Health Evidence Review Commission

May 19, 2016

1:30 PM - 4:30 PM

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

Section 1.0

Call to Order

AGENDA

HEALTH EVIDENCE REVIEW COMMISSION

Wilsonville Training Center, Rooms 111-112

May 19, 2016

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	Som Saha	
2	1:35 PM	Approval of Minutes (3/10/2016)	Som Saha	X
3	1:40 PM	Director's Report	Darren Coffman	
4	2.00 PM	Value-based Benefits Subcommittee Report	Ariel Smits Cat Livingston	X
5	2:45 PM	Discussion of Multisector Intervention Evidence Review Work	Cat Livingston	
6	3:30 PM	Clarification of Coverage Guidance Evidence Submission Policy	Darren Coffman	X
7	3:45 PM	Discuss Presentation of Evidence in GRADE-informed Framework in Coverage Guidances	Jason Gingerich Cat Livingston	X
8	4:20 PM	Next Steps • Schedule next meeting – August 11, 2016 Wilsonville Training Center, Rooms 111-112	Som Saha	
9	4:30 PM	Adjournment	Som Saha	

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
March 10, 2016

Members Present: Som Saha, MD, MPH, Chair; Beth Westbrook, PsyD; Wiley Chan, MD; Irene Croswell, RPh; Leda Garside, RN, MBA; Susan Williams, MD; Kim Tippens, ND, MPH; Derrick Sorweide, DO; Chris Labhart; Holly Jo Hodges, MD; Gary Allen, DMD.

Members Absent: Mark Gibson; Kevin Olson, MD.

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Denise Taray, RN; Jason Gingerich (by phone); Daphne Peck (by phone).

Also Attending: Lorren Sandt (Caring Ambassadors); Renee Taylor (Dexcom); Kim Wentz, MD, MPH, (Oregon Health Authority); Erica Pettigrew, MD (OHSU); Valerie King, MD MPH, Adam Obley, MD, MPH, and Craig Mosbaek (OHSU Center for Evidence-based Policy); Barbara Marcant (SJM); Alejandro Perez, MD (Providence); Kriti Amerson (Willamette Valley Medical Center).

Call to Order

Som Saha, Chair of the Health Evidence Review Commission (HERC), called the meeting to order, role was called.

Minutes Approval

MOTION: To approve the minutes of the January 14, 2016 meeting as presented. CARRIES 11-0.

Director's Report

Membership Update
Kevin Olson, an oncologist who has been the Value-based Benefits Subcommittee (VbBS) chair since the commission began, was appointed as a Commissioner. He was unable to attend this meeting. Dr. Olson is the Providence Cancer Center executive medical director.

Kim Tippens, a naturopathic physician with a master's degree in oriental medicine and acupuncture, was appointed as a Commissioner. She is a professor at Naturopathic College of Medicine. Tippens will also participate on the Evidence-based Guidelines Subcommittee (EbGS). Former Commissioner Dr. Vern Saboe, Tippen's predecessor as the complementary and alternative medicine representative to the Commission, will now participate on VbBS, filling the place of former member Laura Ocker.

Dr. Tim Keenen has resigned from the Health Technology Assessment Subcommittee (HTAS) due to regular scheduling conflicts with meeting day. Keenen recruited Dr. Clyde Farris, a recently retired orthopedic surgeon who is still active in the specialty association, to participate on the subcommittee.

MOTION: To appoint Dr. Clyde Farris to HTAS. Carries: 11-0.

Coverage Guidance Process

Coffman said there have been several instances when topics are coming up for their 2-year review and a new study is expected out in the next 6-12 months. In some cases the commission may want to hold off the review until that study is released. He proposed having coverage guidances in that status "affirmed, but with a caveat that new studies are imminent" for the current 2-year review, then opened for review after the new studies are complete. Saha suggested there be no caveat which would lead to questioning the current coverage guidance. The topic could be reopened at any time.

Coffman asked whether a re-review should occur every two years or is there a point where, say after two re-reviews with no changes to the coverage guidance, that the commission would consider putting the topic on hiatus? After that point the commission could always bring it back for consideration if a new compelling systematic review is found or an external party suggests a review. Saha expressed concern about retiring topics in such a fashion, feeling that may lead to stagnation.

Saha advocated for a leaner process and said rescanning each topic every two years can be time consuming. He asked for a time estimate using the current rescanning process. Obley said it is actually quick; writing the 1-2 page report addressing scope questions is the part that is time consuming. After discussion, members decided reports should only be completed for topics were there have been studies significant enough to make staff believe it might change the current guidance. Topics that do not meet that milestone can be a list of topics with a blurb stating there were no significant changes in studies.

In summary, the proposed expedited rescan process allows Center for Evidence-based Practice and HERC staff permission to determine which topics:

- Should be scheduled for rescan every two years to be brought to HERC to consider new evidence
- May be included in a list of topics for which the rescan topics showed no evidence that would influence the existing coverage guidance recommendations.

Additionally, it was proposed that topics should not be retired unless that topic is no longer relevant to practice or there is another way to decide about coverage beside the HERC process.

MOTION: To approve the expedited rescan process. CARRIES: 11-0

Prioritized List

Smits began a discussion about formalizing the process to remove procedures from the Prioritized List. Here-to-for, procedures were removed only if there was evidence of ineffectiveness. The consensus reached after discussion is to also allow removal if the harms outweigh the potential benefits. Staff will prepare a written statement to present at the next meeting.

Prioritized List Publishing

The Commission publishes two Prioritized Lists a year, January and October. Smits proposed adding any changes that have a potentially significant financial impact to the January list each year, to coincide with

the ability to incorporate rate changes into CCO contracts for the next calendar year. October changes would be limited to technical issues, minor corrections and wording changes.

Staff Update
Coffman introduced the Oregon Health Authority's new Chief Medical Officer (CMO), Dr. James Rickards, who is a radiologist. Rickards has five areas of responsibility, including oversight of this Commission's work.

Value-based Benefits Subcommittee (VbBS) Report on Prioritized List Changes
Meeting materials, pages 13-94

Ariel Smits reported the VbBS met earlier in the day, March 10, 2016. She summarized the subcommittee's recommendations.

Recommended Code Movement (effective 10/1/16)

- Move several newborn diagnoses to more appropriate covered lines.
- Add diagnosis codes for esophageal hernias with obstruction or gangrene to the covered hernia line with the appropriate treatment codes and delete from the covered GERD/esophagitis line.
- Delete the treatment code for intracranial vascular balloon dilation for atherosclerosis from the Prioritized List due to evidence of harm and lack of evidence of effectiveness.
- Delete the treatment code for intracranial vascular balloon dilation for vasospasm from the Prioritized List due to evidence of harm and lack of evidence of effectiveness.
- Add procedure codes for perioperative pelvic physical therapy and laser hair removal for surgical site preparation to the gender dysphoria line.
- Add various straightforward codes to appropriate lines.

Recommended Guideline Changes (effective 10/1/16)

- Modify the gender dysphoria guideline to remove the requirement for hormone therapy prior to breast or chest surgery, to add laser hair removal for surgical site preparation in the same way as restricted for electrolysis, to clarify when revision surgeries are covered, and to specify that pelvic PT procedures codes are only covered for peri-operative therapy.

Biennial Review Changes (effective 1/1/18)

- Merge the two premature baby lines and prioritize to the upper line position. Move the diagnosis codes for intraventricular hemorrhages to another line to pair with required treatments.
- Merge the congenital infections line and congenital syphilis lines and prioritize at their current position.
- Merge three lines containing endocrine conditions of the newborn and prioritize to approximately the mid position of the lines.
- Add diagnosis codes and change the line title for the line containing omphalitis and newborn mastitis codes, reprioritizing to a slightly lower position.

MOTION: To accept the VbBS recommendations on Prioritized List changes not related to coverage guidances, as stated. See the VbBS minutes of 3/10/2016 for a full description. Carries: 11-0.

Review of Scoping Statements and Scoring for Proposed New Coverage Guidance Topics
Meeting materials, pages 95-106

Livingston led a discussion about certain elements of the scoring criteria including "overall mortality" instead of "disease specific mortality" and whether *quality of life* should be weighed as a "critical outcome" or as an "important outcome." Saha asserted we should avoid blanket statements because those outcomes can change topic by topic.

For this discussion, Saha said these scope statements have been through the subcommittee process and are presented today for approval. What is being deciding today is whether the question is framed correctly for HERC's decision making.

Adam Obley and Livingston gave a brief description of each topic (found in the meeting materials). The topics of Ultrasound-Enhanced Catheter Directed Thrombolysis for Deep Vein Thrombosis and Ultrasound-Enhanced Catheter Directed Thrombolysis for Pulmonary Embolism were not reviewed as their scores were below the threshold for consideration.

