The milk is obtained from a donor human milk bank that meets the quality guidelines established by the department.
2. An electronic web-based prior authorization system using the best medical evidence and care and treatment guidelines consistent with national standards shall be used to verify medical need.

Texas Medicaid

<https://hhs.texas.gov/about-hhs/communications-events/news/2017/02/human-donor-milk-new-reimbursement>

Human donor milk may be reimbursed to hospital providers for services rendered to inpatient clients. Hospital providers may receive reimbursement for the donor human milk service separate from the inpatient Diagnosis-Related Group (DRG) payment.

The Texas Medicaid Provider Procedures Manual does not require prior authorization for this service and HHSC urges MCOs to take this into consideration when developing their own policies around human donor milk. Medicaid clinical policy will require use of revenue code 220 (special charges) with procedure code T2101 as an outpatient hospital service using the Centers for Medicare and Medicaid Services (CMS)-1450 (UB-04) claim form with the most appropriate outpatient type of bill (TOB). Procedure code T2101 may be reimbursed for donor human milk as medically necessary for clients who are 6 months of age and younger.

Hospitals must follow clinical recommendations for administering donor human milk to inpatient clients, and must maintain all applicable and appropriate medical necessity documentation in the client's medical record. The Texas Medicaid Provider Procedures Manual will be updated to reflect this new policy on April 1, 2017.

Aetna, 2018 http://www.aetna.com/cpb/medical/data/1_99/0061.html

Infant formulas are only covered if administered via the tube-feeding route and the criteria for coverage of enteral feedings are met. Infant formulas given orally are not covered. In addition, breast milk additive to prevent necrotizing enterocolitis in premature infants is only covered if administered via the tube-feeding route and the criteria for coverage of enteral feedings are met.

Human Donor Breast Milk

Cost estimates from Allen Merritt, MD

Knowing that donor breast milk costs between \$4-\$5 per ounce and assuming that it is used at approximately 120 -150 ml/kg/day and taking mean adjusted weights at 3, 6, and 9 months one can estimate cost and compare it to premie formula. Enfamil Enfacare costs \$102.86 per can that makes around 24 ounces of formula and one can calculate the price. Similac NeoSure, 3 ounce bottles of 24 bottles cost \$182.95 retail. So an ounce for ounce comparison can be made.

Age Range	Donor Breast Milk**	Enfacare	NeoSure	Prolacta
1-3 months (all days inclusive)	\$9720	\$3591	\$3150	\$25920
4-6 months (all days inclusive)	\$12150	\$4614	\$3678	\$30240
7-9 months (all days inclusive)	\$12960	\$5274	\$4203	\$34569
Totals	\$34830**	\$13479	\$11931	\$90729

Infants who solely receive breast milk (whether donor or from their mother) will also need a daily fortifier that costs approximately \$2.40 per day or an additional \$1080 for human milk fortifier.

HERC Staff Summary

Human breast milk is the best source of nutrition for most infants. Among low birth weight infants, donor breast milk is associated with improved morbidity including lower rates of necrotizing enterocolitis and possibly less bronchopulmonary dysplasia, sepsis and retinopathy of prematurity. Formula increases growth rates compared to human milk. Donor human milk is more expensive than formula, but has many health benefits. There is insufficient evidence to support a specific duration of donor breast milk. There may be significant implementation concerns (coordination with WIC, paying for the milk bank, etc).

HERC Staff Recommendations:

1. **Move T2102 Human breast milk processing, storage and distribution only to:**
 - a. Line 2 BIRTH OF INFANT
 - b. Line 11 RESPIRATORY CONDITIONS OF FETUS AND NEWBORN
 - c. Line 16 LOW BIRTH WEIGHT; PREMATURE NEWBORN
 - d. Line 18 FEEDING PROBLEMS IN NEWBORNS
 - e. Line 34 OTHER CONGENITAL ANOMALIES OF MUSCULOSKELETAL SYSTEM
 - i. **Modify Line 34 Title** to ~~OTHER~~ CONGENITAL ANOMALIES OF ~~MUSCULOSKELETAL SYSTEM~~ ABDOMINAL STRUCTURES
 - f. Line 48 CHRONIC RESPIRATORY DISEASE ARISING IN THE NEONATAL PERIOD
 - g. Line 88 NECROTIZING ENTEROCOLITIS IN FETUS OR NEWBORN

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- h. Line 101 CONGENITAL ANOMALIES OF DIGESTIVE SYSTEM AND ABDOMINAL WALL EXCLUDING NECROSIS; CHRONIC INTESTINAL PSEUDO-OBSTRUCTION

2. Adopt a guideline note. Consider one of the options below.

OPTION 1

GUIDELINE NOTE XXX DONOR BREAST MILK FOR HIGH RISK INFANTS

Line 2, 11, 16, 18, 34, 48, 88, 101

Donor breast milk is included on these lines for infants up to 6 months of age (adjusted for gestational age) who are low birth weight (<1500g), have underlying gastrointestinal disease (e.g. gastroschisis), are at risk for bronchopulmonary dysplasia, or have intolerance to multiple formulas AND where maternal breast milk is not available or sufficient to meet the infant's needs, despite lactation support for the mother.

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

OPTION 2

GUIDELINE NOTE XXX DONOR BREAST MILK FOR VERY LOW BIRTH WEIGHT INFANTS

Line 16

Donor breast milk is included on this line for infants up to 3 months of age (adjusted for gestational age) who were low birth weight (<1500g), and where maternal breast milk is not available or sufficient to meet the infants' needs, despite lactation support for the mother.

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

Testicular Hypofunction/Low Testosterone

Question: Should physiologic testicular hypofunction be moved to a lower priority position on the Prioritized List?

Question source: Walter Hardin, Medical Director Tuality Health Alliance

Issue: As many men age, their testosterone levels decrease. Many of these men receive treatment with exogenous testosterone, but there is controversy about the safety and efficacy of testosterone supplementation in men without profoundly low testosterone levels. Men with profoundly low testosterone levels have some type of diagnosis such as hypopituitarism, men who are status post orchiectomy, etc. The FDA recently added wording to the drug label requiring men get information on increased risk of cardiovascular events. Many men have vague complaints as they age, such as fatigue or lower muscle strength, or experience erectile dysfunction, all of which are at times treated with testosterone therapy. The presence of low serum testosterone is 9.0% in men aged 45 to 54 years, 16.5% in men aged 55 to 64 years, and 18.3% in men aged 65 to 74 years. Age related hypogonadism (e.g. lower testosterone in the older male population) is not necessarily a disease and may be asymptomatic and / or may be related or associated with many chronic illnesses.

From the American Urological Association: Hypogonadism is defined as biochemically low testosterone levels in the setting of a cluster of symptoms, which may include reduced sexual desire (libido) and activity, decreased spontaneous erections, decreased energy and depressed mood. Men with hypogonadism may also experience reduced muscle mass and strength and increased body fat. Hypogonadism may also contribute to reduced bone mineral density and anemia.

Currently, FFS P&T PA criteria have no limits on testosterone therapy. Review of private payer and other Medicaid programs find most limit testosterone to men with profoundly low levels or special cases such as treatment of gender dysphoria.

Current Prioritized List status

Testicular hypofunction (ICD-10 E29.1) and related diagnoses such as other testicular dysfunction (ICD-10 E29.8) and testicular dysfunction, unspecified (ICD-10 E29.9) are on line 467 GONADAL DYSFUNCTION, MENOPAUSAL MANAGEMENT

Evidence

- 1) **Xu 2013**, Systematic review and meta-analysis of testosterone therapy
<https://bmcmmedicine.biomedcentral.com/track/pdf/10.1186/1741-7015-11-108>
 - a. N=27 trials (2,994 men)
 - i. Only trials last 12+ weeks reporting cardiovascular related events were included
 - b. Testosterone therapy increased the risk of a cardiovascular-related event (odds ratio (OR) 1.54, 95% confidence interval (CI) 1.09 to 2.18).
 - c. The cardiovascular-related event rate was lower in trials funded by the pharmaceutical industry (4% (66/1,651)) than in other trials (8% (114/1,343)). The effect of testosterone therapy varied with source of funding (P-value for interaction 0.03), but not with baseline testosterone level (P-value for interaction 0.70). In trials not funded by the pharmaceutical industry the risk of a cardiovascular-related event on testosterone

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therapy was greater (OR 2.06, 95% CI 1.34 to 3.17) than in pharmaceutical industry funded trials (OR 0.89, 95% CI 0.50 to 1.60).

- a. Conclusions: The effects of testosterone on cardiovascular-related events varied with source of funding. Nevertheless, overall and particularly in trials not funded by the pharmaceutical industry, exogenous testosterone increased the risk of cardiovascular-related events, with corresponding implications for the use of testosterone therapy.
- 2) **Elliott 2017**, Systematic review and meta-analysis of testosterone therapy
<https://bmjopen.bmj.com/content/bmjopen/7/11/e015284.full.pdf>
- a. N=87 RCTs and 51 non randomized studies
 - i. Most were at high or unclear risk of bias, with short duration of treatment and follow
 - b. When compared as a class against placebo, testosterone replacement therapy (TRT) improved quality of life (standardized mean difference (SMD) -0.26, 95% CI -0.41 to -0.11), libido (SMD 0.33, 95% CI 0.16 to 0.50), depression (SMD -0.23, 95% CI -0.44 to -0.01) and erectile function (SMD 0.25, 95% CI 0.10 to 0.41). Most individual TRTs were significantly better than placebo at improving libido (6/10). Only one TRT was better than placebo at improving quality of life, and no individual TRTs improved depression or erectile function. There was no increased risk of adverse events, with the exception of withdrawals due to adverse events with the use of some TRTs.
 - c. Conclusion Despite a class effect of improving quality of life, depression, erectile function and libido, major improvements were not observed with the use of any individual product. We observed no statistically significant increase in the risk of adverse events; however, longer term high- quality trials are needed to fully assess the risk of harm.
- 3) **Alexander 2017**, Systematic review and meta-analysis of risks of testosterone therapy
[https://www.amjmed.com/article/S0002-9343\(16\)31024-5/pdf](https://www.amjmed.com/article/S0002-9343(16)31024-5/pdf)
- a. N=39 RCTs, 10 observational studies
 - b. In meta-analysis of data from 30 RCTs, compared with placebo, exogenous testosterone treatment did not show any significant increase in risk of myocardial infarction (odds ratio [OR] 0.87; 95% CI, 0.39-1.93; 16 RCTs), stroke (OR 2.17; 95% CI, 0.63-7.54; 9 RCTs), or mortality (OR 0.88; 95% CI, 0.55-1.41; 20 RCTs).
 - c. CONCLUSIONS: We did not find any significant association between exogenous testosterone treatment and myocardial infarction, stroke, or mortality in randomized controlled trials. The very low quality of the evidence precludes definitive conclusion on the cardiovascular effects of testosterone.
- 4) **Fernandez-Balsells 2010**, Systematic review and meta-analysis of risks of testosterone therapy
<https://academic.oup.com/jcem/article/95/6/2560/2597959>
- d. N=51 studies
 - i. Low to medium methodological quality
 - ii. Follow up 3 months to 3 years.
 - e. Testosterone treatment was associated with a significant increase in hemoglobin [weighted mean difference (WMD), 0.80 g/dl;95%confidence interval (CI), 0.45 to 1.14] and hematocrit (WMD, 3.18%; 95% CI, 1.35 to 5.01), and a decrease in high-density lipoprotein cholesterol (WMD, -0.49 mg/dl; 95% CI, -0.85 to -0.13). There was no significant effect on mortality, prostate, or cardiovascular outcomes.
 - f. Conclusions: The adverse effects of testosterone therapy include an increase in hemoglobin and hematocrit and a small decrease in high-density lipoprotein cholesterol. These findings are of unknown clinical significance. Current evidence about the safety of

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testosterone treatment in men in terms of patient-important outcomes is of low quality and is hampered by the brief study follow-up.

Expert groups

1) **American Urological Association 2015:**

a. The American Urological Association (AUA) concludes that there is conflicting evidence about the impact of testosterone therapy on cardiovascular risks. Definitive studies have not been performed. The FDA drug safety communication cautions that benefits and risks of testosterone products for low testosterone due to aging are not clearly established. The potential adverse effects of testosterone therapy should be discussed prior to treatment. These include acne, breast swelling or tenderness, increased red blood cell count, swelling of the feet or ankles, reduced testicular size and infertility. Current evidence does not provide any definitive answers regarding the risks of testosterone therapy on prostate cancer and cardiovascular disease, and patients should be so informed.

2) **Endocrine Society** (Bhasin 2018) <https://academic.oup.com/jcem/article/103/5/1715/4939465>

- a. We recommend making a diagnosis of hypogonadism only in men with symptoms and signs consistent with testosterone (T) deficiency and unequivocally and consistently low serum T concentrations. We recommend measuring fasting morning total T concentrations using an accurate and reliable assay as the initial diagnostic test. We recommend confirming the diagnosis by repeating the measurement of morning fasting total T concentrations.
- b. We recommend T therapy for men with symptomatic T deficiency to induce and maintain secondary sex characteristics and correct symptoms of hypogonadism after discussing the potential benefits and risks of therapy and of monitoring therapy and involving the patient in decision making.
- c. We recommend against starting T therapy in patients who are planning fertility in the near term or have any of the following conditions: breast or prostate cancer, a palpable prostate nodule or induration, prostate-specific antigen level >4 ng/mL, prostate-specific antigen >3 ng/mL in men at increased risk of prostate cancer (e.g., African Americans and men with a first-degree relative with diagnosed prostate cancer) without further urological evaluation, elevated hematocrit, untreated severe obstructive sleep apnea, severe lower urinary tract symptoms, uncontrolled heart failure, myocardial infarction or stroke within the last 6 months, or thrombophilia.

Other policies

1) **CVS Caremark**, depo-testosterone

- a. Depo-Testosterone (testosterone cypionate injection) will be covered with prior authorization when the following criteria are met:
- The drug is being prescribed for a male patient with congenital or acquired primary hypogonadism (i.e., testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchidectomy) OR
 - The drug is being prescribed for a male patient with congenital or acquired hypogonadotropic hypogonadism (i.e., gonadotropin or luteinizing hormone-releasing hormone [LHRH] deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation)
- AND

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- i. The patient has NOT received testosterone medication in the last 12 months AND
- ii. The patient had or currently has at least TWO confirmed low testosterone levels according to current practice guidelines or your standard lab reference values OR
- i. The drug is being prescribed for a male patient with congenital or acquired primary hypogonadism (i.e., testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchidectomy) OR
- ii. The drug is being prescribed for a male patient with congenital or acquired hypogonadotropic hypogonadism (i.e., gonadotropin or luteinizing hormone-releasing hormone [LHRH] deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation) AND
- i. The patient has received testosterone medication in the last 12 months AND
- ii. The patient had or currently has at least ONE confirmed low testosterone level according to current practice guidelines or your standard lab reference values

Other Medicaid policies

1) Washington Medicaid

- a. Testosterone replacement therapy (TRT) may be considered medically necessary when used for the following conditions:
 - i. Primary Hypogonadism (congenital or acquired)
 - ii. Hypogonadotropic Hypogonadism (congenital or acquired)
 - iii. HIV-associated weight loss
 - iv. Chronic, high-dose glucocorticoid-therapy
 - v. Men with osteoporosis or young men with low trauma fractures
 - vi. Delayed Puberty
 - vii. Metastatic Breast Cancer
 - viii. Transgender Health
- b. *Testosterone Replacement Therapy (TRT) may be considered medically necessary for the treatment of hypogonadism when the patient meets criteria 1–3 of the INCLUSION CRITERIA and none of the EXCLUSION CRITERIA*
 - i. *Inclusion criteria:*
 - 1. Patient is male, 18 years of age or older; AND
 - 2. Patient has had TWO morning (between 8 a.m. to 10 a.m.) tests (at least 1 week apart) at baseline demonstrating low testosterone levels as defined by the following criteria:
 - a. Total serum testosterone level less than 300ng/dL (10.4nmol/L); OR
 - b. Total serum testosterone level less than 350ng/dL (12.1nmol/L) AND free serum testosterone level less than 50pg/mL (or 0.174nmol/L)
 - c. Second morning test should follow excluding reversible illnesses, drugs, and nutritional deficiencies. Providers should also include LH and FSH draws to guide diagnosis as primary or secondary hypogonadism; AND
 - 3. Patient has received ONE of the following diagnoses:

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- a. Primary Hypogonadism (congenital or acquired): as defined as testicular failure due to such conditions as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter's syndrome, chemotherapy, trauma, or toxic damage from alcohol or heavy metals; OR
 - b. Hypogonadotropic Hypogonadism (congenital or acquired): as defined by idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma or radiation; OR
 - c. HIV-associated weight loss (defined as <90% of ideal body weight or weight loss of >10% in the last 6 months); OR
 - d. Chronic, high-dose glucocorticoid-therapy (defined as more than 5mg/day of prednisone or equivalent daily for greater than two (2) weeks; OR
 - e. Men with osteoporosis or young men with low trauma fractures
- c. Exclusion criteria:
- i. Patient has ANY of the following contraindications:
 1. Breast cancer or known or suspected prostate cancer
 2. Elevated hematocrit (>50%)
 3. Untreated severe obstructive sleep apnea
 4. Severe lower urinary tract symptoms
 5. Uncontrolled or poorly-controlled heart failure
 - ii. Patient has experienced a major cardiovascular event (such as a myocardial infraction, stroke, acute coronary syndrome) in the past six months
 - iii. Patient has uncontrolled or poorly-controlled benign prostate hyperplasia or is at a higher risk of prostate cancer, such as elevation of PSA after initiating TRT
 - iv. Patient is intending on using testosterone for the indications of delayed puberty, metastatic breast cancer, or for transgender health care (such as hormone replacement therapy)

2) Indiana Medicaid

- a. Covers testosterone for most cases of low testosterone levels

3) Iowa Medicaid

- a. Patient is male and 18 years of age or older (or 12 years of age and older for testosterone cypionate); and
- b. Patient has two (2) morning pre-treatment testosterone levels below the lower limit of the normal testosterone reference range of the individual laboratory used (attach results); and Patient has primary hypogonadism or hypogonadotropic hypogonadism (further defined below)
 - i. Primary hypogonadism (congenital or acquired) caused by testicular failure due to one of the following: cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome, orchietomy, Klinefelter's syndrome, chemotherapy, toxic damage from alcohol or heavy metals
Hypogonadotropic hypogonadism: idiopathic gonadotropin or luteinizing hormone-releasing (LHRH) deficiency, pituitary-hypothalamic injury from tumors, trauma, or radiation
- c. Patient does not have:
 - i. Breast or prostate cancer
 - ii. Palpable prostate nodule or prostate-specific antigen (PSA) > 4ng/mL

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- iii. Hematocrit > 50%
- iv. Untreated severe obstructive sleep apnea
- v. Severe lower urinary tract symptoms
- vi. Uncontrolled or poorly controlled heart failure

P&T feedback:

Testosterone medications are low cost and are therefore low priority for PA controls.

COO feedback:

Some CCOs indicated they would PA testosterone medications, other indicated that when they had PA's in the past, they approved most and it was not worth the pharmacy team time/effort.

VbBS Issue Summaries 10-4-2018

Testicular Hypofunction/Low Testosterone

HERC staff summary:

Testosterone therapy for physiologic low testosterone levels have equivocal evidence of effectiveness and evidence of cardiovascular harms, particularly in non-industry sponsored studies. These medications are of low cost. Many private insurers and other state Medicaid programs have restrictions on testosterone therapy for physiologic low testosterone levels.

HERC staff recommendations

- 1) Add a new guideline to line 467 GONADAL DYSFUNCTION, MENOPAUSAL MANAGEMENT as shown below

GUIDELINE NOTE XXX TESTOSTERONE REPLACEMENT FOR TESTICULAR HYPOFUNCTION

Line 467

Testosterone replacement therapy is included on this line for testicular hypofunction or dysfunction only when all of the following inclusion criteria are met and none of the exclusion criteria apply:

Inclusion criteria:

- 1) The patient is a male 18 years of age or older; AND
- 2) The patient has had TWO morning (between 8 a.m. to 10 a.m.) tests (at least 1 week apart) at baseline demonstrating low testosterone levels as defined by the following criteria:
 - a. Total serum testosterone level less than 300ng/dL (10.4nmol/L); OR
 - b. Total serum testosterone level less than 350ng/dL (12.1nmol/L) AND free serum testosterone level less than 50pg/mL (or 0.174nmol/L); AND
- 3) Patient has received ONE of the following diagnoses:
 - a. Primary Hypogonadism (congenital or acquired): as defined as testicular failure due to such conditions as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchidectomy, Klinefelter's syndrome, chemotherapy, trauma, or toxic damage from alcohol or heavy metals; OR
 - b. Hypogonadotropic Hypogonadism (congenital or acquired): as defined by idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma or radiation

Exclusion criteria:

- 1) Patient has ANY of the following contraindications:
 - a. Breast cancer or known or suspected prostate cancer
 - b. Elevated hematocrit (>50%)
 - c. Untreated severe obstructive sleep apnea
 - d. Severe lower urinary tract symptoms
 - e. Uncontrolled or poorly-controlled heart failure
- 2) Patient has experienced a major cardiovascular event (such as a myocardial infraction, stroke, acute coronary syndrome) in the past six months
- 3) Patient has uncontrolled or poorly-controlled benign prostate hyperplasia or is at a higher risk of prostate cancer, such as elevation of PSA after initiating testosterone replacement therapy

This guideline does not apply to testosterone replacement therapy for HIV-associated weight loss, delayed puberty, treatment of metastatic breast cancer, or transgender health.

iStent for Glaucoma with Cataract Removal

Question: Should iStent® (CPT 0191T) be added to the Prioritized List for treatment of glaucoma?

Question source: Holly Jo Hodges, CCO medical director

Issue: The CPT code used for the iStent is current not on the Prioritized List or any other list of codes at HSD. This type of CPT code is normally temporary, but 0191T has been in use for over 5 years. Dr. Hodges has seen requests for this procedure, and would like to have it reviewed for efficacy. CPT 0191T description is "Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork."

Open-angle glaucoma is a chronic condition associated with elevated intraocular pressure and leads to progressive damage to the optic nerve. Treatment is usually eye drops containing drugs that either reduce the production of aqueous humor or increase its drainage. Surgical procedures such as trabeculectomy, drainage tubes, deep sclerectomy, viscocanalostomy or laser trabeculoplasty may also be used.

iStent is a small device designed to fit into Schlemm's canal to facilitate aqueous drainage from the anterior chamber. It is considered a type of trabecular stent bypass surgery. As approved by the FDA on June 25, 2012, the iStent "...is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure (IOP) in adult patients with mild or moderate open-angle glaucoma currently treated with ocular hypotensive medication." iStent is not FDA approved for use outside of cataract surgery.

Evidence

- 1) **Zhang 2016**, Cochrane review of combined surgery for cataracts and glaucoma vs cataract surgery alone
<https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD008671.pub3/epdf/full>
 - a. N=9 RCTs (655 patients, 657 eyes)
 - i. 3 studies used iStent implants
 - ii. Follow up 12-30 months
 - iii. Overall quality of evidence was low
 - b. All of these studies found a statistically significant greater decrease in mean IOP postoperatively in the combined surgery group compared with cataract surgery alone; the mean difference (MD) was -1.62 mmHg (95% confidence interval (CI) -2.61 to -0.64; 489 eyes) among six studies with data at one year follow-up
 - c. two studies found the mean number of medications used postoperatively at one year was about one less in the combined surgery group than the cataract surgery alone group (MD -0.69, 95% CI -1.28 to -0.10; 301 eyes)
 - d. participants in the combined surgery group were about 50% less likely compared with the cataract surgery alone group to use one or more IOP-lowering medications one year postoperatively (risk ratio (RR) 0.47, 95% CI 0.28 to 0.80; 453 eyes).
 - e. six studies reported no significant differences in visual acuity and two studies reported no significant differences in visual fields between the two intervention groups postoperatively (data not analyzable).
 - f. The effect of combined surgery versus cataract surgery alone on the need for reoperation to control IOP at one year was uncertain (RR 1.13, 95% CI 0.15 to 8.25; 382

iStent for Glaucoma with Cataract Removal

eyes). Also uncertain was whether eyes in the combined surgery group required more interventions for surgical complications than those in the cataract surgery alone group (RR 1.06, 95% CI 0.34 to 3.35; 382 eyes). No study reported any vision-related quality of life data or cost outcome.

- g. Complications were reported at 12 months (two studies), 12 to 18 months (one study), and two years (four studies) after surgery. Due to the small number of events reported across studies and treatment groups, the difference between groups was uncertain for all reported adverse events.
 - h. Authors' conclusions—There is low quality evidence that combined cataract and glaucoma surgery may result in better IOP control at one year compared with cataract surgery alone. The evidence was uncertain in terms of complications from the surgeries. Additional high-quality RCTs measuring clinically meaningful and patient-important outcomes are required to provide evidence to support treatment recommendations.
- 2) **NICE 2017**, Trabecular stent bypass microsurgery for open angle glaucoma
- a. Current evidence on the safety of trabecular stent bypass microsurgery for open-angle glaucoma raises no major safety concerns. Evidence on efficacy is adequate in quality and quantity.
 - b. N=1 systematic review and meta-analysis of 2,143 patients from 32 studies comparing stent insertion combined with phacoemulsification against phacoemulsification alone in patients with glaucoma and cataract, there was a statistically significant decrease in intraocular pressure (IOP) from baseline in the combined group compared against the phacoemulsification-only group at a follow-up of 12 to 58 months (standardised mean deviation [SMD] -0.46, 95% confidence interval [CI] -0.87 to -0.06, 4 randomised controlled trials [RCTs], I²=47%, p=0.128). There was also a statistically significant reduction in the number of topical glaucoma medications used after the procedure in the combined group compared against the phacoemulsification-only group (SMD -0.65, 95% CI -1.18 to -0.12, 3 studies; I²=58%, p=0.092).
 - a. In a systematic review and meta-analysis of 248 patients (5 studies) with mild to moderate glaucoma treated by stent insertion alone, there was a statistically significant reduction in IOP from baseline after implantation of 1 stent at a follow-up of 6 to 18 months (SMD -1.95, 95% CI -3.41 to -0.49, 3 studies; I²=96%, p=0.000 (sic)) and of 3 stents at 6-month follow-up (SMD -4.26, 95% CI -5.18 to -3.33, 1 study). But there was not a statistically significant reduction in IOP from baseline after implantation of 2 stents at 6 to 12 months (SMD -3.08, 95% CI -6.90 to 0.74, 2 studies; I²=98%, p=0.000 (sic)).
 - a. Safety
 - a. No differences were seen between groups (combined procedures vs phacoemulsification-only group) in severe loss of corrected distance visual acuity, macular edema, vitreomacular traction, or need for secondary procedures
 - b. Studies reported small numbers of patients with optic disc hemorrhage, hyphema, subconjunctival hemorrhage, hypotony, intraocular inflammation, cataract progression, iris synechiae, posterior capsule opacification, iris atrophy, uveitis, dry eye with combined procedures
 - c. In the systematic review and meta-analysis of 2,143 patients, stent malposition was reported in 2 to 18% of patients in 6 studies, stent occlusion was reported in 4 to 15% of patients in 4 studies and blockage of the opening of the stent lumen was reported in 15% of patients in 1 study.

iStent for Glaucoma with Cataract Removal

- d. In the systematic review and meta-analysis of 248 patients, a need to reposition the stent was reported in 2% of patients in 1 study, stent not visible upon gonioscopy was reported in 13% of patients in 1 study, and stent replacement was reported in 5% of patients in 1 study.

HERC staff summary:

iStent appears to be effective at reducing intraocular pressure and reducing glaucoma medication amount. It appears to be a safe procedure. Trusted sources such as NICE recommend utilization. This procedure is only FDA approved when done in conjunction with cataract surgery, and CMS rules require that these services be bundled together; therefore, there should be minimal cost increase with coverage.

HERC staff recommendation:

- 1) Add CPT 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach, into the trabecular meshwork) to line 139 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE

Humeral Osteotomy for Recurrent Shoulder Dislocation

Question: should procedure codes for proximal humeral osteotomy be paired with recurrent shoulder dislocation?

Question source: HSD claims reconsideration

Issue: When recurrent shoulder dislocation results in proximal humeral bone loss, humeral osteotomy is one procedure which is standard to minimize risk of future dislocation and best restore function to the shoulder. These procedures can be rotational osteotomy of the proximal humerus or partial or total humeral head arthroplasty, depending on the clinical situation.

Rotational osteotomy of the proximal humerus is also an option that has been described to deal with large humeral head defects in younger patients to delay the need for prosthetic replacement. A standard deltopectoral approach is utilized to expose the proximal humerus and an oscillating saw is then used to complete a transverse osteotomy through the surgical neck. The humeral shaft is rotated externally to 5–10 degrees more than the position of instability measured on physical exam and the osteotomy is then secured using a rigid fixation implant such as a blade plate. Imbrication of the anterior capsule and subscapularis tendon is then done in conjunction with the bony procedure.

The review by Mascarenhas et al (2014)

(<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4124833/pdf/AORTH2014-640952.pdf>) includes summary of a review by Weber et al. of 180 rotational subcapital humeral osteotomies with shortening of the subscapularis tendon and capsule for recurrent shoulder instability. The overall redislocation rate was 5.7% and the rate of nontraumatic redislocation was 1.1%. Limitation of motion of more than 10 degrees was present in only 3.9% of patients. The average loss of external rotation was less than 5 degrees without noticeable diminution of power or function in most patients. The results were good to excellent in 90% of cases as determined by the Rowe score.

Similar procedures are paired with other joint recurrent dislocations on the List.

Current Prioritized List status

ICD10 M24.41 (Recurrent dislocation, shoulder) is on line 359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS

CPT 24400 (Osteotomy, humerus, with or without internal fixation) is on lines 441 MALUNION AND NONUNION OF FRACTURE

CPT 22420 (Osteoplasty, humerus (eg, shortening or lengthening) (excluding 64876)) is on lines 184,255,400,556

HERC staff recommendation:

- 1) Add CPT 24400 (Osteotomy, humerus, with or without internal fixation) and 22420 (Osteoplasty, humerus (eg, shortening or lengthening) to line 359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS

Section 3.0

Coverage Guidances

Single Fraction Radiotherapy for Palliation of Bone Metastases

Draft Coverage Guidance for HERC Consideration

October 4, 2018

Background

- Cancer that has metastasized to the bones can rarely be cured, but can be treated to slow the cancer's growth and reduce pain
- Effects of bone metastases on patients' quality of life
 - Severe pain
 - Impaired mobility
 - Pathologic fractures
 - Spinal cord compression
 - Bone marrow aplasia
 - Hypercalcemia

Background

- Prostate and breast cancers cause up to 70% of bone metastases because of the high incidence and long clinical course of these cancers
- Treatment decisions for bone metastases based on
 - Type of index cancer
 - Whether bone metastases are localized or widespread
 - Evidence of extraskkeletal metastases
 - Treatment history
 - Symptoms
 - Patient's general state of health

Background

- Treatments for bone metastases
 - Bisphosphonates
 - Denosumab
 - Ablation
 - Surgery
 - Radiotherapy
- Radiotherapy is an effective treatment for bone metastases
 - Pain response rate is more than 60%

Background

- Single fraction or multiple fraction radiotherapy can be used as treatment for painful bone metastases
 - More commonly used for uncomplicated bone metastases, (i.e., not at risk for imminent pathologic fracture and not causing neurologic compromise due to spinal cord compression)
- Most common single fraction treatment regimen is 8 Gy
- Common multiple fraction regimens generally deliver 2 Gy to 4 Gy doses with 5 to 10 fractions
 - Total radiation is less with single fraction compared to multiple fraction

Scope Statement

- Populations
 - Patients receiving palliative radiotherapy for painful bone metastases
- Interventions
 - Single fraction radiotherapy
- Comparators
 - Multiple fraction radiotherapy

Scope Statement

- Critical Outcomes
 - Pain
 - Morbidity associated with bone metastases (e.g., pathologic fractures, spinal cord compression)
 - Quality of life
- Important Outcomes
 - Need for retreatment
 - Harms

Evidence Summary

- For the treatment of uncomplicated painful bone metastases, single fraction and multiple fraction treatment regimens result in similar outcomes with respect to pain relief, acute toxicity, pathologic fractures, and spinal cord compression
- Patients treated with single fraction radiotherapy are more likely to require retreatment
- 1 large RCT found no significant differences in quality of life outcomes comparing single fraction and multiple fraction regimens

Payer Policies

- Washington State Medicaid Program
 - No Washington Medicaid coverage policy was found for single fraction radiotherapy for bone metastases
- Medicare
 - No National Coverage Determinations or Local Coverage Determinations were identified for single fraction radiotherapy for bone metastases
- Private payers
 - Aetna, Cigna, Moda, and Regence: no coverage policies for single fraction radiotherapy for bone metastases were found

Guidelines

- 4 guidelines were identified with recommendations on single fraction radiation for bone metastases:
 - American Society for Radiation Oncology (ASTRO) guidelines on palliative radiotherapy for bone metastases
 - American College of Radiology ACR Appropriateness Criteria® on non-spine bone metastases
 - American College of Chest Physicians guidelines on symptom management for lung cancer patients
 - European Association of Urology guidelines on pain management and palliative care for patients with urologic cancers

Guidelines

- All 4 of these guidelines state
 - Single fraction radiotherapy is equivalent to multiple fraction radiotherapy in relieving pain
 - Retreatment rates are higher for single fraction versus multiple fraction radiotherapy
 - Single fraction radiotherapy is more convenient for patients
- Quality measure from ASTRO:
 - Percentage of patients, regardless of age, with a diagnosis of bone metastases and no history of previous radiation who receive external beam radiotherapy with any of the recommended fractionation schemes (i.e., 30Gy/10fxns, 24Gy/6fxns, 20Gy/5fxns, 8Gy/1fxn)

Discussion

Values and Preferences

Many patients with painful bone metastases (and their caregivers) would highly value the decreased burden of time, travel, and cost that is associated with single fraction radiotherapy. Preference for single dose treatment might be highest for patients with limited life expectancy.