- Genetic Testing of Thyroid Nodules
    - Used to test non-cancerous nodules to determine if further treatment is required.
- Noninvasive Testing For Liver Fibrosis in Chronic Hepatitis C Patients
    - Used in place of liver biopsy to justify treatment.
        - Public testimony was received from Lorren Sandt, Caring Ambassadors, who warned that rural Oregon facilities might not have the equipment for this type of testing. Further, she submitted a letter from CMS stating that limiting hepatitis C treatment violates Medicaid law. The Pharmacy & Therapeutics (P&T) Committee refused to hear her testimony about it, saying treatment coverage is HERC's responsibility.
- Prostatic Urethral Lift for Treatment of Benign Prostatic Hypertrophy
    - Rescan based on new published data because this new procedure is less invasive than alternatives.
- Sacral Nerve Stimulation for Non-Obstructive Urinary Retention
    - Implanted devise that helps patient empty bladder and not need catheterization.
- Digital Breast Tomosynthesis (3d Mammography) For Breast Cancer Screening In Average Risk Women
    - This might be a more effective screening modality for younger women or women with dense breasts.
- Fecal Microbiota Transplants for C. difficile
    - For hard-to-treat bacterial infections causing extreme diarrhea, a stool transplant might be effective.
- Genetic Tests for Selection of Antidepressant Therapy
    - Pharmacogenetic tests designed to prospectively (or after a patent has started a medication for depression that isn't working) determine which medication is most appropriate based on how they will metabolize it and therefore the likelihood of a response to the treatment.
- Interventions to Reduce Tobacco Use during Pregnancy
    - Rename *Tobacco Cessation during Pregnancy*
    - Multi-sector interventions to promote abstinence from smoking during pregnancy.

- Gastrointestinal Motility Tests
    - Which kind of tests are needed to determine if the stomach does not empty in a normal time frame.
- Timing of Long-Acting Reversible Contraceptive Placement
    - IUDs and other implants: When should they be implanted post-partum/post-abortion? Expulsion rates are a concern.
    - Wentz added that the issue with OHP is largely implementation related.
- Percutaneous Interventions for Low Back Pain
    - Rename to *Corticosteroid Injections for Low Pack Pain*
    - Compare this treatment to all other types of treatment for low back pain.

MOTION: To approve the scope statement as presented. CARRIES: 11-0

Prioritization of Coverage Guidance Topics
Meeting materials, pages 107-125

Livingston and Saha began the discussion of the proposed changes to the coverage guidance topic scoring system. Recommended changes include clarification that the disease burden is from the individual perspective (not population), tightening of the language of several sections to provide more precision and clarity, the addition of a new row on potential of intervention to improve health outcomes, and clarification to scoring descriptions (pages 107-108 for details).

For future coverage guidance scoring, members discussed using the current multiplier category of "meaningful coverage guidance" as a yes/no question to be answered before any of the other scoring is considered. If no, nothing else should be done and the topic should not be considered for a future coverage guidance. If yes, consider the scoring criteria questions. Coffman noted that this was already being done in many cases by staff in generating the list of topics being considered today.

Saha said CCOs are empowered to spend their global budget dollars to improve the health of their patients outside of a traditionally used diagnosis/procedure code model. Some topics we take up as coverage guidances will also have another document listing best practices for other interventions, called multisector interventions. These topics should not have to be scored the same way as coverage guidances.

Labhart stated his concern about the CCO in his county meeting their metric targets for smoking cessation, potentially costing his county tens of thousands of dollars. He added his concern that the CCOs across the state are not aligned with the work of this Commission. He pled with the members to bear in mind what CCOs have to accomplish.

Coffman asked that HERC use the currently approved scale for today's set of recommendations and use the new model, if accepted, for scoring potential topics in future years.

MOTION: To change the scoring criterion "Meaningful Coverage Guidance" to be a prerequisite in the consideration of future topics. Carries: 11-0.

MOTION: To approve changes to the scoring documents as amended. Carries: 11-0.

Topics and final scoring presented (with assigned subcommittee in parentheses):

- Timing of Long-Acting Reversible Contraceptive Placement (EbGS), Score 66
- Digital Breast Tomosynthesis (3d Mammography) for Breast Cancer Screening in Average Risk Women (EbGS), Score 60
- Continuous Glucose Monitoring in Diabetes Mellitus (HTAS), Score 54
- Genetic Tests for Selection of Antidepressant Therapy (EbGS), Score 48
- Fecal Microbiota Transplants for C. difficile (EbGS), Score 45
- Tobacco Cessation during Pregnancy (EbGS), Score 45
- Percutaneous Interventions for Low Back Pain (EbGS), Score 45
- Recurrent Acute Otitis Media in Children (EbGS), Score 42
- Noninvasive Testing for Liver Fibrosis in Chronic Hepatitis C Patients (HTAS), Score 39
- Prostatic Urethral Lift for Treatment of Benign Prostatic Hypertrophy (HTAS), Score 36
- Sleep Apnea Diagnosis in Adults (HTAS), Score 36
- Sacral Nerve Stimulation for Non-Obstructive Urinary Retention (HTAS), Score 33
- Genetic Testing of Thyroid Nodules (HTAS), Score 30
- Gastrointestinal Motility Tests (EbGS), Score 27

MOTION: To accept the prioritization of topic scoring, generally starting with reviews of topics with higher scores. CARRIES: 11-0.

Topic Retirements

These topics were initially approved for potential coverage guidance development, but a coverage guidance has never been developed for the reasons listed:

- Telepsychiatry and Telecounseling
    - Significant implementation issues; unlikely to influence care
    - Westbrook asked if HERC could do a drug review
        - Coffman said the Commission is prohibited from conducting drug reviews
- Nitric oxide for the diagnosis and management of asthma
    - Lack of community interest, limited evidence base, insufficient controversy to merit an in-depth review
- Transitional care interventions to prevent readmissions for people with heart failure
    - Significant implementation issues; unlikely to influence care
- Treatments for acquired nontraumatic cognitive impairment/dementia
    - Significant implementation issues; unlikely to influence care

MOTION: To accept staff's recommendation to drop these topics from consideration for a future coverage guidance. CARRIES: 11-0.

Coverage Guidance Topic: Skin Substitutes for Chronic Skin Ulcers

Meeting materials, pages 127-222

Obley presented the proposed coverage guidance from EbGS. This coverage guidance focuses on two types of ulcers:

- Diabetic foot ulcers (DFU)
    - Caused by atherosclerosis impeding blood flow to extremities and neuropathy that reduces a person's ability to detect an injury, which can lead to infection and amputation
- Venous leg ulcers (VLU)
    - Caused by venous insufficiency

Skin substitutes were initially used to treat burns. Skin ulcers occur more frequently than burns and skin substitutes are now used more commonly for treatment of chronic ulcers (not healed in 30 days of standard treatment). Skin substitutes stimulate the body to regenerate lost tissue. There are over 70 skin substitute products approved for use in humans and are derived from donor tissue, living human or animal tissues/cells or are acellular animal-derived or biosynthetic products. Obley pointed out that not all products are indicated for every wound.

The identified evidence evaluated the effectiveness of eight skin substitutes currently sold in the United States. Obley said the evidence shows moderate or low certainly of benefit in the cases where a recommendation for coverage could be made. Studies suggested during the public comment period were also reviewed. The instances where at least a low certainty of benefit were reviewed for various critical and important outcomes:

- Apligraf®
    - DFU: Complete wound healing: moderate certainty of benefit; Adverse events: low certainty of no harm
    - VLU: Complete wound healing: low certainty of benefit; Time to complete wound healing: Low certainty of benefit
- Dermagraft®
    - Complete wound healing: low certainty of benefit; Time to complete wound healing: low certainty of benefit
- EpiFix®
- Grafix®
- Graftjacket®
- OASIS®
    - Complete wound healing: low certainty of benefit; Complete wound healing: low certainty of benefit
- Talymed®
- Theraskin®

Prerequisites for coverage are also suggested to be included in the box language (based on combination of study criteria and expert input):

- Appropriate wound care required
- Appropriate patient characteristics
- Diabetic control (<12)
- Adequate blood flow
- Failure of prior therapy
- Participation in tobacco cessation required

Livingston said there were a number of late-breaking studies as we came to the end of this coverage guidance process. When this has happened in the past, we have waited to look at these

products/procedures until the next 2-year review unless they would clearly change the recommendation.

Livingston reviewed product costs, which were included in the coverage guidance for informational purposes, but did not drive the recommendations (Appendix E: Frequency of Application and Cost of Skin Substitutes, meeting materials pages 190-191). It appears some products may be more costly than others, particularly when accounting for the potential of product waste with those that can only be ordered in larger sheets.

Livingstone touched on the GRADE-Informed Framework (page 129-140) and reviewed potential changes to the Prioritized List as a result of the draft coverage guidance.

Public comment:
Dr. Alejandro Perez, Regional Medical Director of Providence Wound Care and Hyperbaric Medicine Program and president of the Columbia Wound Care Consortium, offered testimony. He declared no conflicts of interest. Dr. Perez expressed concern that he had not heard of our process before now and was critical of the Commission's outreach to the specialty community. Coffman noted a specialty representative was appointed as an ad hoc expert during EbGS's review of the topic.

Dr. Perez noted two studies (one that was included in the coverage guidance process, Lavery, 2014) and one that was not (Zellen, 2014) that he feels might affect the coverage guidance conclusions.

Commission discussion led to a decision to open the topic up for an additional 21-day comment period followed by a review at the June EbGS meeting. It is anticipated that it will then be brought back to the August HERC meeting for final consideration.

Coverage Guidance Topic: Metabolic and Bariatric Surgery
Meeting materials, pages 223-331

Saha gave a brief review about the proposed coverage guidance from HTAS. The subcommittee received a single public comment expressing support for the draft coverage guidance. This work will fold into the Obesity Task Force's work in the management of obesity as a biennial review topic.

Public Comment

There was no public comment at this time.

Adjournment

Meeting adjourned at 4:30 pm. Next meeting will be from 1:30-4:30 pm on Thursday, May 19, 2016 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 March 10, 2016

For specific coding recommendations and guideline wording, please see the text of the 3/10/2016 VbBS minutes.