Discussion

Resource Allocation

Single fraction radiotherapy is less costly than multiple fraction treatment. In addition to direct savings in procedure costs, there are potential savings in travel costs (and other costs borne by patients and families). These savings are moderated somewhat by the increased need for retreatment after single dose therapy.

Single fraction radiotherapy is nonetheless an expensive intervention that is a challenge to cover under prevailing hospice care payment methodology.

Discussion

Other Considerations

Professional society guidelines emphasize the comparable efficacy and side effects of single fraction compared to multiple fraction radiotherapy.

European Association of Urology guidelines state that single fraction radiotherapy “remains the treatment of choice for alleviating bone pain.” This treatment option might be underutilized in the U.S.

Discussion

Balance of Benefits and Harms

Single fraction radiotherapy has efficacy comparable to multiple fraction treatment, with no significant differences noted in pain relief, quality of life measurements, or morbidity associated with uncomplicated bone metastases. Rates of acute radiation toxicity show no significant differences. Single fraction radiotherapy is associated with a higher need for retreatment (although retreatment with another single fraction is not inferior to retreatment with multiple fraction therapy).

Discussion

Rationale

Our recommendation for coverage of single fraction radiotherapy is based on a substantial body of evidence demonstrating comparable results to multiple fraction treatment. Single dose treatment is less costly and more convenient, making it the preferred option for many patients, and most valued by patients with limited life expectancy. Our recommendation is strong, and utilization of single fraction radiotherapy for painful bone metastases is encouraged.

Draft Coverage Guidance

Single fraction radiotherapy for palliation of bone metastases is recommended for coverage (*strong recommendation*). Single fraction radiotherapy should be given strong consideration for use over multiple fraction radiotherapy when clinically appropriate (e.g., not contraindicated by risk of imminent pathologic fracture, worsening neurologic compromise or radioresistant histologies such as sarcoma, melanoma, and renal cell carcinoma).

Health Evidence Review Commission (HERC)

Coverage Guidance:

Single Fraction Radiotherapy for Palliation of Bone Metastases

DRAFT for HERC meeting 10/4/2018

HERC Coverage Guidance

Single fraction radiotherapy for palliation of bone metastases is recommended for coverage (*strong recommendation*). Single fraction radiotherapy should be given strong consideration for use over multiple fraction radiotherapy when clinically appropriate (e.g., not contraindicated by risk of imminent pathologic fracture, worsening neurologic compromise or radioresistant histologies such as sarcoma, melanoma, and renal cell carcinoma).

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

Rationales for each recommendation appear below in the GRADE table.

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Rationale for development of coverage guidances and multisector intervention reports

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as plan administrators seek to improve patient 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 clinical interventions and modes of care, evidence is evaluated using an adaptation of the 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 may be dependent on the environment in which the intervention is implemented.

GRADE-Informed Framework

HERC develops recommendations by using the concepts of the Grading of Recommendations, Assessment, Development, and Evaluation (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 makes an assessment of 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, estimated resource allocation, values and preferences, and other considerations are assessments of HERC.

Should single fraction radiotherapy be recommended for coverage for painful bone metastases?

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>	Resource Allocation	Values and Preferences	Other Considerations
Pain <i>(Critical outcome)</i>	Overall response 61% for single fraction vs. 62% for multiple fraction ARD = 1% NNT = 100 OR 0.98 (95% CI 0.95 to 1.01) ●●●● (High confidence, based on 26 RCTs, n = 6,099)	Single fraction radiotherapy is less costly than multiple fraction treatment. In addition to direct savings in procedure costs, there are	Many patients with painful bone metastases (and their caregivers) would highly value the decreased burden of time,	Professional society guidelines emphasize the comparable efficacy and side effects of single fraction compared to

Should single fraction radiotherapy be recommended for coverage for painful bone metastases?

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource Allocation	Values and Preferences	Other Considerations
Morbidity associated with bone metastases <i>(Critical outcome)</i>	<p>Pathologic fracture occurred in 3.6% of single fraction patients vs. 3.0% of multiple fraction patients ARD = 0.6% NNH = 166 OR 1.21 (95% CI 0.76 to 1.95) ●●●○ (Moderate confidence, based on 12 RCTs, n = 4,437)</p> <p>Spinal cord compression occurred in 2.8% of single fraction patients vs. 1.9% of multiple fraction patients ARD = 0.9% NNH = 111 OR 1.44 (95% CI 0.9 to 2.3) ●●●○ (Moderate confidence, based on 6 RCTs, n = 2,886)</p>	<p>potential savings in travel costs (and other costs borne by patients and families). These savings are moderated somewhat by the increased need for retreatment after single dose therapy.</p> <p>Single fraction radiotherapy is nonetheless an expensive intervention that is a challenge to cover under prevailing hospice care payment methodology.</p>	<p>travel, and cost that is associated with single fraction radiotherapy. Preference for single dose treatment might be highest for patients with limited life expectancy.</p>	<p>multiple fraction radiotherapy.</p> <p>European Association of Urology guidelines state that single fraction radiotherapy “remains the treatment of choice for alleviating bone pain.” This treatment option might be underutilized in the U.S.</p>
	<p>Quality of life <i>(Critical outcome)</i></p> <p>No significant differences in quality of life ratings at up to 2 years, except for a small temporary decline in physical health domain scores during the first month after treatment for patients receiving multiple fractions (Cohen’s d effect size 0.12 to 0.17) ●●●● (High confidence, based on 1 RCT, n = 1,115)</p>			

Should single fraction radiotherapy be recommended for coverage for painful bone metastases?

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource Allocation	Values and Preferences	Other Considerations
Need for retreatment <i>(Important outcome)</i>	Retreatment rate of 20% for single fraction vs. 8% for multiple fraction ARD = 12% NNH = 8 OR 2.42 (95% CI 1.87 to 3.12) ●●●● (High confidence, based on 16 RCTs, n = 4,950)			
Harms <i>(Important outcome)</i>	No significant differences in rates of acute radiation toxicities ●●●○ (Moderate confidence, based on 26 RCTs, n = 6,099)			

Balance of benefits and harms: Single fraction radiotherapy has efficacy comparable to multiple fraction treatment, with no significant differences noted in pain relief, quality of life measurements, or morbidity associated with uncomplicated bone metastases. Rates of acute radiation toxicity show no significant differences. Single fraction radiotherapy is associated with a higher need for retreatment (although retreatment with another single fraction is not inferior to retreatment with multiple fraction therapy).

Rationale: Our recommendation for coverage of single fraction radiotherapy is based on a substantial body of evidence demonstrating comparable results to multiple fraction treatment. Single dose treatment is less costly and more convenient, making it the preferred option for many patients, and most valued by patients with limited life expectancy. Our recommendation is strong, and utilization of single fraction radiotherapy for painful bone metastases is encouraged.

Recommendation: Single fraction radiotherapy for palliation of bone metastases is recommended for coverage (strong recommendation). Single fraction radiotherapy should be given strong consideration for use over multiple fraction radiotherapy when clinically appropriate (e.g., not contraindicated by risk of imminent pathologic fracture, worsening neurologic compromise or radioresistant histologies such as sarcoma, melanoma and renal cell carcinoma).

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

Background

When cancer has metastasized to the bones, the cancer can rarely be cured, but often can be treated to slow its growth (Macedo et al., 2017) and reduce pain. Bone metastases can have important effects on a patient's quality of life and are characterized by severe pain, impaired mobility, pathologic fractures, spinal cord compression, bone marrow aplasia, and hypercalcemia (Macedo et al., 2017). Prostate and breast cancers cause up to 70% of bone metastases because of the high incidence and relatively long clinical course of these cancers (Macedo et al., 2017).

Treatment decisions for bone metastases depend on patient and cancer characteristics, such as the type of index cancer, whether bone metastases are localized or widespread, evidence of extraskeletal metastases, treatment history, symptoms, and the patient's general state of health (Macedo et al., 2017). Treatments for bone metastases include bisphosphonates, denosumab, ablation, surgery, and radiotherapy (Macedo et al., 2017). Radiotherapy is an effective treatment for patients with painful bone metastases: the pain response rate is more than 60% (Westhoff et al., 2016).

Indications

Single fraction or multiple fraction radiotherapy is used as a palliative treatment for patients with painful bone metastases. Uncomplicated bone metastases (i.e., not at risk for imminent pathologic fracture and not causing neurologic compromise due to spinal cord compression) can often be treated effectively with radiotherapy (Rich et al., 2018). When radiotherapy is indicated for the treatment of uncomplicated painful bone metastases, the most common single fraction treatment regimen is 8 Gy; common multiple fraction regimens generally deliver 20 to 30 Gy in five to ten fractions.

Technology Description

Single fraction radiotherapy involves one application of external radiation treatment, and multiple fraction radiotherapy involves multiple applications of external radiation treatment over time. Multiple fraction radiotherapy is generally at lower doses than single fraction radiotherapy, although the total radiation dose is higher with multiple fraction versus single fraction radiotherapy.

Evidence Review

Rich et al., 2018

Rich et al. (2018) published a recent fair-quality systematic review and meta-analysis of 29 randomized controlled trials (RCTs) comparing single and multiple fraction radiotherapy regimens for the treatment of uncomplicated painful bone metastases. This article updated a previous systematic review published in 2012 with five additional studies. Studies involving complicated bone metastases and those that used nonconventional radiotherapy modalities were excluded. The authors noted that the majority of patients in the included studies had breast or prostate cancer. Most studies compared a single treatment of 8 Gy to 30 Gy in 10 fractions, or 20 Gy in five fractions. For trials with three arms (i.e., single fraction compared to different multiple fractionation regimens), each comparison to single fraction was considered separately. The primary outcomes of interest for this review were complete response rate and overall response rate (as defined in the individual trials), and secondary outcomes included retreatment rates, pathologic fracture rates, spinal cord compression rates, and acute toxicities. Overall response was commonly defined as a two-point improvement in pain scores; complete

response was commonly defined as complete relief of pain at the treated site. The main limitation of this review is the absence of risk of bias assessments for the included studies.

In the intention-to-treat analysis for the primary outcome of overall response rate, 26 trials with more than 6,000 participants contributed to the meta-analysis. The meta-analytic odds ratio for overall response was not statistically significantly different between the single fraction and multiple fraction arms (61% for single fraction vs. 62% for multiple fraction, OR 0.98, 95% CI 0.95 to 1.01, $p = 0.25$). Similarly, in the 21 trials with more than 5,000 participants that contributed to the meta-analysis for complete response rate, there were no statistically significant differences between the two arms (23% for single fraction vs. 24% for multiple fraction, OR 0.97, 95% CI 0.89 to 1.06, $p = 0.55$).

For the secondary outcome of retreatment, 16 trials with approximately 5,000 patients showed that retreatment rates were statistically significantly greater in the single fraction arm compared to the multiple fraction arm (20% vs. 8%, OR 2.42, 95% CI 1.87 to 3.12, $p < 0.01$). For the 12 studies reporting on pathologic fractures ($n = 4,437$), there were no statistically significant differences between the two arms (3.6% for single fraction vs. 3.0% for multiple fractions, OR 1.21, 95% CI 0.76 to 1.95, $p = 0.08$). Similarly, for six studies reporting on spinal cord compression ($n = 2,886$), there were no statistically significant differences between the two arms (2.8% for single fraction vs. 1.9% for multiple fractions, OR 1.44, 95% CI 0.90 to 2.3, $p = 0.13$). The authors noted that there were no significant differences between the arms in the rates of acute toxicity, but cautioned that the applicable data were not collected using standardized definitions.

The authors observed that because patients with breast and prostate cancer and longer life expectancy were included in trials with longer-term follow-up, the results are applicable to patients with more favorable prognoses. In the two included trials that followed patients to 26 and 52 weeks, the durability of pain relief was similar between the single fraction and multiple fraction regimens. The authors noted that although some clinicians have expressed concern that single fraction treatment to spinal metastases could result in greater toxicity, such a selected patient population has not been prospectively studied, and the extant data does not corroborate those concerns.

The authors concluded that, consistent with previous systematic reviews on this subject, single fraction regimens produce response rates similar to multiple fraction regimens without an increase in acute toxicity, pathologic fractures, or spinal cord compression, but that patients who received single fraction treatments are more likely to require retreatment.

Chow et al., 2017

The Chow et al. (2017) fair-quality systematic review analyzed studies that compared single fraction regimens with differing doses. The authors did not perform a meta-analysis and noted that the small number of studies that used single fraction doses other than 8 Gy mean that the results must be interpreted cautiously. Only three studies directly compared single fraction regimens using differing doses. In the studies that made direct comparisons, 8 Gy single fraction regimens performed better than 4 Gy or 6 Gy single fraction regimens with respect to response rates and need for retreatment. The authors concluded that 8 Gy should be the standard dose for most single fraction regimens for painful bone metastases.

Westhoff et al., 2016

Westhoff et al. (2016) analyzed long-term quality of life outcomes derived from the Dutch Bone Metastasis Study, an RCT that compared 8 Gy single fraction radiotherapy to six fractions of 4 Gy in 1,157 patients with painful bone metastases between 1996 and 1998. Most patients in this trial had breast, prostate, or lung cancer. Participants completed quality of life questionnaires weekly for 13 weeks after treatment and then monthly for up to two years. The questionnaires were the Rotterdam Symptom Checklist, three questions on side effects of radiation therapy, and two items taken from the European Organisation for Research and Treatment of Cancer Core Quality of Life Questionnaire. Quality of life data were evaluable for 1,115 participants (96%). Components of the various questionnaires were divided into domains of physical, psychosocial, and functional quality of life. When comparing single fraction and multiple fraction regimens, the authors found comparable quality of life outcomes, except for a temporary worsening of physical domain scores in the multiple fraction group in the first month after treatment. However, the magnitude of the difference in the physical domain score (Cohen's *d* effect size of 0.12 to 0.17 lower than in the single fraction group) was not regarded as clinically relevant.

Chow et al., 2014

Chow et al. (2014) conducted a multicenter randomized controlled noninferiority trial comparing a single 8 Gy radiotherapy treatment to a 20 Gy multiple fraction regimen for the retreatment of previously irradiated painful bone metastases. The trial was not blinded. Of the 850 patients randomly assigned (1:1) to treatment groups, only 258 patients in the single fraction arm and 263 patients in the multiple fraction arm received the assigned treatment and had evaluable data at the two month follow-up. Approximately two-thirds of the enrolled patients had previously been treated with a single fraction regimen. The two groups were similar with respect to baseline characteristics. Most patients had breast, prostate, or lung cancer. In the intention-to-treat analysis of overall pain response at two months, 28% of the patients in the single fraction arm and 32% of patients in the multiple fraction arm reported an overall pain response ($p = 0.21$, upper bound of the 95% CI 9.2%, which was within the prespecified noninferiority margin of 10%). In the per-protocol analysis (which was limited to patients with evaluable data), 45% of patients in the single fraction arm and 51% of patients in the multiple fraction arm reported overall pain response ($p = 0.17$, upper bound of the 95% CI 13.2%, which exceeded the prespecified noninferiority margin of 10%). There were not statistically significant differences in quality of life between the two arms as assessed by the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-C30 at up to six months. There were no statistically significant differences between the two arms with respect to in-field pathologic fractures or spinal cord compression. Acute toxicities (lack of appetite, vomiting, diarrhea, skin redness) assessed at 14 days after treatment were more common in patients in the multiple fraction arm, but the only serious adverse event observed in the trial was an episode of myocardial ischemia that occurred in one patient in the single fraction arm 166 days after treatment. In a logistic regression analysis of the per-protocol model, there was no significant interaction between prior treatment fractionation regimen and overall pain response during retreatment.

Rudzianskiene et al., 2017

Rudzianskiene et al. (2017) conducted a single-center RCT comparing 8 Gy single fraction radiotherapy to a 30 Gy 10 fraction regimen for the treatment of multiple myeloma. Eligible patients were over age 18, had a verified diagnosis of multiple myeloma with painful bone lesions, and had a Karnofsky

performance score greater than 40%. Of the 101 patients enrolled, 58 patients were randomized to the control arm (30 Gy in 10 fractions) and 43 were randomized to the experimental arm (8 Gy single fraction). The groups were generally similar at baseline, although there were differences between the groups with respect to age, baseline pain scores, and the anatomic site of the planned treatment. For the primary outcomes of pain relief, there were no statistically significant differences between the arms for overall response (74.4% for single fraction vs. 84.5% for multiple fraction, $p = 0.2$), or for complete pain response (68.8% for single fraction vs. 69.4% for multiple fraction, $p = 0.952$). Quality of life indices, as measured by the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-C30, only showed significant improvements over baseline in the multiple fraction arm, but the authors cautioned that the imbalance in patient characteristics at baseline might explain this observation. Acute toxicities did not vary between the two groups.

Evidence Summary

Compared to multiple fraction treatment regimens, single fraction radiotherapy for the treatment of uncomplicated painful bone metastases results in similar outcomes with respect to pain relief, acute toxicity, pathologic fractures, and spinal cord compression. However, patients treated with single fraction radiotherapy are more likely to require retreatment. An analysis from one of the larger RCTs comparing multiple and single fraction regimens found no significant differences in quality of life outcomes.

Policy Landscape

Payer Coverage Policies

Medicaid

No Washington Medicaid coverage policy was found for single fraction radiotherapy for bone metastases.

Medicare

No National Coverage Determinations or Local Coverage Determinations were found for single fraction radiotherapy for bone metastases.

Private Payers

No coverage policies for single fraction radiotherapy for bone metastases were found for Aetna, Cigna, Moda, or Regence.

Recommendations from Others

Four guidelines were identified that include recommendations about the use of single fraction radiation for bone metastases:

- American Society for Radiation Oncology (ASTRO) guidelines on palliative radiotherapy for bone metastases (Lutz et al., 2017)
- American College of Radiology ACR Appropriateness Criteria® on non-spine bone metastases (American College of Radiology, 214)
- American College of Chest Physicians on symptom management for lung cancer patients (Simoff et al., 2013)

- European Association of Urology published on pain management and palliative care for patients with urologic cancers (Paez Borda et al., 2014)

All four of these guidelines state that single fraction radiotherapy is equivalent to multiple fraction radiotherapy in relieving pain, retreatment rates are higher for single fraction versus multiple fraction radiotherapy, and single fraction radiotherapy is more convenient for patients. More details on these guidelines are provided below.

The ASTRO guidelines conclude that:

- An updated review of high-quality data continues to show pain relief equivalency following a single 8 Gy fraction, 20 Gy in 5 fractions, 24 Gy in 6 fractions, and 30 Gy in 10 fractions for patients with previously unirradiated painful bone metastases. Patients should be made aware that single fraction radiotherapy is associated with a higher incidence of retreatment to the same painful site than is fractionated treatment.
- A single 8 Gy fraction provides noninferior pain relief compared with a more prolonged radiotherapy course in painful spinal sites and may therefore be particularly convenient and sensible for patients with limited life expectancy.
- There continues to be no suggestion from available high-quality data that single fraction radiotherapy produces unacceptable rates of long-term side effects that might limit its use for patients with painful bone metastases. The evidence regarding an association between higher risk for pathologic fracture after single fraction radiotherapy versus fractionated therapy remains equivocal.
- The panel reiterates that the use of surgery, radionuclides, bisphosphonates, or kyphoplasty/vertebroplasty does not obviate the need for radiotherapy for patients with painful bone metastases, although 2 recent trials have suggested the potential for similar, albeit less rapid, bone pain relief in prostate cancer patients following an infusion of ibandronate when compared with a single fraction radiotherapy.

The strength of evidence for each of these recommendations from the ASTRO guidelines is either moderate or high, and the strength of recommendation is strong for all of the recommendations.

The American College of Radiology last reviewed the guidelines on non-spine bone metastases in 2014 and concluded that:

- Prospective randomized trials have proven equivalent pain relief with varied fractionation schemes, including 8 Gy in 1 fraction, 20 Gy in 5 fractions, 24 Gy in 6 fractions, or 30 Gy in 10 fractions. Prolonged courses are associated with a lower incidence of retreatment, although shorter courses maximize patient and caregiver convenience by reducing the number of trips to the radiation department.
- Patients who undergo surgical stabilization for impending or completed pathologic fracture of a long bone may be treated with postoperative radiotherapy to 30 Gy in 10 fractions, 24 Gy in 6 fractions, 20 Gy in 5 fractions, or 8 Gy in a single fraction.

The American College of Chest Physicians published guidelines in 2013 that recommended external radiation therapy for lung cancer patients who have pain due to bone metastases. The guidelines concluded that a single fraction of 8 Gy is equally effective for immediate relief of pain as higher fractionated doses of external radiation therapy. In addition, single-fraction radiotherapy is less

expensive than multiple fraction radiotherapy, more cost-effective, and more convenient from the patient's perspective.

The European Association of Urology 2014 guidelines on pain management and palliative care for patients with urologic cancers rated the level of evidence (LE) for recommendations using these categories:

- 1a: Evidence obtained from meta-analysis of randomized trials
- 1b: Evidence obtained from at least one randomized trial
- 2a: Evidence obtained from one well-designed controlled study without randomization
- 2b: Evidence obtained from at least one other type of well-designed quasi-experimental study
- 3: Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies, and case reports
- 4: Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities

The European Association of Urology guidelines include these recommendations on treatment for bone metastases:

- Single-fraction radiotherapy is as effective as multiple fraction radiotherapy in relieving metastatic bone pain (LE: 1a).
- The rates of retreatment and pathologic fractures are significantly higher after single fraction radiotherapy (LE: 1a).
- Single-fraction radiotherapy remains the treatment of choice for alleviating bone pain because of its greater convenience for patients (LE: 1a), faster patient turnover for the radiotherapy unit, and lower costs (LE: 3); the recommended dose is 8 Gy (LE: 1a).
- Pain relief can be achieved with lower doses (LE: 1b), and these lower doses should be borne in mind if a third retreatment is necessary, or if there is concern about radiation tolerance (LE: 2b).

Quality Measures

Two quality measures were identified when searching the [National Quality Measures Clearinghouse](#) for single fraction radiotherapy for bone metastases.

In 2017, the American Society of Radiation Oncology developed a [quality measure on the use of radiotherapy for bone metastases](#): the percentage of patients, regardless of age, with a diagnosis of bone metastases and no history of previous radiation who receive external beam radiotherapy with any of the recommended fractionation schemes (i.e., 30Gy/10fxns, 24Gy/6fxns, 20Gy/5fxns, 8Gy/1fxn).

The [RAND Corporation quality measure](#) developed in 2010 recommended offering single fraction radiation: percentage of patients with advanced cancer who received radiation treatment for painful bone metastases for whom single fraction radiation was offered, or there was documentation of a contraindication to single fraction treatment.

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Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

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Appendix A. GRADE Table Element Descriptions

Element	Description
Balance of benefits and harms	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. An estimate that is not statistically significant or has a confidence interval crossing a predetermined clinical decision threshold will be downgraded.
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed in the absence of likely cost offsets—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted
Other considerations	Other considerations include issues about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.

Strong recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors., but further research or additional information could lead to a different conclusion.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the balance of benefits and harms, cost and resource allocation, and values and preferences, but further research or additional information could lead to a different conclusion.

Confidence in estimate rating across studies for the intervention/outcome

Assessment of confidence in estimate includes factors such as risk of bias, precision, directness, consistency and publication bias.

High: The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

Moderate: The subcommittee is moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical

sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

Low: The subcommittee's confidence in the estimate of effect is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

Very low: The subcommittee has very little confidence in the estimate of effect: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

DRAFT

Appendix B. GRADE Evidence Profile

Quality Assessment (Confidence in Estimate of Effect)							
No. of Studies	Study Design(s)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Factors	Quality
Pain							
26	RCT	Unclear ¹	Not serious	Not serious	Not serious		High ●●●●
Morbidity							
12 (pathologic fracture) 6 (spinal cord compression)	RCT	Unclear ¹	Not serious	Not serious	Serious ²		Moderate ●●●○
Quality of life							
1	RCT	Low	N/A	Not serious	Not serious		High ●●●●
Need for retreatment							
16	RCT	Unclear ¹	Not serious	Not serious	Not serious		High ●●●●
Harms							
26	RCT	Unclear ¹	Not serious	Not serious	Not serious		High ●●●●

¹The systematic review that informed this estimate did not provide individual or overall risk of bias assessments.

²The 95% confidence interval cannot exclude clinically meaningful benefits or harms.

Appendix C. Methods

Scope Statement

Populations

Patients receiving palliative radiotherapy for painful bone metastases

Population scoping notes: None

Interventions

Single fraction radiotherapy

Intervention exclusions: None

Comparators

Multiple fraction radiotherapy

Outcomes

Critical: Pain, morbidity associated with bone metastases (e.g., pathologic fractures, spinal cord compression), quality of life

Important: Need for retreatment, harms

Considered but not selected for the GRADE table: None

Key Questions

KQ1: What is the comparative effectiveness of single fraction radiotherapy for palliation of painful bone metastases?

KQ2: Does the effectiveness of single fraction radiotherapy for painful bone metastases vary by:

- a. Patient characteristics (e.g., expected length of life)
- b. Type of cancer
- c. Total planned dose of radiotherapy
- d. Number of treatment sites
- e. Location of sites

KQ3: What are the harms of single fraction radiotherapy for palliation of painful bone metastases?

Search Strategy

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, and technology assessments that met 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 for single fraction and bone metastases. The search was limited to publications in English published since 2013. In addition, a MEDLINE® search was conducted for randomized controlled trials published after the search dates of the most recent systematic review selected for each indication.

Searches for clinical practice guidelines were limited to those published since 2013. A search for relevant clinical practice guidelines was also conducted using MEDLINE® and the following sources:

Australian Government National Health and Medical Research Council (NHMRC)
Canadian Agency for Drugs and Technologies in Health (CADTH)
Centers for Disease Control and Prevention (CDC), Community Preventive Services
National Guidelines Clearinghouse
National Institute for Health and Care Excellence (NICE)
Scottish Intercollegiate Guidelines Network (SIGN)
United States Preventive Services Task Force (USPSTF)
Veterans Administration/Department of Defense (VA/DoD) Clinical Practice Guidelines

Inclusion/Exclusion Criteria

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, randomized controlled trials, or clinical practice guidelines.

Appendix D. Applicable Codes

CODES	DESCRIPTION
CPT Codes	
77261-77263	Therapeutic radiology treatment planning
77280, 77285, 77290	Therapeutic radiology simulation-aided field setting
77300	Basic radiation dosimetry calculation
77306-77307	Teletherapy isodose plan
77331	Special dosimetry
77332-77334	Treatment devices, design and construction
77336,77370	Medical physics consultation
77401-77416	Radiation treatment delivery
77417	Port verification films/electronic portal imaging for verification
77431	Radiation therapy management, complete course of therapy consisting of one or two fractions
HCPCS Level II Codes	
G6003-G6014	Radiation treatment delivery
ICD-10-PCS Codes	
DP00-DP0C	Beam radiation of bone
ICD-10-CM Codes	
C79.51	Secondary malignant neoplasm of bone
Z51.5	Encounter for palliative care

Note: Inclusion on this list does not guarantee coverage.

CG: Single Fraction Radiotherapy for Palliation of Bone Metastases

Question: How should the draft Coverage Guidance **Single Fraction Radiotherapy for Palliation of Bone Metastases** be applied to the Prioritized List?

Question source: HERC Staff, HTAS

Issue:

The HTAS approved the following draft “box language”:

Single fraction radiotherapy for palliation of bone metastases is recommended for coverage (*strong recommendation*). Single fraction radiotherapy should be given strong consideration for use over multiple fraction radiotherapy when clinically appropriate (e.g., not contraindicated by risk of imminent pathologic fracture, worsening neurologic compromise or radioresistant histologies such as sarcoma, melanoma, and renal cell carcinoma).

Rationale for Recommendations

Both single fraction and multiple fraction radiotherapy are used as palliative treatments for patients with painful bone metastases. Uncomplicated bone metastases (i.e., not at risk for imminent pathologic fracture and not causing neurologic compromise due to spinal cord compression) can often be treated effectively with radiotherapy.

Single fraction radiotherapy has efficacy comparable to multiple fraction treatment, with no significant differences noted in pain relief, quality of life measurements, or morbidity associated with uncomplicated bone metastases. Rates of acute radiation toxicity show no significant differences. Single fraction radiotherapy is associated with a higher need for retreatment, but retreatment with another single fraction is not inferior to retreatment with multiple fraction therapy.

Our recommendation for coverage of single fraction radiotherapy is based on a substantial body of evidence demonstrating comparable results to multiple fraction treatment. Single dose treatment is less costly and more convenient, making it the preferred option for many patients, and most valued by patients with limited life expectancy. Our recommendation is strong, and utilization of single fraction radiotherapy for painful bone metastases is encouraged.

Current Prioritized List Status: Codes

Applicable diagnostic and procedural codes related to radiation therapy services are found on multiple cancer lines (and on some non-cancer lines, as well). The recommendation in this coverage guidance will not change placement of these codes.

CODES	DESCRIPTION	Current placement
CPT Codes		
77261-77263	Therapeutic radiology treatment planning	Various cancer lines with radiation treatment
77280, 77285, 77290	Therapeutic radiology simulation-aided field setting	Various cancer lines with radiation treatment

CG: Single Fraction Radiotherapy for Palliation of Bone Metastases

77300	Basic radiation dosimetry calculation	Various cancer lines with radiation treatment
77306-77307	Teletherapy isodose plan	Various cancer lines with radiation treatment
77331	Special dosimetry	Various cancer lines with radiation treatment
77332-77334	Treatment devices, design and construction	Various cancer lines with radiation treatment
77336,77370	Medical physics consultation	Various cancer lines with radiation treatment
77401-77416	Radiation treatment delivery	Various cancer lines with radiation treatment
77417	Port verification films/electronic portal imaging for verification	Various cancer lines with radiation treatment
77431	Radiation therapy management, complete course of therapy consisting of one or two fractions	Various cancer lines with radiation treatment
HCPCS Level II Codes		
G6003-G6014	Radiation treatment delivery	Various cancer lines with radiation treatment
ICD-10-PCS Codes		
DP00-DP0C	Beam radiation of bone	
ICD-10-CM Codes		
C79.51	Secondary malignant neoplasm of bone	Line 201 CANCER OF BONES
Z51.5	Encounter for palliative care	Diagnostic Workup File

Current Prioritized List Guidelines:

GUIDELINE NOTE 12, TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT

Lines 93,112-116,125,129,133,135,157,158,163,179,191,200,201,209,211,215,216,218,230,235,238,239,259-263,271,276,286,287,294,314-316,329,372,396,397,418,433,589,600

Cancer is a complex group of diseases with treatments that vary depending on the specific subtype of cancer and the patient's unique medical and social situation. Goals of appropriate cancer therapy can vary from intent to cure, disease burden reduction, disease stabilization and control of symptoms. Cancer care must always take place in the context of the patient's support systems, overall health, and core values. Patients should have access to appropriate peer-reviewed clinical trials of cancer therapies. A comprehensive multidisciplinary approach to treatment should be offered including palliative care services (see STATEMENT OF INTENT 1, PALLIATIVE CARE).

Treatment with intent to prolong survival is not a covered service for patients who have progressive metastatic cancer with

- A) Severe co-morbidities unrelated to the cancer that result in significant impairment in two or more major organ systems which would affect efficacy and/or toxicity of therapy;
- OR

CG: Single Fraction Radiotherapy for Palliation of Bone Metastases

- B) A continued decline in spite of best available therapy with a non reversible Karnofsky Performance Status or Palliative Performance score of <50% with ECOG performance status of 3 or higher which are not due to a pre-existing disability.