RECOMMENDED CODE MOVEMENT (effective 10/1/16)

- Move several newborn diagnoses to more appropriate covered lines.
- Add diagnosis codes for esophageal hernias with obstruction or gangrene to the covered hernia line with the appropriate treatment codes and delete from the covered GERD/esophagitis line.
- Delete the treatment code for intracranial vascular balloon dilation for atherosclerosis from the Prioritized List due to evidence of harm and lack of evidence of effectiveness.
- Delete the treatment code for intracranial vascular balloon dilation for vasospasm from the Prioritized List due to evidence of harm and lack of evidence of effectiveness.
- Add procedure codes for perioperative pelvic physical therapy and laser hair removal for surgical site preparation to the gender dysphoria line.
- Add various straightforward codes to appropriate lines.

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- Several newborn lines with hematologic conditions were considered for merging but not approved.
- Waiving the requirement to live as the desired gender for 1 year prior to breast or chest surgery for gender dysphoria was not approved.

RECOMMENDED GUIDELINE CHANGES (effective 10/1/16 unless)

- Modify the gender dysphoria guideline to remove the requirement for hormone therapy prior to breast or chest surgery, to add laser hair removal for surgical site preparation in the same way as restricted for electrolysis, to clarify when revision surgeries are covered, and to specify that pelvic PT procedures codes are only covered for peri-operative therapy.

BIENNIAL REVIEW CHANGES (effective 1/1/18)

- Merge the two premature baby lines and prioritize to the upper line position. Move the diagnosis codes for intraventricular hemorrhages to another line to pair with required treatments.
- Merge the congenital infections line and congenital syphilis lines and prioritize at their current position.
- Merge three lines containing endocrine conditions of the newborn and prioritize to approximately the mid position of the lines.
- Add diagnosis codes and change the line title for the line containing omphalitis and newborn mastitis codes, reprioritizing to a slightly lower position.

VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
March 10, 2016
8:30 AM – 1:00 PM

Members Present: Susan Williams, MD, Chair Pro Tempore; David Pollack, MD; Irene Croswell, RPh; Holly Jo Hodges, MD; Vern Saboe, DC; Gary Allen, DMD.

Members Absent: Kevin Olson, MD; Mark Gibson.

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Denise Taray, RN; Daphne Peck (by phone).

Also Attending: Kim Wentz, MD, MPH, and Jim Rickards, MD (Oregon Health Authority); Valerie King, MD, MPH, and Adam Obley, MD, MPH (OHSU Center for Evidence-based Policy); Megan Bird, MD, and Valerie Halpin, MD (Legacy); Amy Penkin (OHSU); Maura Roche and Andrea Zekis (Basic Rights Oregon); Casey Parks (Oregonian); Kimberly Ruscher, MD, and Garret Zallen, MD (via phone) (PeaceHealth); Brenna Legaard; Tobi Rates (Autism Speaks Oregon); Rebekah Brewis (PDX TransPride); Dan Unumb, Esq. (via phone) (Autism Speaks).

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

  The meeting was called to order at 8:45 am and roll was called. Minutes from the January 14, 2016 VbBS meeting were reviewed and approved.

  Staff reviewed errata published since the January meeting. There were no questions about these items.

  Smits introduced the idea of having the October 1 Prioritized List changes only include those without significant fiscal impact. Those changes expected to have significant fiscal impact would be included in January 1 Prioritized List changes to coincide with the next CCO contract period. The subcommittee was generally in favor of this change. Hodges felt that this change would be very helpful for the health plans.

  Vern Saboe, DC was introduced as a new member of VBBS. He comes from the HERC and EGBS and has a long history with the Health Services Commission as well. Dr. Saboe spoke to his background in both policy and clinical expertise.

  Livingston announced that the Obesity Task Force has started to meet and will give recommendations for biennial review changes for coverage of obesity later in the year.

- **Topic: Straightforward/Consent Agenda**

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

Recommended Actions:

1) Add 20924 (Tendon graft, from a distance (eg, palmaris, toe extensor, plantaris)) to line 436 INTERNAL DERANGEMENT OF KNEE AND LIGAMENTOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT
2) Add D62 (Acute posthemorrhagic anemia) to line 152 ACQUIRED HEMOLYTIC ANEMIAS and remove from line 122 NUTRITIONAL DEFICIENCIES
3) Add 96150-96155 (Health and behavior assessment) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
4) Remove 64505, 64508, 64510, 64517, 64520, and 64530 (Injection, anesthetic agent) from line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
5) Add L66.2 (Folliculitis decalvans), L66.8 (Other cicatricial alopecia) and L66.9 (Cicatricial alopecia, unspecified) to line 517 HIDRADENITIS SUPPURATIVA; DISSECTING CELLULITIS OF THE SCALP
6) Remove L66.2, L66.3 (Perifolliculitis capitis abscedens), L66.8 and L66.9 from line 588 DISEASE OF NAILS, HAIR AND HAIR FOLLICLES
7) Remove 92507-92508, 92526, 92607-92609, and 92633 (Speech therapy services) and all CPT codes for inpatient and ICU care from line 501 CALCIUM PYROPHOSPHATE DEPOSITION DISEASE (CPPD) AND HYDROXYAPETITE DEPOSITION DISEASE
8) Add E11.49 (Type 2 diabetes mellitus with other diabetic neurological complication) and E11.59 (Type 2 diabetes mellitus with other circulatory complications) and E11.628 (Type 2 diabetes mellitus with other skin complications) to line 169 PREVENTIVE FOOT CARE IN HIGH RISK PATIENTS
9) Remove 27175-27185 (Treatment of slipped femoral epiphysis) from lines 431 ACUTE PERIPHERAL MOTOR AND DIGITAL NERVE INJURY and 508 PERIPHERAL ENTHESOPATHIES
10) Add 96904 (Whole body integumentary photography, for monitoring of high risk patients with dysplastic nevus syndrome or a history of dysplastic nevi, or patients with a personal or familial history of melanoma) to lines 234 MALIGNANT MELANOMA OF SKIN, 280 CANCER OF SKIN, EXCLUDING MALIGNANT MELANOMA and 631 BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES
11) Remove 96904 from lines 60, 217, 363, 378, 413, 430, 493, 525, 535, 536, 544 and 548
12) Add roseacea ICD-10 diagnosis codes to line 525 ROSACEA; ACNE and remove from line 507 ERYTHEMATOUS CONDITIONS
    a. L71.1 Rhinophyma
    b. L71.8 Other rosacea
    c. L71.9 Rosacea, unspecified
13) Remove CPT 11450-11471 (Excision of skin and subcutaneous tissue for hidradenitis) from lines 378 ACNE CONGLOBATA (SEVERE CYSTIC ACNE), 525 ROSACEA; ACNE and 631 BENIGN NEOPLASMS OF SKIN AND OTHER SOFT TISSUES

14) Add E50.0-E50.3 (Vitamin A deficiency with conjunctival or corneal xerosis) to line 122 NUTRITIONAL DEFICIENCIES and remove from line 456 EXOPHTHALMOS AND CYSTS OF THE EYE AND ORBIT
15) Add E50.3 (Vitamin A deficiency with corneal ulceration and xerosis) to line 249 CORNEAL ULCER; SUPERFICIAL INJURY OF EYE AND ADNEXA
16) Remove E50.5 (Vitamin A deficiency with night blindness) from line 455 DISORDERS OF REFRACTION AND ACCOMMODATION

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

- **Topic: 2018 Biennial Review—Newborn Line Merging**

Discussion: Smits reviewed the meeting handout with updated staff recommendations for merging various newborn condition lines. The subcommittee generally agreed with all the staff recommendations. The merging of various hematologic conditions was deemed too complicated and liable to have unintended consequences. The changes were accepted as recommended by staff, but the suggested hematologic line changes were not accepted and staff was directed to not pursue this question further.

Recommended Actions:

1) Effective October 1, 2016
    a. Remove P54.0 (Neonatal hematemesis) from the dysfunction lines (lines 75, 297, 350 and 382) and keep only on line 296 ADRENAL OR CUTANEOUS HEMORRHAGE OF FETUS OR NEONATE
    b. Remove P55 (Hemolytic disease of newborn) from the dysfunction lines (lines 75, 297, 350 and 382) and keep only on line 106 HEMOLYTIC DISEASE DUE TO ISOIMMUNIZATION, ANEMIA DUE TO TRANSPLACENTAL HEMORRHAGE, AND FETAL AND NEONATAL JAUNDICE
    c. Add the following codes found only on the dysfunction lines to line 2 BIRTH OF INFANT and remove from the dysfunction lines (lines 75, 297, 350 and 382)
        i. P05.01-P05.08, P05.11-P05.2 Newborn light for gestational age
    d. Remove E80.4-E80.8 from line 106 HEMOLYTIC DISEASE DUE TO ISOIMMUNIZATION, ANEMIA DUE TO TRANSPLACENTAL HEMORRHAGE, AND FETAL AND NEONATAL JAUNDICE and add to line 64 METABOLIC DISORDERS to match similar diagnoses.
        i. E80.4 Gilbert syndrome
        ii. E80.5 Crigler-Najjar syndrome
        iii. E80.6 Other disorders of bilirubin metabolism
        iv. E80.7 Disorders of bilirubin metabolism, unspecified
    e. Remove P54.1-P54.3 from line 106 HEMOLYTIC DISEASE DUE TO ISOIMMUNIZATION, ANEMIA DUE TO TRANSPLACENTAL HEMORRHAGE, AND

FETAL AND NEONATAL JAUNDICE and add to line 60 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE

i. P54.1 Neonatal melena
ii. P54.2 Neonatal rectal hemorrhage
iii. P54.3 Other neonatal gastrointestinal hemorrhage
iv. Line 60 contains all endoscopy and other treatment codes as well as NICU codes

2) Make the biennial review changes to lines effective January 1, 2018 as noted in Appendix B.