Treatments with intent to relieve symptoms or improve quality of life are covered as defined in STATEMENT OF INTENT 1, PALLIATIVE CARE.

Examples include:

- A) Single-dose radiation therapy for painful bone metastases with the intent to relieve pain and improve quality of life.
- B) Surgical decompression for malignant bowel obstruction.
- C) Medication therapy such as chemotherapy with low toxicity/low side effect agents with the goal to decrease pain from bulky disease or other identified complications. Cost of chemotherapy and alternative medication(s) should also be considered.

To qualify for treatment coverage, the cancer patient must have a documented discussion about treatment goals, treatment prognosis and the side effects, and knowledge of the realistic expectations of treatment efficacy. This discussion may take place with the patient's oncologist, primary care provider, or other health care provider, but preferably in a collaborative interdisciplinary care coordination discussion. Treatment must be provided via evidence-driven pathways (such as NCCN, ASCO, ASH, ASBMT, or NIH Guidelines) when available.

STATEMENT OF INTENT 1: PALLIATIVE CARE

It is the intent of the Commission that palliative care services are covered for patients with a life-threatening or serious progressive illness to alleviate symptoms and improve quality of life.

Palliative care services should include culturally appropriate discussions and medical decision making aligned with patient's personal goals of therapy, assessment of symptom burden, assistance with advance care planning, care coordination, emotional, psychosocial and spiritual support for patients and their families. Palliative care services may be provided concurrently with life prolonging/curative treatments.

Some examples of services associated with an encounter for palliative care (ICD-10 Z51.5) that should be available to patients without regard to Prioritized List line placement:

- A) Inpatient palliative care consultations
 - 1) Hospital Care E&M (CPT 99218-99233)
- B) Outpatient palliative care consultations provided in either the office or home setting
 - 1) E&M Services (CPT 99201-99215)
 - 2) Transitional Care Management Services (CPT 99495-6)
 - 3) Advance Care Planning (CPT 99497-8)
 - 4) Chronic Care Management (CPT 99487-99490)
- C) Psychological support and grief counseling (CPT 99201-99215)
- D) Medical equipment and supplies for the management of symptomatic complications or support activities of daily living
- E) Medications or acupuncture to reduce pain and symptom burden
- F) Surgical procedures or therapeutic interventions to relieve pain or symptom burden

CG: Single Fraction Radiotherapy for Palliation of Bone Metastases

Other services associated with palliative care includes:

- A) Social Work
- B) Clinical Chaplain/ Spiritual Care
- C) Care Coordination

It is NOT the intent of the Commission that coverage for palliative care encompasses those treatments that seek to prolong life despite substantial burdens of treatment and limited chance of benefit. See Guideline Note 12 TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT.

CG: Single Fraction Radiotherapy for Palliation of Bone Metastases

HERC Staff Recommendations:

- 1) Revise Guideline Note 12, as follows:

GUIDELINE NOTE 12, PATIENT-CENTERED CARE OF ADVANCED CANCER ~~TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT~~

Cancer is a complex group of diseases with treatments that vary depending on the specific subtype of cancer and the patient's unique medical and social situation. Goals of appropriate cancer therapy can vary from intent to cure, disease burden reduction, disease stabilization and control of symptoms. Cancer care must always take place in the context of the patient's support systems, overall health, and core values. Patients should have access to appropriate peer-reviewed clinical trials of cancer therapies. A comprehensive multidisciplinary approach to treatment should be offered including palliative care services (see STATEMENT OF INTENT 1, PALLIATIVE CARE).

Treatment with intent to prolong survival is not a covered service for patients who have progressive metastatic cancer with

- A) Severe co-morbidities unrelated to the cancer that result in significant impairment in two or more major organ systems which would affect efficacy and/or toxicity of therapy; OR
- B) A continued decline in spite of best available therapy with a non-reversible Karnofsky Performance Status or Palliative Performance score of <50% with ECOG performance status of 3 or higher which are not due to a pre-existing disability.

Treatments with intent to relieve symptoms or improve quality of life are covered as defined in STATEMENT OF INTENT 1, PALLIATIVE CARE.

Examples include:

- A) Single-dose radiation therapy for painful bone metastases with the intent to relieve pain and improve quality of life. [Single fraction radiotherapy should be given strong consideration for use over multiple fraction radiotherapy when clinically appropriate \(e.g., not contraindicated by risk of imminent pathologic fracture, worsening neurologic compromise or radioresistant histologies such as sarcoma, melanoma, and renal cell carcinoma\).](#)
- B) Surgical decompression for malignant bowel obstruction.
- C) Medication therapy such as chemotherapy with low toxicity/low side effect agents with the goal to decrease pain from bulky disease or other identified complications. Cost of chemotherapy and alternative medication(s) should also be considered.

To qualify for treatment coverage, the cancer patient must have a documented discussion about treatment goals, treatment prognosis and the side effects, and knowledge of the realistic expectations of treatment efficacy. This discussion may take place with the patient's oncologist, primary care provider, or other health care provider, but preferably in a collaborative interdisciplinary care coordination discussion. Treatment must be provided via evidence-driven pathways (such as NCCN, ASCO, ASH, ASBMT, or NIH Guidelines) when available.

CG: Single Fraction Radiotherapy for Palliation of Bone Metastases

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

2) Revise Statement of Intent 1, as follows:

STATEMENT OF INTENT 1: PALLIATIVE CARE

It is the intent of the Commission that palliative care services are covered for patients with a life-threatening or serious progressive illness to alleviate symptoms and improve quality of life.

Palliative care services should include culturally appropriate discussions and medical decision making aligned with patient's personal goals of therapy, assessment of symptom burden, assistance with advance care planning, care coordination, emotional, psychosocial and spiritual support for patients and their families. Palliative care services may be provided concurrently with life prolonging/curative treatments.

Some examples of services associated with an encounter for palliative care (ICD-10 Z51.5) that should be available to patients without regard to Prioritized List line placement:

- G) Inpatient palliative care consultations
 - 1) Hospital Care E&M (CPT 99218-99233)
- H) Outpatient palliative care consultations provided in either the office or home setting
 - 1) E&M Services (CPT 99201-99215)
 - 2) Transitional Care Management Services (CPT 99495-6)
 - 3) Advance Care Planning (CPT 99497-8)
 - 4) Chronic Care Management (CPT 99487-99490)
- I) Psychological support and grief counseling (CPT 99201-99215)
- J) Medical equipment and supplies for the management of symptomatic complications or support activities of daily living
- K) Medications or acupuncture to reduce pain and symptom burden
- L) Surgical procedures or therapeutic interventions ([for example, palliative radiation therapy](#)) to relieve pain or symptom burden

Other services associated with palliative care includes:

- D) Social Work
- E) Clinical Chaplain/ Spiritual Care
- F) Care Coordination

It is NOT the intent of the Commission that coverage for palliative care encompasses those treatments that seek to prolong life despite substantial burdens of treatment and limited chance of benefit. See Guideline Note 12 [PATIENT-CENTERED CARE OF ADVANCED CANCER. TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT.](#)

3) No change in Prioritized List placement of radiation therapy services is recommended based on this coverage guidance.

HERC Coverage Guidance: Single Fraction Radiotherapy for Palliation of Bone Metastases Disposition of Public Comments

Commenters

Identification	Stakeholder
	No public comments were received

DRAFT



CardioMEMS™ for Heart Failure Monitoring

Draft Coverage Guidance for HERC Consideration

October 4, 2018

Background

- Heart failure occurs when the heart muscle is damaged and cannot meet the body's needs for blood and oxygen
- Nearly 6 million adults in the U.S. have heart failure
- Heart failure is a contributing cause to 1 in 9 deaths
- About 50% of people who develop heart failure die within 5 years of diagnosis
- Annual economic costs of heart failure in the U.S. are estimated at \$30.7 billion

Background

- Risk factors for heart failure:
 - Coronary heart disease
 - Hypertension
 - Diabetes
- Behavioral risk factors:
 - Cigarette smoking
 - Diet high in fat, cholesterol, and sodium
 - Physical inactivity
 - Obesity

Background

- Early diagnosis and treatment can improve outcomes for patients with heart failure
- Treatment usually involves medications, behavioral interventions focusing on diet and physical activity, and daily monitoring of symptoms
- Heart failure can be difficult to monitor
 - Subtle onset of decompensation

Background

- Interventions to monitor ambulatory heart failure patients:
 - Increased self-care and self-management
 - Home visitations by providers
 - Structured telephone support
 - Telemonitoring
 - Remote monitoring through the use of implantable devices, such as CardioMEMS™

Background

- CardioMEMS™ measures pulmonary artery hemodynamic data to inform decisions to initiate or modify treatments for heart failure
 - Implantable wireless sensor with delivery catheter, permanently implanted into the distal pulmonary artery
- Data are transmitted to the patient database on a secure website

Background

- CardioMEMS™ is indicated for New York Heart Association (NYHA) Class III heart failure patients who have been hospitalized for heart failure in previous year
 - Contraindicated for patients who cannot take dual antiplatelet or anticoagulant medication for 1 month after implant of the device
- Manufacturer lists the potential adverse events:
 - Infection, arrhythmias, bleeding, hematoma, thrombus, myocardial infarction, transient ischemic attack, stroke, device embolization, and death
- Received FDA premarket approval in 2014

Scope Statement

- Populations
 - Adults with chronic heart failure
- Interventions
 - CardioMEMS™ heart failure monitoring system
- Comparators
 - Usual care (e.g., daily weight measurements, symptom reporting, frequent encounters), heart rate variability monitors, intrathoracic impedance monitors

Scope Statement

- Critical Outcomes
 - All-cause mortality
 - Cardiovascular mortality
 - Heart failure-related hospitalizations
- Important Outcomes
 - Quality of life
 - Harms

Scope Statement

Key Questions

1. What is the comparative effectiveness of CardioMEMS™ for the management of patients with chronic systolic heart failure?
2. How does the comparative effectiveness of CardioMEMS™ vary by:
 - a. Age
 - b. Gender
 - c. Race/ethnicity
 - d. Comorbid medical conditions
 - e. Prior and current treatments
 - f. Previous hospitalization for acute decompensated heart failure
 - g. Heart failure etiology
 - h. Preserved vs. reduced ejection fraction
 - i. Treatment setting (inpatient/outpatient)
 - j. Patient adherence to prior treatment and monitoring plans
 - k. New York Heart Association class/American College of Cardiology stage
3. What are the harms of CardioMEMS™?

Evidence Sources

- Pivotal trial is the CardioMEMS™ Heart Sensor Allows Monitoring of Pressures to Improve Outcomes in NYHA III Heart Failure Patients (CHAMPION) trial
 - Randomized, single-blind, multicenter trial of 550 patients who all underwent implantation of the CardioMEMS™ device
 - Enrolled adults with a diagnosis of heart failure for at least three months with NYHA functional Class III symptoms and at least one heart failure-related hospitalization in the preceding 12 months
 - Patients must have been on optimal or best-tolerated guideline-directed heart failure therapies
 - Prior to discharge from the hospital, patients were randomized
 - Treatment: clinicians could access readings from the device
 - Control: clinicians could not access readings from the device

Evidence Summary

- There is low-quality evidence from a single, seriously flawed RCT that CardioMEMS™ reduces the risk of heart failure-related hospitalization in patients with NYHA Class III heart failure who have had a previous admission for heart failure
- This finding was consistent for patients with preserved LV function and patients with reduced function, but in the initial trial, this result was not significant among women
- The trial was mainly limited by its single-blind design, manufacturer funding and involvement, and concerns (raised by an FDA advisory panel) related to the statistical analysis plan and improper communications between the sponsor and study investigators in the experimental group
- The evidence for a reduction in all-cause mortality, improved quality of life, and harms is very low because it is further limited by imprecision in the estimates

GRADE Table

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
All-cause mortality (Critical outcome)	19% for CardioMEMS™ vs. 23% for control HR 0.80 (95% CI 0.55 to 1.15, p = 0.23) ●○○○ (Very low confidence, based on 1 RCT, n = 550)
Cardiovascular mortality (Critical outcome)	Not reported
Heart failure-related hospitalization (Critical outcome)	0.46 events per patient-year for CardioMEMS™ vs. 0.68 events per patient year for control HR 0.67 (95% CI 0.55 to 0.80, p < 0.001) Approximate NNT = 5 ●●○○ (Low confidence, based on 1 RCT, n = 550)

GRADE Table

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate
Quality of life (Important outcome)	<p>Improved Minnesota Living with Heart Failure Questionnaire score in the CardioMEMS™ group (45) vs. the control group (51), (105 point scale, p = 0.02)</p> <p>●○○○ (Very low confidence, based on 1 RCT, n = 550)</p>
Harms (Important outcome)	<p>15 serious procedure-related or device-related adverse events were reported (4 bleeding events, 3 events related to interruption of anticoagulation, 2 exacerbations of atrial arrhythmias, 2 febrile illnesses, 1 in-situ pulmonary thrombus, 1 episode of cardiogenic shock, 1 episode of atypical chest pain, and 1 delivery-system failure that required snare retrieval)</p> <p>Approximate NNH = 37</p> <p>●○○○ (Very low confidence, based on 1 RCT, n = 550)</p>

Payer Policies

- Washington State Medicaid Program
 - No coverage policy was identified for CardioMEMS™
- Medicare
 - No Medicare National Coverage Determination was found for CardioMEMS™
 - One Local Coverage Determination was found for CardioMEMS™, which considers the device investigational and non-covered unless in an approved clinical trial
- Private Payers
 - Cigna policy and Regence do not cover CardioMEMS™
 - No coverage policies for CardioMEMS™ found for Aetna or Moda

Guidelines

- American College of Cardiology’s 2017 Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment summarized the evidence on CardioMEMS™ and concluded:
 - “This suggests that in well-selected patients with recurrent congestion, this highly specialized monitoring strategy may guide therapeutic decision making. The impact on mortality is unknown.”
- European Society of Cardiology poor-quality 2016 guidelines on diagnosis and treatment of acute and chronic heart failure:
 - CardioMEMS™ could be considered in symptomatic heart failure patients who have had a previous hospitalization for heart failure (Class IIb: conflicting evidence or a divergence of opinion about the usefulness or efficacy)

Discussion

Values and Preferences

We would assume that patients would strongly prefer to avoid heart failure exacerbations and repeated heart failure hospitalizations. However, this preference would be tempered by the serious adverse event rate of 15/550 that includes events such as arrhythmias, bleeding, and shock. More rare but plausible concerns include infection, thrombosis, and device migration; the study might have been underpowered to detect these events.

Given the noninvasiveness of alternatives (e.g., using a scale and communication with clinic staff), we would expect high variability in preferences.

Discussion

Resource Allocation

The cost of the CardioMEMS™ device is substantial. The cost of the device, implantation, and complications in 2016 dollars is reportedly close to \$19,000. Ongoing monitoring is necessary and would increase costs associated with the device. If this device were effective at reducing hospitalizations and morbidity and mortality, it has the potential to be cost-effective.

Discussion

Other Considerations

All of the reports are derived from a single trial (CHAMPION) for which there are concerns about bias.

There are concerns about external validity given that the monitoring and recommendations of the data obtained through CardioMEMS™ was interpreted by specialty heart failure centers (with assistance of device manufacturer consultation). It is unclear how adoption of this technology within non-specialty centers could modify its potential effectiveness.

Discussion

Balance of Benefits and Harms

We have low confidence that CardioMEMS™ decreases the rate of heart failure-related hospitalization, very low confidence that it improves quality of life, and very low confidence that there is a mortality benefit. We have very low confidence that it is associated with serious adverse events. While the balance of benefits and harms weighs in favor of the intervention, based on the limited evidence, it is unclear that the benefit outweighs the risk.

Discussion

Rationale

The balance of benefits and harms weighs in favor of the intervention, but it is very expensive and invasive, and preferences would likely be highly variable. Given that the evidence is derived from only one trial that has concern of bias, a confirmatory trial is necessary to improve the confidence regarding the potential benefit of this intervention.

CardioMEMS™ is not recommended for coverage for heart failure monitoring (*weak recommendation*).

Health Evidence Review Commission (HERC)

Coverage Guidance: CardioMEMS™ for Heart Failure Monitoring

DRAFT for VbBS/HERC meeting materials 10/4/2018

HERC Coverage Guidance

CardioMEMS™ is not recommended for coverage for heart failure monitoring (*weak recommendation*).

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

Rationales for each recommendation appear below in the GRADE table.