MOTION: To approve the recommendations in the meeting handout material as amended. CARRIES 6-0.

- **Topic: Diaphragmatic hernia**

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

Recommended Actions:

1) Add ICD-10 K44.0 (Diaphragmatic hernia with obstruction, without gangrene) and K44.1 (Diaphragmatic hernia with gangrene) to line 172 COMPLICATED HERNIAS; UNCOMPLICATED INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER; PERSISTENT HYDROCELE and remove from line 385 ESOPHAGITIS; ESOPHAGEAL AND INTRAESOPHAGEAL HERNIAS
2) Add the CPT codes for repair of complicated diaphragmatic hernia to line 172 and remove from line 385
    a. 39503 Repair, neonatal diaphragmatic hernia, with or without chest tube insertion and with or without creation of ventral hernia
    b. 39540 Repair, diaphragmatic hernia (other than neonatal), traumatic; acute
    c. 39541 Repair, diaphragmatic hernia (other than neonatal), traumatic; chronic
    d. 39560 Resection, diaphragm; with simple repair (eg, primary suture)
    e. 39561 Resection, diaphragm; with complex repair (eg, prosthetic material, local muscle flap)
3) Change the line title for line 385
    a. Condition: ESOPHAGITIS; GERD~~; ESOPHAGEAL AND INTRAESOPHAGEAL HERNIAS~~

MOTION: To approve the code change recommendations. CARRIES 6-0.

- **Topic: Intracranial stenting and angioplasty for atherosclerosis**

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

Recommended Actions:

1) Remove 61630 (Balloon angioplasty, intracranial (eg, atherosclerotic stenosis), percutaneous) from line 200 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN and place on the Services Recommended for Non-Coverage Table
2) Affirm placement of 61635 (Transcatheter placement of intravascular stent(s), intracranial (eg, atherosclerotic stenosis), including balloon angioplasty, if performed) on the Services Recommended for Non-Coverage Table

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

- **Topic: Balloon dilation of intracranial vasospasm**

Discussion: Smits reviewed the summary document. There was discussion about the HERC policy for removing a service from the Prioritized List. The current algorithm does not include evidence of harm as a criterion. The subcommittee recommended that harm be taken into account and that HERC staff formulate a new policy for the website. The subcommittee determined that balloon dilation of intracranial vasospasm should be removed from the List due to evidence of harm and placed on the Services Recommended for Non-Coverage Table.

Recommended Actions:

1) Remove CPT 61640-61642 Balloon dilation of intracranial vasospasm, percutaneous) from line 200 SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN and place on the Services Recommended for Non-Coverage Table

MOTION: To approve the coding changes listed as "option 1" in the meeting materials. CARRIES 6-0.

- **Topic: Hormone requirements for chest surgery in the gender dysphoria guideline/other gender dysphoria issues**

Discussion: Smits reviewed the summary of the topic in the meeting materials. Testimony was heard from Dr. Megan Bird, MD and Amy Penkin, MSW regarding their support for removing hormone therapy as a prerequisite for breast/chest surgery. Williams raised a question about what would constitute a non-medical contraindication to hormone prior to breast/chest surgery. Bird responded that patients have various reasons not to take hormones such as nausea, emotional problems, exacerbation of mental illness, or identification as gender neutral and therefore not wanting to take hormones at all. The subcommittee later debated the hormone requirement prior to breast or chest surgery. Hodges argued that breast augmentation needs estrogens for optimal outcomes, and stated

she was uncomfortable with the idea of allowing patients to opt out of hormone therapy on the basis of preference without contraindication or intolerance. Wentz was concerned about the equity of requiring trials of drugs prior to procedures for other conditions (such as requiring a trial of OCPs prior to hysterectomy for menorrhagia) but not requiring a trial of a drug prior to a chest/breast procedure for this condition. Bird argued that there was an ethical issue with not allowing patients to access a needed therapy based on refusal of one particular therapy. The final decision was that patients should be allowed to opt out of hormone therapy prior to breast or chest surgery, and additional wording was added to the requirement for estrogen prior to mammoplasty which allowed "intolerance or patient refusal" as allowable indications for not requiring hormones. Smits pointed out that this basically made the estrogen before mammoplasty clause have the only binding effect of disallowing surgery if a patient reaches Tanner stage 5 with estrogens alone; this was felt to be fine as such a patient would have, by definition, adequate adult female breast tissue and any issues with size will then be cosmetic only.

There was minimal discussion about the staff proposal to remove the requirement for living as the desired gender for 1 year prior to chest surgery. The experts advocated for removing this requirement as a safety issue. It was pointed out that there was already a clause that would exempt a patient from this requirement if two providers documented that it was a safety issue. The staff proposed change was not accepted.

Bird testified regarding the use of laser for hair removal. She stated that laser treatment can permanently eliminate dark hair and therefore reduce the need for electrolysis and the amount of time for treatment. A typical treatment regimen is 4-6 months of laser (separate by 4-6 weeks due to hair growth cycles for each area), then followed up with electrolysis for any non-responding hair. Hodges raised concerns that laser hair removal may not be permanent and asked the experts whether electrolysis would be sufficient for the Prioritized List coverage. The experts responded that electrolysis coverage would be enough to allow surgical site preparation, but that laser allows faster treatment and is less painful. The subcommittee asked the experts for guidance regarding what is a standard need for a hair removal regimen, but the experts felt that hair removal was very individualized and could not recommend guidelines. The decision was made to add laser hair removal as an option.

Williams asked if the experts were seeing requests for revisions which were being denied, and the reasons for the denials. Bird replied that standard types of surgical complications such as fistulas have the repair of the fistula covered, but not subsequent reconstruction that might be required (new donor sites not covered, larger procedures not covered). The experts have also seen denials for chronic pain, revisions of older procedures like silicone injections that need removal, etc. Williams asked about what constitutes chronic pain. Bird replied pain can result from scarring, pulling, or other wound/healing issues. The clause regarding revisions to surgeries was accepted, with additional wording that the complication must be directly related to the surgery.

Bird had concerns about requiring tobacco cessation prior to genital surgery. Vaginoplasty has a high rate of failure with smoking, higher than other types of gender conforming surgeries like hysterectomy. The subcommittee debated including a requirement for smoking cessation in the gender dysphoria guideline, or referring to gender dysphoria procedures in the more general tobacco cessation for elective surgery guideline yet to be established. The decision was to have the restrictions in the elective surgery guideline. There was discussion about whether the restriction should be for cessation at 4 weeks, 6 weeks, or 8 weeks prior to surgery. Bird noted that the best outcomes for hysterectomy were with 8 weeks of cessation, but that the abstinent period required for best outcomes was different with different genital surgeries.

The recommended addition of pelvic physical therapy to the gender dysphoria guideline was discussed. There was a discussion about adding the PT included in this guideline to the totals referenced in GN 6 REHABILITATIVE THERAPIES. The subcommittee agreed with this change and wording was added to reference GN6 in the gender dysphoria guideline. It was noted that urinary incontinence has PT in its treatment guideline that is not referenced in GN6, and staff was instructed to propose adding this line/guideline to GN6.

Recommended Actions:

1) Modify GN 127, GENDER DYSPHORIA as shown in Appendix A
2) Add laser hair removal for surgical site preparation (CPT 17110, 17111) to line 317 GENDER DYSPHORIA
    a. 17110: Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; up to 14 lesions
    b. 17111: 15 or more lesions
3) Add pelvic physical therapy to line 317 GENDER DYSPHORIA
    a. 97001 Physical therapy evaluation
    b. 97002 Physical therapy re-evaluation
    c. 97110 Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
    d. 97140 Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes
    e. 97530 Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes
4) Staff to review a tobacco cessation requirement for vaginoplasty as part of the larger tobacco smoking and elective procedures guideline still under discussion

MOTION: To approve the recommendations as amended. CARRIES 6-0.

- **Topic: Acupuncture for tobacco cessation**

  This topic was tabled until the May, 2016 VBBS meeting.

- **Topic: Hyperbaric oxygen**

  This topic was tabled until the May, 2016 VBBS meeting.

- **Topic: Pectus excavatum and pectus caravatum**

  Discussion: Smits reviewed the summary document and staff recommendations.

  Dr. Ruscher testified that pectus excavatum (PE) results in cardiac impairment and exercise impairment in many children. She requested addition of coverage of treatment of PE for patients meeting certain criteria. She has gotten denials from health plans, which delays surgery to the point where the chest wall is not as elastic and will not respond to surgery as well and results in a more difficult repair. Pectus caravatum (PC) does not have major physiologic effects, but has major physical appearance issues. The treatment of PC is the use of braces, which is not invasive. For bracing, a patient needs a surgery consult, and PT consult and brace fitting. She requested coverage for moderate to severe PC (no accepted scoring system to differentiate severity of the condition exists), and PT coverage including an initial consult and 3 follow-up visits.

  Dr. Zellen testified that PE is the single condition where he hears dramatic thanks from families for the ability of the child to exercise and interact with peers. He noted that brace might need to be altered with breast development in girls, or for breakage, etc for both sexes.