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Rationale for development of coverage guidances and multisector intervention reports

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as plan administrators seek to improve patients' experience of care, population health, and the cost-effectiveness of health care. In the era of public and private sector health system transformation, reaching these goals requires a focus on maximizing the benefits and minimizing the harms and costs of health interventions.

HERC uses the following principles in selecting topics for its reports to guide public and private payers:

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

HERC bases its reports on a review of the best available research applicable to the intervention(s) in question. For coverage guidances, which focus on diagnostic and clinical interventions, evidence is evaluated using an adaptation of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat, or manage disease at a population level. In some cases, HERC has reviewed evidence and identified effective interventions, but has not made formal coverage recommendations when these policies are implemented in settings other than traditional health care delivery systems because effectiveness could depend on the environment in which the intervention is implemented.

GRADE Table

HERC develops recommendations by using the concepts of the GRADE system. GRADE is a transparent and structured process for developing and presenting evidence and for performing the steps involved in developing recommendations. The table below lists the elements that determine the strength of a recommendation. HERC reviews the evidence and assesses each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Estimates of effect are derived from the evidence presented in this document. Assessments of confidence are from the published systematic reviews and meta-analyses, where available and judged to be reliable.

In some cases, no systematic reviews or meta-analyses encompass the most current literature. In those cases, HERC may describe the additional evidence or alter the assessments of confidence in light of all available information. Such assessments are informed by clinical epidemiologists from the Center for Evidence-based Policy. Unless otherwise noted, statements regarding resource allocation, values and preferences, and other considerations are the assessments of HERC, as informed by the evidence reviewed, public testimony, and subcommittee discussion.

Recommendations for coverage are based on the balance of benefit and harms, resource allocation, values and preferences, and other considerations. See Appendix A for more details about the factors that constitute the GRADE table.

DRAFT

GRADE Table

Should CardioMEMS™ be recommended for coverage for heart failure monitoring?

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource Allocation	Values and Preferences	Other Considerations
All-cause mortality <i>(Critical outcome)</i>	19% for CardioMEMS™ vs. 23% for control HR 0.80 (95% CI 0.55 to 1.15, p = 0.23) ●○○○ <i>(Very low confidence, based on 1 RCT, n = 550)</i>	The cost of the CardioMEMS™ device is substantial. The cost of the device, implantation, and complications in 2016 dollars is reportedly close to \$19,000. Ongoing monitoring is necessary and would increase costs associated with the device. If this device were effective at reducing hospitalizations and further morbidity and mortality, it has the potential to be cost-effective.	We would assume that patients would strongly prefer to avoid heart failure exacerbations and repeated heart failure hospitalizations. However, this preference would be tempered by the serious adverse event rate of 15/550 that includes events such as arrhythmias, bleeding, and shock. More rare but plausible concerns include infection, thrombosis, and device migration; the study might have been underpowered to detect these events. Given the noninvasiveness of alternatives (e.g., using a scale and communication with clinic staff), we would expect high variability in preferences.	All of the reports are derived from a single trial (CHAMPION) for which there are concerns about bias. There are concerns about external validity given that the monitoring and recommendations of the data obtained through CardioMEMS™ was interpreted by specialty heart failure centers (with assistance of device manufacturer consultation). It is unclear how adoption of this technology within non-specialty centers may modify its potential effectiveness.

GRADE Table

Should CardioMEMS™ be recommended for coverage for heart failure monitoring?

Outcomes	Estimate of Effect for Outcome/ <i>Confidence in Estimate</i>	Resource Allocation	Values and Preferences	Other Considerations
Cardiovascular mortality <i>(Critical outcome)</i>	Not reported			
Heart failure-related hospitalization <i>(Critical outcome)</i>	0.46 events per patient-year for CardioMEMS™ vs. 0.68 events per patient year for control HR 0.67 (95% CI 0.55 to 0.80, p < 0.001) Approximate NNT = 5 ●●○○ (Low confidence, based on 1 RCT, n = 550)			
Quality of life <i>(Important outcome)</i>	Improved Minnesota Living with Heart Failure Questionnaire score in the CardioMEMS™ group (45) vs. the control group (51), (105 point scale, p = 0.02) ●○○○ (Very low confidence, based on 1 RCT, n = 550)			

GRADE Table

Should CardioMEMS™ be recommended for coverage for heart failure monitoring?

Outcomes	Estimate of Effect for Outcome/ Confidence in Estimate	Resource Allocation	Values and Preferences	Other Considerations
Harms (Important outcome)	15 serious procedure-related or device-related adverse events were reported (4 bleeding events, 3 events related to interruption of anticoagulation, 2 exacerbations of atrial arrhythmias, 2 febrile illnesses, 1 in-situ pulmonary thrombus, 1 episode of cardiogenic shock, 1 episode of atypical chest pain, and 1 delivery-system failure that required snare retrieval) Approximate NNH = 37 ●○○○ (Very low confidence, based on 1 RCT, n = 550)			

Balance of benefits and harms: We have low confidence that CardioMEMS™ decreases the rate of heart failure-related hospitalization, very low confidence that it improves quality of life, and very low confidence that there is a mortality benefit. We have very low confidence that it is associated with serious adverse events. While the balance of benefits and harms weighs in favor of the intervention, based on the limited evidence it is unclear that the benefit outweighs the risk.

Rationale: The balance of benefits and harms weighs in favor of the intervention, but it is very expensive and invasive, and preferences would likely be highly variable. Given that the evidence is derived from only one trial that has concern of bias, a confirmatory trial is necessary to improve the confidence regarding the potential benefit of this intervention.

Recommendation: CardioMEMS™ is not recommended for coverage for heart failure monitoring (*weak recommendation*).

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

Background

Heart failure occurs when the heart muscle is damaged to the extent that it cannot meet the body's needs for blood and oxygen (American Health Association, 2018). About 5.7 million adults in the U.S. have heart failure, and heart failure is a contributing cause to one in nine deaths (Heidenreich et al., 2013). About half of people who develop heart failure die within five years of diagnosis (Heidenreich et al., 2013). The annual economic costs of heart failure in the U.S. are estimated at \$30.7 billion, including the costs of health care services, medications, and missed days of work (Mozaffarian et al., 2016).

Risk factors for heart failure include coronary heart disease, myocardial infarction, hypertension, and diabetes. Behavioral risk factors include cigarette smoking; a diet high in fat, cholesterol, and sodium; physical inactivity; and being obese (Centers for Disease Control and Prevention [CDC], 2016). Early diagnosis and treatment can improve outcomes for patients with heart failure, and treatment usually involves medications, behavioral interventions focusing on diet and physical activity, and daily monitoring of symptoms (CDC, 2016).

Heart failure symptoms and disease progression can be difficult to monitor because of subtle onset of decompensation, medication regimens, the complexities of lifestyle changes, and interactions with comorbid conditions (Bui & Fonarow 2012). Interventions to monitor ambulatory heart failure patients include increased self-care and self-management; home visitations by providers; structured telephone support; telemonitoring; and remote monitoring through the use of implantable devices, such as CardioMEMS™ (Bui & Fonarow 2012). Because of penalties imposed by the Centers for Medicare and Medicaid Services (CMS) for heart failure readmissions, preventing rehospitalization has become a major focus of health insurers and hospital systems (Boccuti & Casillas, 2017).

Indications

CardioMEMS™ is indicated for wirelessly measuring and monitoring pulmonary artery pressure and heart rate in New York Heart Association (NYHA) Class III heart failure patients who have been hospitalized for heart failure in the previous year. CardioMEMS™ is contraindicated for patients who are unable to take dual antiplatelet or anticoagulants for one month after implant of the device (Abbott, 2018).

Technology Description

CardioMEMS™ measures pulmonary artery hemodynamic data that physicians can use to initiate or modify treatments for heart failure. The CardioMEMS™ heart failure monitoring system includes the implantable wireless sensor with delivery catheter, a patient-based or clinic-based electronics system, and a patient database. The wireless sensor is permanently implanted into the distal pulmonary artery (CardioMEMS, 2014). The manufacturer lists the potential adverse events from implanting CardioMEMS™ as infection, arrhythmias, bleeding, hematoma, thrombus, myocardial infarction, transient ischemic attack, stroke, device embolization, and death (Abbott 2018).

The data provided by CardioMEMS™ are heart rate; pulmonary artery waveform; and systolic, diastolic, and mean pulmonary artery pressure. These data are transmitted to the patient database on a secure website (CardioMEMS, 2014). CardioMEMS™ received premarket approval from the U.S. Food and Drug Administration (FDA) in May 2014 (FDA, 2014a).

Evidence Review

Abraham et al., 2011

The pivotal trial examining the effectiveness of the implantable hemodynamic monitoring system (IHMS) is known as the CardioMEMS™ Heart Sensor Allows Monitoring of Pressures to Improve Outcomes in NYHA III Heart Failure Patients (CHAMPION) trial. Its initial results were published in February 2011.

The CHAMPION trial enrolled adults with a diagnosis of heart failure for at least three months with NYHA functional Class III symptoms and at least one heart failure-related hospitalization in the preceding 12 months. Patients were eligible without respect to the left ventricular ejection fraction. To be eligible, patients must have been on optimal or best-tolerated guideline-directed heart failure therapies. Major exclusion criteria were a history of recurrent pulmonary embolism or deep venous thrombosis, Stage IV or V chronic kidney disease, implantation of cardiac resynchronization device in the three months prior to enrollments, recent major adverse cardiovascular events, and hypersensitivity to aspirin or clopidogrel.

CHAMPION was designed as a randomized, single-blind, multicenter trial and was conducted at 64 sites in the United States. The study enrolled 550 patients who all underwent implantation of the CardioMEMS™ device and were admitted to the hospital overnight for observation. Prior to discharge from the hospital, patients were randomized (1:1) to an experimental arm (in which treating clinicians could access readings from the device) and to a control arm (in which treating clinicians could not access readings from the device). All patients were instructed to take pressure readings every day to ensure that patients were blinded to their treatment allocation. In the experimental group, invasive hemodynamic data were reviewed at least weekly, and more often if changes were made in the treatments. Patients in both groups were seen by their treating clinician at one, three, and six months, then every six months. Each study site was required to balance the number of patient contacts between the experimental and control groups. The primary outcomes were the rate of heart failure-related hospitalizations, freedom from device-related complications, and freedom from pressure sensor failure, all measured at six months. The secondary outcome measures were change in mean pulmonary artery pressure, proportion of patients with heart failure-related hospitalization, days alive outside the hospital, and quality of life as measured by the Minnesota Living with Heart Failure Questionnaire (MLHFQ), all measured at six months. Outcomes assessment and adjudication were performed by an independent, blinded committee.

The trial was conducted between September 2007 and October 2009. Overall, 550 patients were enrolled and had the device implanted. There were 270 patients randomized to the experimental arm and 280 patients randomized to the control arm. The mean age of patients was 61 years, roughly 72% of patients were men, and roughly 80% had a left ventricle (LV) ejection fraction of < 40%. Approximately 75% of patients were on ACE inhibitors, 90% were on beta blockers, and 40% were on aldosterone antagonists at baseline. The two groups were generally comparable with respect to baseline characteristics, but there were small differences with respect to the following:

- Proportion of patients with LV ejection fraction > 40% (62 [23%] in the experimental group vs. 57 [20%] in the control group)
- Proportion of patients with coronary artery disease (182 [67%] in the experimental group vs. 202 [72%] in the control group)

- Proportion of patients with atrial flutter or atrial fibrillation (120 [44%] in the experimental group vs. 135 [48%] in the control group)
- Proportion of patients on nitrates (64 [24%] in the experimental group vs. 56 [20%] in the control group).

All patients remained in their assigned treatment group until the six month follow-up period was completed for every enrollee; the mean follow-up duration during the randomized portion of the trial was 15 months. Six month follow-up was available for 244 patients in the experimental arm and 254 patients in the control arm. The overall rate of attrition was approximately 10% and was non-differential. The study authors used intention-to-treat analysis.

For the primary efficacy outcome of heart failure-related hospitalizations at up to six months, there were fewer events in the experimental arm (84 events, 0.32 events per patient per six months) compared with the control arm (120 events, 0.44 events per patient per six months); this equated to a statistically significant reduction of 28% (HR 0.72, 95% CI 0.60 to 0.85, $p = 0.0002$, number needed to treat [NNT] 8). The authors found a statistically significant reduction in events in the experimental arm (HR 0.63, 95% CI 0.52 to 0.77, $p < 0.0001$, NNT 4) for the pre-specified supplemental efficacy endpoint of heart failure-related hospitalizations during the complete randomized follow-up period. For the safety-related primary endpoints, there were no pressure sensor failures, and there were 15 serious procedure-related or device-related adverse events (four bleeding events, three events related to interruption of anticoagulation, two exacerbations of atrial arrhythmias, two febrile illnesses, one in-situ pulmonary thrombus, one episode of cardiogenic shock, one episode of atypical chest pain, and one delivery-system failure that required snare retrieval).

Relevant secondary outcomes were a lower proportion of patients admitted to the hospital at six months in the experimental group (20% vs. 29% in the control group, RR 0.71, 95% CI 0.53 to 0.96, $p = 0.03$), small but statistically significant improvements in days alive outside the hospital at six months (174.4 vs. 172.1, $p = 0.02$), and MLHFQ score at six months (45 vs. 51, $p = 0.02$). There was no statistically significant difference in survival at six months (HR 0.77, 95% CI 0.40 to 1.51, $p = 0.45$). In a pre-specified subgroup analysis by LV systolic function, the rate of heart failure-related hospitalizations was lower in the experimental arm in both subgroups (0.16 per patient per six months vs. 0.33 per patient per six months for patients with preserved ejection fraction; 0.36 per patient per six months vs. 0.47 per patient per six months for patients with reduced ejection fraction).

The authors also conducted an incompletely reported cost-effectiveness analysis. Using a hypothetical cohort of patients with a five-year time horizon, the authors estimated that the treatment group gained 0.306 quality-adjusted life years (QALY) at an incremental cost of \$4,282, leading to an incremental cost-effectiveness ratio of \$13,979 per QALY gained. The authors did not specify the perspective, clearly outline all assumptions or report sensitivity analyses, and did not state whether a customary discounting rate was applied.

Potential sources of bias in the initial report of the CHAMPION trial were that study clinicians (who were ultimately responsible for decisions regarding hospitalization) were not blinded to the treatment group (performance bias), that the device manufacturer sponsored the trial and was involved in data collection and management, and that all authors disclosed conflicts of interest (including consultancies, research grants, or employment).

At the initial FDA Circulatory System Devices Panel meeting at which CardioMEMS™ was discussed in 2011, several criticisms of the design, conduct, and reporting of the CHAMPION trial were leveled (Loh, Barbash, & Waksman, 2013). Three major concerns were outlined. First, FDA statisticians questioned the robustness of the statistical models used in the analysis of heart failure admissions. As an example, if an alternative bootstrap model was applied, as few as two additional hospitalizations in the experimental arm would have increased the likelihood of a type I error to greater than 10% (i.e., p value in excess of 0.1). Second, an FDA Division of Bioresearch Monitoring audit found evidence that unblinded representatives of the sponsor or principal investigators communicated with study sites to make specific treatment recommendations for some patients in the experimental group. Third, in a post-hoc subgroup analysis by gender, the putative efficacy of the device was not observed in women for whom the hazard ratio for heart failure-related hospitalization was 1.15 (95% CI 0.83 to 1.59, p = 0.3953). Partly on the basis of these concerns, the advisory panel voted (7 to 3) that there was not reasonable assurance that the device was effective.

The manufacturer and principal investigators responded to these criticisms at a subsequent FDA advisory panel meeting. They provided additional analyses emphasizing that the number of communications with specific recommendations to treating clinicians was small and that a propensity score analysis comparing experimental group patients whose clinicians did not receive investigator communications to a matched group of controls found a similar reduction in heart failure-related hospitalizations. They also contended that the absence of efficacy in women stemmed from a small number of women in the trial and an excess number of deaths in the control group (which reduced their time in the study); using a combined endpoint of mortality or heart failure-related hospitalization, there was not a treatment-by-gender interaction at a p value of 0.05 (although the FDA pointed out that under a more customary p value cutoff of 0.15 for tests of interaction, the observed subgroup difference remained). Despite the additional information and analyses, the advisory panel again voted (7 to 4) that there was not “reasonable assurance” that the device was effective. The FDA disagreed with the advisory panel’s determination, noting that:

When considering the totality of effectiveness data, the consistency of the results indicate a positive treatment effect in reducing HFR hospitalizations. This positive treatment effect seen in the Open Access (Part 2) of the study also agrees with the positive treatment effect seen in the Randomized Access (Part 1). However, because of the confounding effect of the nurse communications from Part 1 and the limitations of the ancillary analyses from Part 2, there remains some uncertainty regarding the magnitude of that positive effect. (FDA, 2014b, p. 89)

Adamson et al., 2014

This study, derived from the previously described CHAMPION trial, reported the effectiveness of CardioMEMS™ in patients with preserved left ventricular function. Of the 550 patients enrolled in the CHAMPION trial, 119 had a left ventricular ejection fraction (EF) > 40% (mean EF 50.6%). Because the American Heart Association and American College of Cardiology consensus definition for heart failure with preserved ejection fraction changed in 2013, the authors also provided a subgroup analysis based on the newer EF cutoff of 50% (n = 66 patients). In general, within the subgroup of patients with preserved ejection fraction, the baseline patient characteristics were similar between the experimental and control groups. Compared to those with reduced EF, patients with preserved EF were more likely to

have comorbid diabetes and cerebrovascular disease and less likely to have a history of myocardial infarction or hypotension.

In the preserved EF group (> 40%), for the primary efficacy endpoint of heart failure-related hospitalization at six months, there were 11 hospitalizations in the experimental arm (0.18 events per patient per six months) and 19 hospitalizations in the control arm (0.33 events per patient per six months) (incidence rate ratio [IRR] 0.54, 95% CI 0.38 to 0.70, $p < 0.0001$). Among the group of patients with EF > 50%, for the primary efficacy endpoint of heart failure-related hospitalization at six months, there were nine hospitalizations in the experimental arm (0.18 events per patient per six months) and 10 hospitalizations in the control arm (0.35 events per patient per six months) (IRR 0.50, 95% CI 0.29 to 0.86, $p = 0.0129$). The authors stated that the greater event rate in the control group, despite a numerically similar number of events, derived from a shorter combined follow-up period in the control group.

During the complete randomized follow-up period (mean 17.6 months), for patients with preserved EF (> 40%) there were 29 hospitalizations in the experimental arm (0.43 events per patient per year) and 59 hospitalizations in the control arm (0.86 events per patient per year) (IRR 0.50, 95% CI 0.35 to 0.70, $p < 0.0001$). Among the group of patients with EF > 50%, there were 13 hospitalizations in the experimental arm (0.41 events per patient per year) and 31 hospitalizations in the control arm (1.39 events per patient per year) (IRR 0.30, 95% CI 0.18 to 0.48, $p < 0.0001$).

At the six-month follow-up, the proportion of patients with preserved EF (> 40%) who were hospitalized was 12.9% in the experimental arm and 22.8% in the control arm. During the complete randomized follow-up period, the proportion of patients with preserved EF (> 40%) who were hospitalized was 29% in the experimental arm and 38.6% in the control arm. The authors did not report the proportion of patients with EF > 50% who were hospitalized during either timeframe.

Adamson et al., 2016

This study, derived from the previously described CHAMPION trial, reported the effectiveness of CardioMEMS™ in reducing the risk of 30-day readmissions among a subgroup of Medicare-eligible participants. Of the 550 patients enrolled in the trial, 245 were older than 65 at the time of device implantation. Compared to the overall study population, this group was largely composed of white men with ischemic cardiomyopathy and reduced LV ejection fraction. Within the subgroup, the mean LV ejection fraction was lower in the control group (30.4% vs. 34.6%), and the baseline pulmonary artery pressures were slightly higher in the control group. The reason for hospitalization was prospectively adjudicated by an independent group of cardiologists, although the authors did not state that these adjudicators were blinded to the treatment group.

The mean follow-up time in the subgroup was 515 days. During this follow-up period, there were 175 total heart failure-related hospitalizations, of which 155 were considered index admissions that contributed to the analysis. Overall, there were 44 all-cause readmissions, of which 21 were heart failure-related. The overall rate of heart failure-related hospitalizations was 0.34 events per patient per year in the experimental group, compared to 0.67 events per patient per year in the control group (HR 0.51, 95% CI 0.37 to 0.70, $p < 0.0001$). The rate of 30-day all-cause readmission was 0.07 events per patient per year in the experimental group, compared to 0.18 events per patient per year in the control group (HR 0.42, 95% CI 0.22 to 0.80, $p = 0.008$). The rate of 30-day heart failure readmission was 0.02

events per patient per year in the experimental group, compared to 0.10 events per patient per year in the control group (HR 0.23, 95% CI 0.08 to 0.68, p = 0.008).

During the open access period, 63 control arm patients were followed for a mean of 13 months. After these patients had entered the open access period (and clinicians had access to hemodynamic measurements), the heart failure-related hospitalization rate was 0.35 events per patient per year compared to a rate of 0.67 events per person per year during the randomized phase of the trial. More than half (n = 135) of the originally randomized patients in this subgroup completed the full randomized portion of the trial.

Abraham et al., 2016

This report, derived from the previously described CHAMPION trial, reported complete results of the trial after the open access period. As patients enrolled in the trial, they remained in their randomly allocated treatment group until the last patient completed six months of follow-up. At that point, pressure measurements for patients in the control arm during the randomized portion of the trial were made available to the treating clinicians. Patients were followed for an average of 13 months in the open access period. No communications between the sponsor and study clinicians occurred during the open access period. The statistical analysis plan was developed in conjunction with the FDA.

Of the original 550 patients enrolled in the trial, 347 patients completed the full randomized access period (177 in the experimental group and 170 in the control group). The study withdrawals that occurred during the randomized access portion of the trial were most commonly due to death. During the open access period, an additional 43 patients in the former control group and 58 patients in the former experimental group withdrew.

Complete outcomes from the randomized access portion of the trial at a mean follow-up duration of 18 months were reported as follows:

	Randomized access experimental group	Randomized access control group	Statistical analysis
Heart failure admissions	n = 182 0.46 events per patient-year	n = 279 0.68 events per patient-year	HR 0.67 (0.55 to 0.80) p < 0.0001
Deaths and heart failure admissions	n = 232 0.58 events per patient-year	n = 343 0.84 events per patient-year	HR 0.69 (0.59 to 0.82) p < 0.0001
Death	n = 50 (19%)	n = 64 (23%)	HR 0.80 (0.55 to 1.15) p = 0.23
Death or first admission for heart failure	n = 121 (45%)	n = 145 (52%)	HR 0.77 (0.60 to 0.98) p = 0.033
All-cause admissions	n = 554	n = 672	HR 0.84 (0.75 to 0.95) p = 0.0032

	Randomized access experimental group	Randomized access control group	Statistical analysis
	1.38 events per patient-year	1.65 events per patient-year	
Deaths and all-cause admissions	n = 604 1.51 events per patient-year	n = 736 1.80 events per patient-year	HR 0.84 (0.76 to 0.94) p = 0.0017

Outcomes comparing the randomized access control group to the open-access former control group were reported as follows:

	Randomized access control group	Open-access former control group	Statistical analysis
Heart failure admissions	n = 279 0.68 events per patient-year	n = 64 0.36 events per patient-year	HR 0.52 (0.40 to 0.69) p < 0.0001
Deaths and heart failure admissions	n = 343 0.84 events per patient-year	n = 85 0.51 events per patient-year	HR 0.61 (0.48 to 0.78) p < 0.0001
Death	n = 64 (23%)	n = 21 (12%)	HR 0.71 (0.43 to 1.17) p = 0.17
Death or first admission for heart failure	n = 145 (52%)	n = 49 (29%)	HR 0.53 (0.38 to 0.73) p < 0.0001
All-cause admissions	n = 672 1.65 events per patient-year	n = 230 1.30 events per patient-year	HR 0.35 (0.67 to 0.92) p = 0.0034
Deaths and all-cause admissions	n = 736 1.80 events per patient-year	n = 251 1.52 events per patient-year	HR 0.85 (0.72 to 0.99) p = 0.0351

Outcomes comparing the randomized access experimental group to the open-access former experimental group were reported as follows:

	Randomized access experimental group	Open-access former experimental group	Statistical analysis
Heart failure admissions	n = 182	n = 78	HR 0.93 (0.70 to 1.22) p = 0.58

	Randomized access experimental group	Open-access former experimental group	Statistical analysis
	0.48 events per patient-year	0.45 events per patient-year	
Deaths and heart failure admissions	n = 232 0.61 events per patient-year	n = 109 0.67 events per patient-year	HR 1.09 (0.86 to 1.39) p = 0.46
Death	n = 50 (19%)	n = 31 (18%)	HR 1.40 (0.89 to 2.23) p = 0.15
Death or first admission for heart failure	n = 121 (45%)	n = 55 (31%)	HR 0.85 (0.61 to 1.17) p = 0.32
All-cause admissions	n = 554 1.51 events per patient-year	n = 218 1.32 events per patient-year	HR 0.87 (0.74 to 1.03) p = 0.10
Deaths and all-cause admissions	n = 604 1.65 events per patient-year	n = 249 1.61 events per patient-year	HR 0.97 (0.83 to 1.14) p = 0.75

Givertz et al., 2017

This study, derived from the previously described CHAMPION trial, reported the effectiveness of CardioMEMS™ in reducing the risk of hospitalization for heart failure or death among patients with reduced ejection fraction who were on at least one guideline-directed medical therapy at baseline. This analysis by baseline tolerance of angiotensin-converting enzyme inhibitor (ACEi)/angiotensin receptor blocker (ARB) and β-Blockers (BB) was not pre-specified. Of the 550 trial participants, 456 had a reduced LV ejection fraction (< 40%). Among patients with reduced EF, 445 patients were on either an ACEi/ARB or a BB at baseline (Group 1), and 337 patients were on ACEi/ARB and BB at baseline.

In the overall group of patients with reduced EF at mean follow-up of 18 months, the rate of hospitalization for heart failure was 0.49 events per patient-year in the experimental group and 0.69 events per patient-year in the control group (HR 0.72, 95% CI 0.59 to 0.88, p = 0.013), and death occurred in 17.6% of experimental group patients compared to 24.4% of the control group patients (HR 0.68, 95% CI 0.45 to 1.02, p = 0.06). Using a Cox proportional hazards model that accounted for changes in the doses of ACEi/ARB and BB, or nitrates and hydralazine, the hazard ratios for mortality were similar and remained statistically nonsignificant.

Among Group 1 patients (those on at least one ACEi/ARB or BB at baseline), the rate of hospitalization for heart failure was 0.45 per patient-year in the experimental group and 0.68 per patient-year in the control group (HR 0.67, 95% CI 0.54 to 0.82, p = 0.0002), and the all-cause mortality rate was 0.171 per patient-year in the control group and 0.107 per patient-year in the experimental group (HR 0.63, 95% CI 0.41 to 0.96, p = 0.0293). Among Group 2 patients (those on both an ACEi/ARB or BB at baseline), the

rate of hospitalization for heart failure was 0.69 per patient-year in the control group and 0.39 per patient-year in the experimental group (HR 0.57, 95% CI 0.45 to 0.73, $p = 0.0002$), and the all-cause mortality rate was 0.155 per patient-year in the control group and 0.067 per patient-year in the experimental group (HR 0.43, 95% CI 0.24 to 0.76, $p = 0.0052$). Using a Cox proportional hazards model that accounted for changes in the doses of ACEi/ARB and BB, or nitrates and hydralazine, the hazard ratios for mortality were similar and remained statistically significant.

Evidence Summary

There is low-quality evidence from a single, seriously flawed randomized controlled trial (RCT) that CardioMEMS™ reduces the risk of heart failure-related hospitalization in patients with NYHA Class III heart failure who have had a previous admission for heart failure. This finding was consistent in patients with both preserved and reduced LV function, but in the initial trial, this result was not significant among women. The evidence for a reduction in all-cause mortality, improved quality of life, and harms is very low because it is further limited by imprecision in the estimates. The trial was mainly limited by its single-blind design, manufacturer funding and involvement, and concerns (raised by an FDA advisory panel) related to the statistical analysis plan and improper communications between the sponsor and study investigators in the experimental group.

Policy Landscape

Payer Coverage Policies

Medicaid

No coverage policy for was identified for CardioMEMS™ for the Washington State Medicaid Program.

Medicare

No Medicare National Coverage Determinations were found for CardioMEMS™. One Local Coverage Determination ([L36419](#)) was found for CardioMEMS™, which considers this device investigational and non-covered unless in an approved clinical trial.

Private Payers

Coverage policies were searched for four private payers: Aetna, Cigna, Moda, and Regence. The [Cigna policy](#) (effective 10/15/2017) and the [Regence policy](#) (effective: 1/1/2018) do not cover CardioMEMS™. No coverage policies for CardioMEMS™ were found for Aetna or Moda.

Recommendations from Others

The 2017 Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment published by the American College of Cardiology summarized the evidence on CardioMEMS™ and then concluded: “This suggests that in well-selected patients with recurrent congestion, this highly specialized monitoring strategy may guide therapeutic decision making. The impact on mortality is unknown. A team-based approach may be necessary to best deploy this monitoring strategy” (Yancy et al., 2017, p. 215).

The poor-quality 2016 guidelines from the European Society of Cardiology on diagnosis and treatment of acute and chronic heart failure state that CardioMEMS™ could be considered in symptomatic heart failure patients who have had a previous hospitalization for heart failure (Ponikowski et al., 2016). The guidelines rate this recommendation as Class IIb, meaning that there is conflicting evidence or a divergence of opinion about the usefulness or efficacy of CardioMEMS™.

Quality Measures

No quality measures were identified when searching the [National Quality Measures Clearinghouse](#) for CardioMEMS or heart failure monitoring. The Clearinghouse lists a number of quality measures related to hospital admissions and health outcomes for patients with heart failure. [One example](#) of a measure, developed by CMS, is the 30-day risk-standardized mortality rate for patients discharged from the hospital with a principal diagnosis of heart failure (mortality defined as death from any cause within 30 days of the start of the index admission). [Another measure](#) developed by CMS is the 30-day risk-standardized hospital readmission rate for patients with heart failure. This measures unplanned hospital readmissions within 30 days of the original discharge date.

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Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

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Appendix A. GRADE Table Element Descriptions

Element	Description
Balance of benefits and harms	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. An estimate that is not statistically significant or has a confidence interval crossing a predetermined clinical decision threshold will be downgraded.
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed in the absence of likely cost offsets—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted
Other considerations	Other considerations include issues about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.

Strong recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors., but further research or additional information could lead to a different conclusion.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the balance of benefits and harms, cost and resource allocation, and values and preferences, but further research or additional information could lead to a different conclusion.

Confidence in estimate rating across studies for the intervention/outcome

Assessment of confidence in estimate includes factors such as risk of bias, precision, directness, consistency and publication bias.

High: The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

Moderate: The subcommittee is moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

Low: The subcommittee's confidence in the estimate of effect is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

Very low: The subcommittee has very little confidence in the estimate of effect: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

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Appendix B. GRADE Evidence Profile

Quality Assessment (Confidence in Estimate of Effect)							
No. of Studies	Study Design(s)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Other Factors	Quality
All-cause mortality							
1	RCT	High	N/A	None	Serious		Very low ●○○○
Cardiovascular mortality							
0	RCT	High	N/A	N/A	N/A		Insufficient evidence
Heart failure-related hospitalization							
1	RCT	High	N/A	None	Not serious		Low ●●○○
Quality of life							
1	RCT	High	N/A	None	Serious		Very low ●○○○
Harms							
1	RCT	High	N/A	None	Serious		Very low ●○○○

Appendix C. Methods

Scope Statement

Populations

Adults with chronic heart failure

Population scoping notes: None

Interventions

CardioMEMS™ heart failure monitoring system

Intervention exclusions: None

Comparators

Usual care (e.g., daily weight measurements, symptom reporting, frequent encounters), heart rate variability monitors, intrathoracic impedance monitors

Outcomes

Critical: All-cause mortality, cardiovascular mortality, heart failure-related hospitalizations

Important: Quality of life, harms

Considered but not selected for the GRADE table: None

Key Questions

KQ1: What is the comparative effectiveness of CardioMEMS™ for the management of patients with chronic systolic heart failure?

KQ2: How does the comparative effectiveness of CardioMEMS™ vary by:

- a. Age
- b. Gender
- c. Race/ethnicity
- d. Comorbid medical conditions
- e. Prior and current treatments
- f. Previous hospitalization for acute decompensated heart failure
- g. Heart failure etiology
- h. Preserved vs. reduced ejection fraction.
- i. Treatment setting (inpatient/outpatient)
- j. Patient adherence to prior treatment and monitoring plans
- k. New York Heart Association class/American College of Cardiology stage

KQ3: What are the harms of CardioMEMS™?