  Wentz asked whether adults with PC have any cardiovascular impacts. Ruscher responded that some adults may have issues if they also have connective tissue disorders. Zellen replied that surgery is very invasive and painful for PE after adolescence, and corrective surgery for PC is a severe surgery not normally done. Therefore the focus is on treatment of adolescents.

  Wentz asked what the efficacy rate is for the use of PC bracing. Ruscher responded that studies show 90% + success rates, which agrees with her clinical experience. Zellen agreed with Ruscher's response.

  Zellen responded to the staff proposed guideline, which required PE to be severe based on the Haller index. This index requires 3D imaging. He and Ruscher do not get this imaging just to confirm clinical findings of severity. This saves money and resources. Both surgeons

recommend allowing expert opinion as an option rather than simply requiring all patients to have an imaging-derived Haller index.

Both Zellen and Ruscher recommended coverage for both PE and PC when there is severe body image disturbance, even with no other cardiac or pulmonary impediments. Pollack felt that severe body disturbance can be a real issue in adolescents.

Williams asked about the harms/complications of PE surgery. Ruscher responded that there has been death reported from bar placed through heart, but that newer surgical techniques elevate the sternum and make other changes to minimize this risk. Other complications include infection (1%), allergic reaction to implant, and bar displaced backwards into the chest. On bar removal, one death has been reported which led to technique change. Recurrence of PE after bar removal is also a risk. Patients might need to limit contact sports while the bar is in place.

The experts recommended not including exercise intolerance as a criteria in the guideline, as many of these kids are not active and cannot get a history and actual testing is expensive (metabolic exercise test) and not a good use of resources.

Williams had issues with including atypical chest pain, exercise limitation, and paradoxical chest movement (without cardiac dysfunction as a result) as criteria for allowing PE surgery.

Coverage for PC was not discussed fully at this meeting; further discussion on coverage of treatment for PC was delayed until the May, 2016 VBBS meeting.

HERC staff was directed to work with the OHP medical directors and Dr. Ruscher and Zellen to rework the proposed guideline for treatment of PE and PC. The VBBS generally felt that PE should be included on a covered line, and also left on an uncovered line, with a guideline to distinguish when it is intended to be covered.

Recommended Actions:

1) Staff will work with experts and CCO Medical Directors to refine guideline wording and bring back for review at the May, 2016 VBBS meeting

- **Topic: Retractile testicles**

This topic was tabled until the May, 2016 VBBS meeting.

- **Topic: Remote imaging for screening and management of retinopathy of prematurity**

This topic was tabled until the May, 2016 VBBS meeting.

- **Topic: Implantable cardiac loop recorders**

  This topic was tabled until the May, 2016 VBBS meeting.

- **Topic: Electric tumor treatment fields for initial treatment of glioblastoma**

  This topic was tabled until the May, 2016 VBBS meeting.

- **Topic: Introduction to issues regarding services for autism and dementia**

  Discussion: Smits reviewed the summary document issues, including the possible removal of autism and dementia diagnosis codes from the dysfunction lines and adding certain procedural codes to the autism and dementia specific lines as the Commission deems fit. Coffman reviewed various legal issues around limiting physical therapy (PT) and occupational therapy (OT) and speech services in GN6 REHABILITATIVE SERVICES, including a recent brief on the topic from the Oregon Department of Justice (DOJ).

  Testimony was heard from Brenna Legaard regarding her successful lawsuit against Providence Health Plan for violation of the Mental Health Parity Act in terms of that plan's limitations to PT/OT/speech services for her autistic child. She disagrees with the Department of Justice brief that PT/OT are physical health benefits. She stated that the law determines that a medical service is a mental health benefit based on the nature of the disorder you are treating. Autism is a mental health disorder and therefore PT/OT are mental health treatments and subject to parity. The Oregon Insurance Division has published guidance on this topic that applies to private insurers but not to OHP, which she provided to the subcommittee for review. She feels that OHP cannot cap therapies intended to treat mental health conditions. Furthermore, she said EPSDT requires all medical necessary PT/OT to treat medical and mental health conditions to children.

  Tobi Rates, the Executive Director of the Autism Society of Oregon and parent of 2 children with autism spectrum disorder, provided testimony. She stated that the current limit of PT/OT/speech of 30 visits per year is not sufficient to meet many children's needs. She feels that this is not morally or legally right, and not good long term fiscal policy because of the long-term costs of treating children who are not given adequate services.

  Dan Unumb, an attorney from Autism Speaks, testified that mental health parity does apply to PT/OT services for mental health conditions and requested the removal of limits on these services when treating mental health conditions. He also feels that age limits for ABA violates mental health parity. EPSDT mandates all medically necessary care to ameliorate developmental physical or mental deficits for children under 21. He read the DOJ judgment

as saying that OHP can limit services by not pairing them on the Prioritized List, but once a service is paired to a mental health condition, OHP cannot put a numerical cap on services. He stated that Oregon is the only state that has limits on PT/OT/speech for medically necessary services.

Pollack raised questions about the definition/meaning of mental health parity.

Wentz asked the experts what the amount of unmet need they estimated existed among Medicaid children. The experts could not put a numerical number on the unmet need, but felt that for some children, the numerical cap did create unmet need. Not all children need more than 30 or 60 PT/OT/speech visits in a year.

This topic was informational only and no significant discussion by the subcommittee occurred and no decisions were made.

Recommended Actions:

1) Staff will continue to work with the Department of Justice and with OHA leadership for guidance on this topic and will bring back to the May, 2016 VBBS meeting.

- **Topic: Coverage Guidance— Skin substitutes for chronic skin ulcers**

Discussion: Obley reviewed the evidence summary and public comment. Livingston highlighted the key discussion points at EbGS (quality of evidence, late breaking studies, reimbursement issues, prerequisites for surgery). She addressed the challenges with estimating average costs of the use of skin substitutes. Livingston reviewed the proposed changes to the Prioritized List based on the draft Coverage Guidance box language. The subcommittee decided to include the full table of those skin substitutes that were recommended/not recommended and including information about a maximum number of applications. Pollack asked why the additional skin substitutes available in the US were not reviewed and Obley clarified that these were included based on the AHRQ systematic review. Livingston discussed that Washington has made a different decision about coverage that may have been influenced by the cost, to which Obley clarified that Washington is rereviewing this topic currently. Williams questioned whether the low evidence was sufficient to justify coverage on the Prioritized List. Livingston and Obley clarified that very low evidence lead to noncoverage recommendations, and that even with low quality evidence it is possible to derive a strong recommendation for coverage. Hodges clarified that those skin substitutes that are recommended by EbGS have at least low quality evidence.

Recommended Actions:

1) Approve proposed guideline note language edits. Include within the guideline note the list of included/not included skin substitutes and the maximum application language (for those skin substitutes that will be included on the Prioritized List).

MOTION: To approve the recommended changes to the Prioritized List based on the Draft Skin Substitutes for Chronic Skin Ulcers Coverage Guidance scheduled for review by HERC. CARRIES 6-0.

- **Topic: Coverage Guidance— Metabolic and bariatric surgery**

Discussion: Staff discussed that no decision needed to be made about the draft Coverage Guidance at this meeting; rather, the intent was to understand subcommittee concerns prior to revisiting this topic with the Obesity Task Force. Obley presented the evidence and public comment. Livingston highlighted key discussion points of the HTAS and Obesity Task Force Phase 1 meeting. Specifically the recommended language on reoperations was discussed in detail. Hodges raised the concern about possible decreased success rates in subsequent operations if the first one was a failure. Additionally, concerns were raised about covering reoperations when there are significant capacity concerns for the OHP population. Obley clarified that the evidence is low quality, and most comes from case series.

The subcommittee raised the question about whether to cover gastric banding at all. Dr. Valerie Halpin clarified that it would be very rare to offer gastric banding, and only after a lot of counseling that a bariatric surgeon would recommend it.

Recommended Actions:

1) The Obesity Task Force to continue discussions, but consider the concerns about reoperation and banding in their deliberations.

- **Public Comment:**

Public comment was received from Rebekah Brewis, Executive Director of PDX TransPride. She requested coverage for facial feminization surgery, which is an access barrier and is a safety issue. She testified to her own difficulties in accessing these services. She noted that New York covers these services due to a legal decision that is was discriminatory based on gender and sexual orientation.

- **Issues for next meeting:**
  - Pectus excavatum and pectus carnitatum
  - Rehabilitative services for autism and dementia
  - Tobacco cessation and elective surgery
  - Acupuncture for tobacco cessation
  - Hyperbaric oxygen
  - Ventral hernias
  - Hypospadias
  - Retractile testicles
  - Remote imaging for screening and management of retinopathy of prematurity
  - Implantable cardiac loop recorders
  - Electric tumor treatment fields for initial treatment of glioblastoma

- **Next meeting:**

  May 19, 2016 at Clackamas Community College, Wilsonville Training Center, Wilsonville Oregon, Rooms 111-112.

- **Adjournment:**

  The meeting adjourned at 1:25 PM.

Appendix A

Revised Guideline Notes

GUIDELINE NOTE 127, GENDER DYSPHORIA

Line 317

Hormone treatment with GnRH analogues for delaying the onset of puberty and/or continued pubertal development is included on this line for gender questioning children and adolescents. This therapy should be initiated at the first physical changes of puberty, confirmed by pubertal levels of estradiol or testosterone, but no earlier than Tanner stages 2-3. Prior to initiation of puberty suppression therapy, adolescents must fulfill eligibility and readiness criteria and must have a comprehensive mental health evaluation. Ongoing psychological care is strongly encouraged for continued puberty suppression therapy.

Cross-sex hormone therapy is included on this line for treatment of adolescents and adults with gender dysphoria who meet appropriate eligibility and readiness criteria. To qualify for cross-sex hormone therapy, the patient must:

1. have persistent, well-documented gender dysphoria
2. have the capacity to make a fully informed decision and to give consent for treatment
3. have any significant medical or mental health concerns reasonably well controlled
4. have a comprehensive mental health evaluation provided in accordance with Version 7 of the World Professional Association for Transgender Health (WPATH) Standards of Care (www.wpath.org).

Sex reassignment surgery is included for patients who are sufficiently physically fit and meet eligibility criteria. To qualify for surgery, the patient must:

1. have persistent, well documented gender dysphoria
2. for genital surgeries, have completed twelve months of continuous hormone therapy as appropriate to the member's gender goals unless hormones are not clinically indicated for the individual
3. have completed twelve months of living in a gender role that is congruent with their gender identity unless a medical and a mental health professional both determine that this requirement is not safe for the patient
4. have the capacity to make a fully informed decision and to give consent for treatment
5. have any significant medical or mental health concerns reasonably well controlled
6. for breast/chest surgeries, have one referral from a mental health professional provided in accordance with version 7 of the WPATH Standards of Care.
7. For genital surgeries, have two referrals from mental health professionals provided in accordance with version 7 of the WPATH Standards of Care.

Electrolysis (CPT 17380) and laser hair removal (CPT 17110, 17111) are ~~is~~ only included on this line ~~for surgical site electrolysis~~ as part of pre-surgical preparation for chest or genital surgical procedures also included on this line. ~~It is~~ These procedures are not included on this line for

facial or other cosmetic procedures or as pre-surgical preparation for a procedure not included on this line.

Mammoplasty (CPT 19316, 19324-19325, 19340, 19342, 19350, 19357-19380) is only included on this line when 12 continuous months of hormonal (estrogen) therapy has failed to result in breast tissue growth of Tanner Stage 5 on the puberty scale OR there is any ~~a medical~~ contraindication to, intolerance of or patient refusal of hormonal therapy.

Revisions to surgeries for the treatment of gender dysphoria are 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.

Pelvic physical therapy (CPT 97001, 97001, 97110, 97140, and 97530) is included on this line only for pre- and post-operative therapy related to genital surgeries also included on this line and as limited in guideline note 6 REHABILITATIVE THERAPIES.

Appendix B
Biennial List Line Changes

Merge lines 17 VERY LOW BIRTH WEIGHT (UNDER 1500 GRAMS) and 23 LOW BIRTH WEIGHT (1500-2500 GRAMS) as shown below:

- Add P10.2 (Intraventricular hemorrhage due to birth injury), P10.3 (Subarachnoid hemorrhage due to birth injury), P52.00-P52.3 (Intraventricular (nontraumatic) hemorrhage of newborn), P52.5 (Subarachnoid (nontraumatic) hemorrhage of newborn) to line 34 SEVERE BIRTH TRAUMA FOR BABY and do not add to the new merged premature baby line
- Rename line 34 SEVERE BIRTH TRAUMA FOR BABY; INTRAVENTRICULAR HEMORRHAGE

Line: **17**
Condition: LOW BIRTH WEIGHT; PREMATURE NEWBORN (See Guideline Notes 64,65)
Treatment: MEDICAL THERAPY
ICD-10: P07 (Disorders of newborn related to short gestation and low birth weight), P83.0 (Sclerema neonatorum)
CPT: 94772,96154,97802-97804,98966-98969,99051,99060,99070,99078,99184, 99201-99239,99281-99285,99291-99404,99408-99416,99429-99449, 99468-99480,99487-99498,99605-99607
HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467

Line prioritization (scores are for line 17; line 23 scores in parentheses)
Category: 1 (1)
Healthy life years: 10 (7)
Suffering: 5 (2)
Population effects: 0 (0)
Vulnerable population: 1 (1)
Tertiary prevention:
Effectiveness: 3 (5)
Need for treatment: 1 (0.8)
Net cost: 0 (2)
Score: 4800 (4000)
Line placement: 17 (23)

Appendix B
Biennial List Line Changes

Merge lines 15 CONGENITAL INFECTIOUS DISEASES and 16 CONGENITAL SYPHILIS as shown below

Line: 15
Condition: CONGENITAL INFECTIOUS DISEASES (See Guideline Notes 64,65)
Treatment: MEDICAL THERAPY
ICD-10: A50 (Congenital syphilis), P35.0-P35.9 (Congenital viral diseases),P37.0-P37.4,P37.8-P37.9 (Other congenital infections and parasitic diseases)
CPT: 96154 (Health and behavior intervention, each 15 minutes, face-to-face; family—unique to line 15),98966-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99416,99429-99449,99468-99480,99487-99498,99605-99607
HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467

Line prioritization (scores are for line 15; line 16 scores in parentheses)
Category: 1 (1)
Healthy life years: 9 (8)
Suffering: 3 (3)
Population effects: 0 (1)
Vulnerable population: 0 (1)
Tertiary prevention:
Effectiveness: 4 (4)
Need for treatment: 1 (1)
Net cost: 4 (2)
Score: 4800 (4800)
Line placement: 15 (16)

Merge lines 21 SYNDROME OF "INFANT OF A DIABETIC MOTHER" AND NEONATAL HYPOGLYCEMIA, 35 NEONATAL THYROTOXICOSIS, and 45 HYPOCALCEMIA, HYPOMAGNESEMIA AND OTHER ENDOCRINE AND METABOLIC DISTURBANCES SPECIFIC TO THE FETUS AND NEWBORN as shown below

- Add P70.2 (Neonatal diabetes mellitus) to the new line and remove from line 36 HEMATOLOGICAL DISORDERS OF FETUS AND NEWBORN
- Add P72.2 (Other transitory neonatal disorders of thyroid function, not elsewhere classified) to the new line and remove from line 13 CONGENITAL HYPOTHYROIDISM

Appendix B
Biennial List Line Changes

Line: ~28
Condition: ENDOCRINE AND METABOLIC DISTURBANCES SPECIFIC TO THE FETUS AND NEWBORN (See Guideline Notes 64,65)
Treatment: MEDICAL THERAPY
ICD-10: P70 (Transient neonatal disorders of carbohydrate metabolism specific to newborn), P71 (Transitory neonatal disorders of calcium and magnesium metabolism), P72.1 (Transitory neonatal hyperthyroidism), P72.2 (Other transitory neonatal disorders of thyroid function, not elsewhere classified), P72.8 (Other specified transitory neonatal endocrine disorders), P72.9 (Transitory neonatal endocrine disorder, unspecified), P74 (Other transitory neonatal electrolyte and metabolic disturbances)
CPT: 96154 (Health and behavior intervention, each 15 minutes, face-to-face; family—unique to line 45),98966-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99416,99429-99449,99468-99480,99487-99498,99605-99607
HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467

Line prioritization (scores are proposed by staff; current line scores shown in parentheses)
Category: 1 (1, 6, 1)
Healthy life years: 6 (6; 8; 5)
Suffering: 1 (1; 3; 1)
Population effects: 0 (0; 0; 0)
Vulnerable population: 0 (1; 0; 0)
Tertiary prevention: NA (NA; 5; NA)
Effectiveness: 5 (5; 5; 5)
Need for treatment: 1 (1; 1; 1)
Net cost: 4 (4; 5; 3)
Score: 3500 (4000; 3300; 3200)
Line placement: approximately 28 (21; 35; 45)

Restructure line 22 OMPHALITIS OF THE NEWBORN AND NEONATAL INFECTIVE MASTITIS

- Add the following codes found only on the dysfunction lines to line 22
  - P39.3 Neonatal urinary tract infection
  - P39.4 Neonatal skin infection
  - P39.8 Other specified infections specific to the perinatal period
- Add P39.9 (Infection specific to the perinatal period, unspecified) to line 22 and remove from the dysfunction lines and line 186 SEPTICEMIA
- Remove all codes found on line 22 from the four dysfunction lines (lines 75, 297, 350 and 382)
  - P38, P39.0, P39.3, P39.4, P39.8. P39.9

Appendix B
Biennial List Line Changes

- Rename line 22 ~~OMPHALITIS OF THE NEWBORN AND NEONATAL INFECTIVE MASTITIS~~ NEONATAL INFECTIONS OTHER THAN SEPSIS
- Rescore line 22 as shown below

Line: **22 (which will move to ~40)**
Condition: ~~OMPHALITIS OF THE NEWBORN AND NEONATAL INFECTIVE MASTITIS~~ NEONATAL INFECTIONS OTHER THAN SEPSIS (See Guideline Notes 64,65)
Treatment: MEDICAL THERAPY
ICD-10: P38.1-P38.9 (Omphalitis),P39.0 (Neonatal infective mastitis), P39.3 (Neonatal urinary tract infection), P39.4 (Neonatal skin infection), P39.8 (Other specified infections specific to the perinatal period), P39.9 (Infection specific to the perinatal period, unspecified)
CPT: 98966-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99416,99429-99449,99468-99480,99487-99498,99605-99607
HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,G0463,G0466,G0467

Line prioritization (scores are staff recommended; current scoring in parentheses)
Category: 1 (1)
Healthy life years: 5 (7)
Suffering: 1 (1)
Population effects: 0 (0)
Vulnerable population: 0 (0)
Tertiary prevention:
Effectiveness: 5 (5)
Need for treatment: 1 (1)
Net cost: 2 (3)
Score: 3000 (4000)
Line placement: 40 (22)

MINUTES

Evidence-based Guidelines Subcommittee

Clackamas Community College
Wilsonville Training Center, Rooms 111-112
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
April 7, 2016
2:00-5:00pm

Members Present: Wiley Chan, MD, Chair; Eric Stecker, MD, MPH, Vice-Chair (by phone); Beth Westbrook, PsyD; George Waldmann, MD (by phone); Alison Little, MD, MPH; Kim Tippens, ND, MPH.