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 2010.

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 for CardioMEMS. The search was limited to publications in English published since 2010. In addition, a MEDLINE® search was conducted for randomized controlled trials published since 2010.

Searches for clinical practice guidelines were limited to those published since 2010. 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	
93451	Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed
93568	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for pulmonary angiography (List separately in addition to code for primary procedure)
93799	Unlisted cardiovascular service or procedure
93297	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional
93299	Interrogation device evaluation(s), (remote) up to 30 days; implantable loop recorder system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional
HCPCS Level II Codes	
C9741	Right heart catheterization with implantation of wireless pressure sensor in the pulmonary artery, including any type of measurement, angiography, imaging supervision, interpretation, and report
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components

Note: Inclusion on this list does not guarantee coverage.

CG - CardioMEMS™ For Heart Failure

Question: How should the Coverage Guidance on CardioMEMS™ For Heart Failure be applied to the Prioritized List?

Question source: Evidence-based Guideline Subcommittee

Issue: Should CardioMEMS be recommended for coverage?

HERC Coverage Guidance

CardioMEMS™ is not recommended for coverage for heart failure monitoring (*weak recommendation*).

CODES	DESCRIPTION	Current Prioritized List Placement
CPT Codes		
93451	Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed	Diagnostic Procedures File
93568	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for pulmonary angiography (List separately in addition to code for primary procedure)	Diagnostic Procedures File
93799	Unlisted cardiovascular service or procedure	Ancillary Procedures File
93297	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system, including analysis of 1 or more recorded physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional	Diagnostic Procedures File
93299	Interrogation device evaluation(s), (remote) up to 30 days; implantable loop recorder system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional	Diagnostic Procedures File
HCPCS Level II Codes		
C9741	Right heart catheterization with implantation of wireless pressure sensor in the pulmonary artery, including any type of measurement, angiography, imaging supervision, interpretation, and report	Diagnostic Procedures File
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components	Not on List

Recommendations:

- 1) **Place C2624 on Line 660** CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS

CG - CardioMEMS™ For Heart Failure

- 2) **Place C9741 on Line 660, remove from the Diagnostic Procedures File**

HERC Coverage Guidance: CardioMEMS™ for Heart Failure Monitoring Disposition of Public Comments

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Discussion Table

IDs/#s	Summary of Issue	Subcommittee Response
A1, B4	Additional observational trials and a conference abstract were submitted supporting the efficacy of CardioMEMS	<p>Observational studies are generally not considered when higher-level studies are available (e.g., RCTs). Conference abstracts are not considered by the HERC.</p> <p>Given the potential harms and high costs associated with CardioMEMS™, higher confidence in the efficacy of CardioMEMS™ and lack of harms would be required for EbGS to recommend coverage.</p>
B3, B4	CardioMEMS is associated with significant improvements in heart failure hospitalizations.	The point estimate is encouraging that CardioMEMS™ could have a significant impact on health outcomes, however, we have low confidence in this estimate because it is based on a single RCT with concern for bias.
B3	Elements of standard of care for preventing heart failure exacerbations have limitations.	The diagnostic accuracy of the current standard of care was outside the scope of the coverage guidance. Significant changes to the standard of care have developed in the last few years to try to decrease heart failure readmissions, which might have affected secular trends.

HERC Coverage Guidance: CardioMEMS™ for Heart Failure Monitoring Disposition of Public Comments

Commenters

Identification	Stakeholder
A	Jacob Abraham, MD <i>[Submitted April 13, 2018]</i>
B	Wendy Chan, Global Director, Health Economics and Reimbursement, Reimbursement (HE&R), Heart Failure Therapies, Abbott <i>[Submitted May 10, 2018]</i>

Public Comments

ID/#	Comment	Disposition
A1	Three citations and a PowerPoint file were submitted.	<p><i>The study by Heywood et al. was observational and only reported on changes in hemodynamic parameters (not on clinical endpoints), and therefore is out of scope.</i></p> <p><i>The study by Desai et al. is essentially a before-and-after study using Medicare claims data for heart failure hospitalizations six months before CardioMEMS™ implantation and six months after implantation. In general, when higher-quality data from RCTs are available, HERC and its subcommittees do not consider the findings of observational studies.</i></p>
B1	Abbott requests reconsideration of the draft Coverage Guidance in revising the designation of the CardioMEMS™ Heart Failure (HF) System as “not recommended for coverage for heart failure monitoring (weak recommendation)” to medically appropriate based on the FDA indication. We believe the CardioMEMS’ technology holds promise and that the totality of the evidence supports HERC’s coverage consideration. Our rationale is summarized below.	<i>Thank you for your comments.</i>

HERC Coverage Guidance: CardioMEMS™ for Heart Failure Monitoring Disposition of Public Comments

ID/#	Comment	Disposition
B2	<p>1. CHAMPION Trial: Trial Validity and Applicability</p> <p>The FDA approved the CHAMPION trial based on successfully achieving the primary safety and efficacy endpoints. As with most pivotal trials, manufacturers work closely with the FDA to ensure completeness of trial design, trial integrity and limitation of confounding issues. The concerns about bias referenced by HERC were evaluated by the FDA with the completion of a clinical and propensity analysis of the CHAMPION trial to determine the influence and impact of nurse communications in terms of characterizing and quantifying the results observed in the trial’s treatment group.¹ These analyses supported that there was no apparent bias associated with the conduct of the trial. Both independent findings by the FDA supported their recommendation for approval of the CardioMEMS HF System based on the totality of the effectiveness data and the consistency of the results indicate a positive treatment effect in reducing HF rehospitalizations for both the Randomized Access (Part 1) and in the Open Access (Part 2) of the CHAMPION study.²</p> <p>HERC indicated in the values and preferences section that “...patients would prefer to avoid heart failure exacerbations and repeated hospitalizations.” The benefit of CardioMEMS for indicated patients shows reductions in repeat hospitalizations with low adverse event rates of <5% which is well within reason and lower than most implantable cardiac devices. Unlike some implantable cardiac devices, there is no battery replacement associated with the CardioMEMS’ sensor after initial implant. The cost savings from preventing decompensation and repeat hospitalizations is significant and translates to \$5,296/patient/year (comprehensive patient management cost reduction, inclusive of HF hospitalizations) from the payer’s perspective.³ We continue to validate the applicability of the CHAMPION results with real-world publications presented in section 3.</p>	<p><i>The coverage guidance outlines the concerns raised by the FDA Circulatory System Devices Panel (and others) and the manufacturer’s response to those concerns. The ultimate conclusions of the advisory panel and the FDA are noted in the coverage guidance.</i></p> <p><i>The coverage guidance acknowledged that the available trial data have demonstrated that CardioMEMS™ results in fewer heart failure hospitalizations. However, the GRADE rating for that outcome was assessed as low confidence because of concerns for a high risk of bias in the design and conduct of the one available RCT.</i></p> <p><i>It should be noted that a wide range of cost-effectiveness estimates have been reported in the peer-reviewed literature. The low confidence in the estimate of effect for reducing heart failure admission raises questions about the accuracy of these analyses.</i></p>
B3	<p>2. Limitations of Current Standard of Care</p>	<p><i>The background section of the coverage guidance acknowledged the difficulty in monitoring heart failure</i></p>

HERC Coverage Guidance: CardioMEMS™ for Heart Failure Monitoring Disposition of Public Comments

ID/#	Comment	Disposition
	<p>Studies have demonstrated that weight change cannot reliably be used as an indicator of rising pressures. Lewin et al. showed that an absolute weight gain of 2 KG (or relative weight gain of 2%) over 48-72 hours had poor sensitivity (only 9% and 17%) for acute decompensation.⁴ Data from the FAST trial showed that at the nominal weight gain threshold of 3lbs in 1 day or 5 lbs. within 3 days, sensitivity for decompensation was 22.5% (ranging from 12.5% to 37.1%).⁵ These data demonstrate that increases in body weight in isolation are not sensitive in assessing clinical deterioration in established heart failure.</p> <p>Multiple trials and studies with enrollment upwards of 8,500 patients have demonstrated that current markers do not lead to improvement on HF hospitalizations.⁶⁻¹⁴ These studies examined signs/symptoms, daily weights, blood pressure, intrathoracic impedance, and remote monitoring via ICD, CRT-D, and CRT-P devices to gauge their impact on HF hospitalization. The results from these studies showed that monitoring these parameters have no impact on lowering HF hospitalizations. In fact, van Veldhuisen et al. showed that intrathoracic impedance increased HF hospitalizations.</p> <p>CardioMEMS' intervention provides reliable prediction via pulmonary artery (PA) pressures to prevent clinical deterioration and rehospitalization. In CHAMPION, patients managed with PA pressure information had significantly less HF-related hospitalizations (28% reduction at 6 months, 33% annualized reduction over 18 months p=0.017), when compared to the control group.¹⁵ During the Open Access Period of CHAMPION (patients in the former control group where physicians had access to their PA pressures), a longitudinal analysis showed PA pressure in the Former Control group resulted in a 48% reduction in HF hospitalization rates (0.36 vs. 0.68, HR 0.52, 95% CI 0.40-0.69, p<0.0001).¹⁶</p>	<p><i>symptoms and progression. Since the CHAMPION trial was conducted, health insurers and health systems have increased their focus on preventing heart failure readmissions using a variety of interventions.</i></p> <p><i>The data presented here relating to heart failure hospitalizations were included in the coverage guidance. We have added the approximate number needed to treat and an approximate number needed to harm to the GRADE table for subcommittee consideration.</i></p>

HERC Coverage Guidance: CardioMEMS™ for Heart Failure Monitoring Disposition of Public Comments

ID/#	Comment	Disposition
B4	<p>3. Real World Evidence</p> <p>Regarding the HERC statement about the adoption of this technology within the non-specialty settings, real-world post-market data continues to support the efficacy and safety of this therapy. Randomized clinical trials provide one perspective in validating the science in a limited setting; whereas, real-world evidence provides insight to the applicability in translating how the technology performs outside the confines of a trial. The real-world evidence supporting CardioMEMS complements the CHAMPION results and provides compelling argument for coverage. These key publications are summarized below:</p> <ul style="list-style-type: none"> • Heywood et al. demonstrated that general-use of implantable hemodynamic technology in a non-trial setting (first consecutive 2,000 patients implanted with CardioMEMS sensor) led to significant lowering of PA pressures.¹⁷ • Desai et al. demonstrated a 45% reduction in HF hospitalizations at 5 months and significant cost reductions associated with HF care at \$7,433/patient-6months and \$11,260/patient-year with data from Medicare claims.¹⁸ • At the 2018 ACC scientific session, Abraham et al., presented a propensity matched cohort of those patients with identical characteristics as those appropriate to receive CardioMEMS but did not receive the implant compared to those that received the CardioMEMS Sensor. This retrospective study from the Medicare claims database showed a 30% reduction in all-cause mortality and a 24% reduction in HF hospitalizations.¹⁹ <p>CardioMEMS continues to perform well outside the clinical trial setting in addressing clinicians’ challenges to manage chronic HF patients proactively. Abbott’s investment in CardioMEMS continues with the GUIDE-HF IDE trial (NCT 03387813) to specifically evaluate the technology in relation to a composite primary endpoint that focuses on</p>	<p><i>The study by Heywood et al. was observational and only reported on changes in hemodynamic parameters (not on clinical endpoints), and therefore is out of scope.</i></p> <p><i>The study by Desai et al. is also observational (essentially a before-and-after study) using Medicare claims data for heart failure hospitalizations six months before CardioMEMS™ implantation and six months after implantation.</i></p> <p><i>In general, when higher-quality data from RCTs are available, HERC and its subcommittees do not consider the findings of observational studies.</i></p> <p><i>Conference abstracts are not considered by HERC or its subcommittees.</i></p> <p><i>Data from the GUIDE-HF randomized trial would likely increase the subcommittee’s confidence in the estimate of effect on heart failure hospitalization and mortality.</i></p>

HERC Coverage Guidance: CardioMEMS™ for Heart Failure Monitoring Disposition of Public Comments

ID/#	Comment	Disposition
	the reduction of HF hospitalizations and mortality and secondary endpoints on improved quality of life and functional assessment.	
B5	CardioMEMS would benefit appropriate patients under Oregon HERC because of the value it provides patients and clinicians in addressing the challenges associated with managing chronic HF. It is our strong desire that HERC consider the latest evidence to support reconsideration and appropriate coverage of hemodynamic monitoring with the CardioMEMS HF System.	<i>Thank you for your comments.</i>

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HERC Coverage Guidance: CardioMEMS™ for Heart Failure Monitoring Disposition of Public Comments

References Provided by Commenters

ID	References
A	<p>Desai, A. S., Bhimaraj, A., Bharmi, R., Jermyn, R., Bhatt, K., Shavelle, D., . . . Heywood, J. T. (2017). Ambulatory Hemodynamic Monitoring Reduces Heart Failure Hospitalizations in "Real-World" Clinical Practice. <i>Journal of the American College of Cardiology</i>, 69(19), 2357-2365. doi: 10.1016/j.jacc.2017.03.009</p> <p>Givertz, M. M., Stevenson, L. W., Costanzo, M. R., Bourge, R. C., Bauman, J. G., Ginn, G., & Abraham, W. T. (2017). Pulmonary Artery Pressure-Guided Management of Patients With Heart Failure and Reduced Ejection Fraction. <i>Journal of the American College of Cardiology</i>, 70(15), 1875-1886. doi: 10.1016/j.jacc.2017.08.010</p> <p>Heywood, J. T., Jermyn, R., Shavelle, D., Abraham, W. T., Bhimaraj, A., Bhatt, K., . . . Stevenson, L. W. (2017). Impact of Practice-Based Management of Pulmonary Artery Pressures in 2000 Patients Implanted With the CardioMEMS Sensor. <i>Circulation</i>, 135(16), 1509-1517. doi: 10.1161/circulationaha.116.026184</p>
B	<ol style="list-style-type: none"> 1. FDA Summary of Safety and Effectiveness Data (SSED): PMA P100045 CardioMEMS HF System, 2014. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P100045 2. FDA Summary of Safety and Effectiveness Data (SSED): PMA P100045 CardioMEMS HF System, 2014. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P100045 3. Martinson M, Bharmi R, Dalal N, Abraham WT, Adamson PB. Pulmonary artery pressure-guided heart failure management: US cost-effectiveness analyses using the results of the CHAMPION clinical trial. <i>Eur J Heart Fail</i> 2017;19:652–660. 4. Lewin J, et al. Clinical deterioration in established heart failure: what is the value of BNP and weight gain in aiding diagnosis? <i>Eur J Heart Fail</i>. 2005 Oct;7(6):953-7. 5. Abraham WT, Compton S, Haas G et al. Intrathoracic Impedance vs. Daily Weight Monitoring for Predicting Worsening Heart Failure Events: Results of the Fluid Accumulation Status Trial (FAST). <i>Congest Heart Fail</i> 2011 March;17(2):51-5. 6. Chaudhry, S. I. et al. (2010). Telemonitoring in patients with heart failure. <i>The New England Journal of Medicine</i>, 363, 2301-2309. 7. Koehler, F., et al. Telemedical Interventional Monitoring in Heart Failure Investigators. (2011). Impact of remote telemedical management on mortality and hospitalizations in ambulatory patients with chronic heart failure: The Telemedical Interventional Monitoring in Heart Failure study. <i>Circulation</i>, 123, 1873-1880. 8. Cleland, J.G et al. TENS-HMS Investigators. (2005) Noninvasive Home Telemonitoring for Patients with Heart Failure at High Risk of Recurrent Admission and Death: The Trans-European Network-Home-Care Management System (TEN-HMS) study. <i>JACC</i>, 45, 1654-1664. 9. Ong, M.K., et al. BEAT-HF Research Group. The Better Effectiveness After Transition – Heart Failure Study - Remote Patient Management After Discharge of Hospitalized Heart Failure Patients. <i>AHA 2015 LBCT</i>. 10. Angermann, C.E., et al. (2012). Mode of Action and Effects of Standardized Collaborative Disease Management on Mortality and Morbidity in Patients with Systolic Heart Failure: The Interdisciplinary Network for Heart Failure (INH) Study. <i>Circ Heart Failure</i> 2012;5;25-35. 11. van Veldhuisen DJ, et al. DOT-HF Investigators. Intrathoracic Impedance Monitoring, Audible Patient Alerts, and Outcome in Patients with Heart Failure. <i>Circulation</i>. 2011 Oct 18;124(16):1719-1726.

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