Members Absent: None

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

Also Attending: Adam Obley, MD, Moira Ray, MD, MPH and Craig Mosbaek (OHSU Center for Evidence-based Policy); Erica Pettigrew, MD (OHSU); Charles Bentz, MD and Duncan Neilson, MD (Legacy Health); Kim Wentz, MD (by phone) and Jessie Little (OHA); Joanne Rogovoy (March of Dimes), Maria Rodriguez (OHSU), Emily Elman (OHA Public Health).

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1. CALL TO ORDER

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

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2. MINUTES REVIEW

No changes were made to the February 4, 2016 minutes.
Minutes approved 6-0.

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3. STAFF REPORT

Coffman welcomed Tippens to the subcommittee. She introduced herself as a naturopath and acupuncturist. She is an assistant professor at the National College of Natural Medicine. She will be serving on HERC as well.

Coffman reported that the HERC has referred the draft coverage guidance on Skin Substitutes for Chronic Skin Ulcers back to EbGS and requested that it be put out for an additional public comment period. This coverage guidance will come back to the subcommittee at its June meeting.

4. DRAFT COVERAGE GUIDANCE: Timing of Long-Acting Reversible Contraceptive (LARC) Placement

Ray reviewed the draft coverage guidance and evidence as presented in the meeting materials. Coffman introduced Maria Rodriguez as appointed expert on the topic. She is an assistant professor at OHSU in the Obstetrics & Gynecology/Generalist Division. Her research has focused on the evaluation and monitoring of family planning programs, including reproductive health outcomes and disparities among the Medicaid Population. She has received research funding from the National Institutes of Health as a Women's Reproductive Health Research Fellow. She has consulted for the World Health Organization. She has been trained as a trainer for Nexplanon insertions.

Livingston also invited Dr. Duncan Neilson to participate as he is familiar with the topic and was already present in preparation for the upcoming discussion of Tobacco Cessation During Pregnancy. Dr. Duncan Neilson is Clinical Vice President, Legacy Health System, Portland. His responsibilities include program development in Women's Services, Quality and Patient Safety measurement and program implementation. He has served in the past as clinical vice president of Legacy's Women's Services and Surgical Services. He has served the commission as an expert on previous obstetric-related topics, including Out-of-Hospital Birth and Elective Induction of Labor.

Chan asked what the comparison was for the observational study which reported higher perforation among women who had delayed insertion and who were breastfeeding. Ray said that the study followed women over time and collected baseline data as well as information about expulsion events, perforation events and other adverse events, then looked retrospectively to find risk factors for the adverse events. Breastfeeding was found to be an independent risk factor for perforation over other factors like nulliparity and recent pregnancy. Chan said that breastfeeding is clearly correlated with time after delivery, but Ray said she believes the association was stronger than one would expect even given that fact.

Waldmann asked why breastfeeding would be associated with a higher risk than immediate postpartum status. Ray explained that it is believed to be related to hormonal changes affecting the uterus after delivery, and that six weeks postpartum is a vulnerable time; Neilson and Rodriguez confirmed this understanding. Rodriguez said it could also be that the placement was guided by ultrasound in the postpartum setting but not in the outpatient setting at 6 weeks. Chan said it may just be time after delivery rather than breastfeeding that is the major risk factor.

Livingston reviewed the resource allocation, values and preferences and other factors influencing the recommendation in the GRADE table. She also explained that despite lack of evidence specific to the timing question, there is CDC guidance saying that it is appropriate to place an implant postpartum or post abortion.

Little asked about the administrative issues surrounding reimbursement for these services. Staff recognized that with this intervention, ensuring appropriate reimbursement is key as the devices are expensive and providers can't be expected to stock them and pay for them if not reimbursed. Neilson shared of his experience at Legacy where they started offering LARC immediately postpartum, but were asked by administrators to stop because it was cost-prohibitive. This is because the global rate for delivery paid to a hospital isn't adjusted as a matter of course if a LARC is placed. He said that there are two separate issues—device manufacturers charging providers hundreds of dollars for a simple device

costing under two dollars to the manufacturer, and insurance companies failing to reimburse providers for their acquisition costs for the devices. Ray said that some states use outpatient billing to pay, while others do a periodic query of their claims data and make an extra payment to reimburse for LARC. Waldmann asked about using a modifier on professional claims. Others stated that there are ways of getting reimbursement for professional services; the issue is paying for the device itself.

Kim Wentz spoke about research she and Oregon Health Plan staff have been doing on reimbursement for LARC devices in the inpatient setting. There are three methods used by 18 states. She believes there are ways for the Oregon Health Plan to pay for these devices, along with their insertion, in all settings, but they need to be implemented. Rodriguez said OHSU has been providing postpartum LARC to uninsured women because of a charitable gift, but that they haven't been available for insured women because of the reimbursement issues. They have not had success getting reimbursement for these devices after discussions with state officials and legislators. The hospital has been donating the physician services, which are fairly minimal in the postpartum setting.

Livingston said that this coverage guidance will advance efforts to get health plans to pay for these devices in all setting. Waldmann said this shouldn't be difficult and that he doesn't understand why we can't solve this problem. Westbrook and Little also expressed support for the coverage guidance. Little requested a separate document to address implementation issues and motivate policymakers to find a solution. Livingston said that Wentz is already beginning some of these discussions now, even though the coverage guidance wouldn't be officially implemented until January for the Oregon Health Plan. The hope is that by January there will be a clear plan.

The subcommittee discussed various options for emphasizing that both the device and insertion should be reimbursed appropriately and bureaucratic barriers addressed. They considered adding language to the recommendation box but decided that this policy aspect should be kept separate from the evidence-based report. Several members and attendees expressed frustration that this issue has not been solved in Oregon despite a lack of philosophical opposition. Livingston directed the subcommittee's attention to sections of the coverage guidances which do address payment and administrative issues.

After discussion the subcommittee requested that staff draft a cover letter to accompany the report, addressing implementation issues and barriers to reimbursement, and describing the administrative issues in the coverage guidance more thoroughly. Waldmann specifically requested that the cover letter address the hospital's discontinuation of postpartum LARC placement as described by Neilson.

Because of an issue with posting sources, the subcommittee deferred voting on the draft coverage guidance until its June meeting**.**

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5. DRAFT COVERAGE GUIDANCE: Tobacco Cessation During Pregnancy

Livingston introduced the report, reminding the subcommittee that this is the first evidence-based report to include multisector interventions (which may occur outside of the clinical setting, and not require any coverage changes from health plans, but nonetheless be effective ways of achieving health outcomes). Staff ran into challenges with the subcommittee's request to separate the document into two separate reports, and so has kept the report together as shown in the meeting materials.

Coffman introduced Dr. Charles Bentz who is the appointed expert on this topic. He is a Medical Director and Professor at the Pacific University College of Health Professions and is in private practice at Fanno Creek Clinic in Portland. In addition to his clinical and academic work, he has published several articles on tobacco-related topics. He has also worked on tobacco-related quality measurement, smoking cessation programs and reimbursement strategies. He has received funding from the National Institutes of Health, the Robert Wood Johnson Foundation, state health organizations, as well as manufacturers of all tobacco cessation products (including nicotine patches, lozenges, gums and sprays as well as bupropion and varenicline).

Coffman also re-introduced Neilson, who has been appointed as an expert for this topic. Neilson declared no conflicts of interest with respect to this topic.

Bentz said other interventions have been studied, such as provider and health system incentives. He asked why they were not included in the review. Bentz said beyond simply covering services, promoting them in the provider community and providing incentives to providers can be important. Obley said that evidence was not found in the evidence review. Bentz also asked about carbon monoxide as feedback. This was not included in the Cochrane review. Livingston asked whether these would have been included in scope. Obley said they may have been grouped under behavioral interventions. This grouping includes everything from the "Five A's" program advocated by the Centers for Disease Control to more intensive interventions. Bentz said that his practice uses carbon monoxide as feedback and that it is actually helpful. Livingston noted that these interventions could be submitted as public comment. Bentz said some of the studies he is referring to were not conducted in pregnant women, and this may explain why they weren't included. Livingston said we would need evidence in the pregnant population.

Chan asked whether there is any reason to think that most interventions effective in other populations would have differential effectiveness in pregnant women? Obley said that the Patnode review does divide pregnant women from the general adult population. He assumes this is because pregnant women may have been excluded from general population studies. Bentz said that pregnant women can be particularly motivated to quit. Sometimes they spontaneously quit or suspend smoking during the pregnancy. He agreed that the behavioral interventions would work in pregnant women. But in designing interventions for pregnant women you need to think about special issues including relapse after the birth. Bentz said all behavioral interventions are tailored by type of tobacco use and cultural factors and pregnancy is another similar factor.

Coffman noted that the Commission has already approved a statement on multisector interventions for tobacco. He suggested that when implemented on the prioritized list, a special statement about pregnant woment could be added to that section.

Westbrook asked about levels of addiction. Neilson said that interentions would need to be tailored to women based on the number of years they smoked and how much they smoked. For instance, behavioral interventions would more likely be effective in a casual smoker. Both clinicians and researchers are reluctant to do drug research on pregnant patients. Thus the drugs are generally reserved for the most nicotine dependent patients, resulting in a biased population for any research that would be done (that is, the study population would include the most difficult-to-treat patients). However, he also said that more dependent patients generally show a better response to nicotine replacement therapy (NRT), because they have more nicotine receptors. He said that there is a strong dose response for behavioral interventions (more intensive counseling is more effective) and that at any intensity of counseling, NRT doubles the quit rate.

Livingston turned the group's attention to the GRADE table for NRT. Most outcomes showed equivalence, though it showed effectiveness for tobacco abstinence during pregnancy. Ordinarily the staff recommendation might be to recommend noncoverage based on this evidence profile. Federal law, however, requires coverage of medication therapy for tobacco cessation for pregnant women in Medicaid, and the prohibition on prior authorization of tobacco cessation aids in the Affordable Care Act would make it difficult for most commercial insurers to restrict coverage. Based on this, the staff recommendation is for the subcommittee to state that it makes no recommendation for this population.

Bentz said that study designs for tobacco cessation during pregnancy are fatally flawed because of high relapse rates among postpartum women. Most studies weren't designed to include postpartum support. He advocated for coverage because there is no harm and because getting people to quit is the most important thing. Because of the ethical issues around conducting trials in this population, it is unlikely that evidence is likely to change. Neilson agreed.

Chan noted that there is no good evidence that NRT has harms. Obley confirmed this, noting that the studies included the pregnancy outcomes for the purpose of showing that NRT is no more harmful than continued smoking based on these outcomes, not to show a benefit of NRT for these outcomes. Chan asked if a recommendation could be made based on the broader evidence base for NRT in nonpregnant populations. Livingston noted that for the nonpregnant population, the outcomes of interest would be chronic obstructive pulmonary disease, asthma and lung cancer, which is different than the outcomes of interest in the pregnant population. Bentz and Neilson agreed that the population is distinct.

After discussion the subcommittee accepted the lack of recommendation for pharmacologic therapy and changed the recommendation for noncoverage for electronic nicotine delivery devices in pregnant women to a strong recommendation.

The subcommittee affirmed the recommendation for coverage for behavioral interventions with little discussion.

For high feedback ultrasound, the subcommittee discussed the large effect size, balanced by the fact that it is based on a single RCT from 1982 with 129 participants. The subcommittee also discussed that in another context, high feedback ultrasound can be considered coercive, as it is used by abortion opponents to influence women's reproductive choices. Westbrook stated that sometimes this is termed "obstetric violence." Bentz noted that even with carbon monoxide feedback, clinicians need to be careful, or patients can become anxious and not return for care. Livingston noted that concerns about psychological distress appear in the values and preferences column.

After discussion, the subcommittee decided that the context of tobacco smoking is sufficiently different than in the case of counseling about abortion and that in this context, smoking cessation can only improve outcomes for the mother and baby. Obley noted that the GRADE assessment from the Cochrane review was low. Livingston noted that with skin substitutes, low quality evidence was considered sufficient. Bentz noted that the cost would be relatively small cost on top of the existing cost of the ultrasound. After discussion the subcommittee decided to make a weak recommendation for coverage, while noting the age of the study.

The subcommittee accepted staff recommendations for financial incentives, partner support, interventions to reduce secondhand smoke exposure, smoke-free legislation and tobacco excise taxes.

There was discussion about how social supports including partner support are supported by evidence in the general population, but the evidence may not exist in pregnancy. Livingston noted that behavioral interventions are covered in general, it would just be an intervention targeted solely at partner support that would not be recommended.

Bentz suggested adding system-level interventions such as provider and plan incentives, though they are difficult to implement. He said systems interventions may be the most important thing that can be done to increase tobacco cessation. Livingston said we didn't find evidence about these interventions, so evidence that these interventions affect pregnancy-related outcomes would need to be submitted during public comment in order to add statements about them in this document.

The subcommittee discussed options for distinguishing between coverage recommendations and statements on multisector evidence. After discussion the subcommittee agreed to use the current format with different colors to highlight the distinctions between the coverage recommendations and evidence statements on multisector interventions as well as the distinctions between the GRADE tables and evidence tables. Chan requested that staff include an explanation of what a multisector intervention is along with the evidence statement. Staff will also make heading changes to clearly delineate which sections relate to multisector interventions.

After brief additional discussion, the subcommittee decided to remove the description of the effects of the multisector interventions to be consistent with the coverage guidance recommendations.

The subcommittee voted to put the draft coverage guidance (as amended) out for a 30-day public comment period by a vote of 5-0 (Stecker absent).

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6. ADJOURNMENT

The meeting was adjourned at 5:00 pm. The next meeting is scheduled for June 2, 2016 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

Staff Report

Section 3.0

VbBS Issue Summaries

Straightforward Issues—May, 2016

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
H0004	Behavioral health counseling and therapy, per 15 minutes	197 AUTISM SPECTRUM DISORDERS	H0004 appears on the other lines with psychotherapy and other mental health treatments. HSD requested that it be added to the autism line	Add H0004 to line 197
61120	Burr hole(s) for ventricular puncture (including injection of gas, contrast media, dye, or radioactive material)	20 HYDROCEPHALUS AND BENIGN INTRACRANIAL HYPERTENSION	HSD requested that 61120 be paired with G91.9 (Hydrocephalus unspecified). 61120 currently is on lines 51,200,338	Add 61120 to line 20
96155	Health and behavior intervention, each 15 minutes, face-to-face; family (without the patient present)	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	96155 was mistakenly added to line 3 at the March, 2016 VBBS meeting. It should remain Ancillary.	Remove 96155 from line 3
H0038 H2027	Self-help/peer services, per 15 minutes Psychoeducational service, per 15 minutes	125 ABUSE AND NEGLECT	H0038 and H2027 are on most mental health lines, but missing from line 125. A provider requested that they be added. Line 125 has a full set of psychotherapy codes, but does not have psychotherapy in the line treatment description.	Add H0038 and H2027 to line 125 Change the treatment description for line 125 to "MEDICAL/PSYCHOTHERAPY"
Z13.5	Encounter for screening for eye and ear disorders	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	A provider requested Z13.5 be added to line 3 to pair with ophthalmology visit CPT codes. The ICD-9 equivalent (V80.2, screening for eye condition) was on line 3.	Add Z13.5 to line 3 Advise HSD to remove Z13.5 from the Informational File

Straightforward Issues—May, 2016

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
78227	Hepatobiliary system imaging, including gallbladder when present; with pharmacologic intervention, including quantitative measurement(s) when performed		78227 is currently Ancillary; however, it is used for evaluation of diseases of the gallbladder and bile ducts and should be Diagnostic.	Advise HSD to remove 78227 from the Ancillary List and add to the Diagnostic List
12041 12042 13131 13132	Repair, intermediate, wounds of neck, hands, feet and/or external genitalia; 2.5 cm or less 2.6 cm to 7.5 cm Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 1.1 cm to 2.5 cm 2.6 cm to 7.5 cm	1 PREGNANCY	HSD requested that these procedures be added to the pregnancy care line for repair of 3rd degree lacerations after delivery. These codes already appear on a variety of lines.	Add 12041, 12042, 13131, and 13132 to line 1
43653	Laparoscopy, surgical; gastrostomy, without construction of gastric tube (eg, Stamm procedure)		CPT 43653 was placed on the Ancillary List in August, 2013, and then later added mistakenly to line 220 CANCER OF STOMACH. Open gastric tube placement procedures (CPT 43830 and 43832) are Ancillary.	Remove 43653 from line 220 Advise HSD to add 43653 to the Ancillary List.

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
50605 50760, 50780-50785 50860	Ureterotomy for insertion of indwelling stent, all types Ureteroureterostomy Ureterostomy	**25** VESICOURETERAL REFLUX **53** CONGENITAL HYDRONEPHROSIS **91** CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM **184** URETERAL STRICTURE OR OBSTRUCTION; HYDRONEPHROSIS; HYDROURETER	Dr. David Lashley requested that 50605, 50760, 50780-50785, and 50860 be added to various urology lines to pair with various congenital abnormalities of the ureters.	Add CPT 50605 to lines 25, 91, and 184 Add CPT 50760, 50780-50785 and 50860 to lines 53, 91 and 184
92227 92228	Remote imaging for detection of retinal disease (eg, retinopathy in a patient with diabetes) with analysis and report under physician supervision, unilateral or bilateral Remote imaging for monitoring and management of active retinal disease (eg, diabetic retinopathy) with physician review, interpretation and report, unilateral or bilateral	**17** VERY LOW BIRTH WEIGHT (UNDER 1500 GRAMS) **23** LOW BIRTH WEIGHT (1500-2500 GRAMS) **278** RETINOPATHY OF PREMATURITY	Casey Eye Institute requested that 92227 and 92228 be paired with H35.1 (Retinopathy of prematurity) and various prematurity ICD-10 codes. These CPT codes are used for the screening and management of retinopathy of prematurity in premature infants in rural NICUs. 92227 is currently on lines 8, 30, 100, 353, and 365 and 92228 is currently on lines 100, 353, and 365. The American Academy of Pediatrics and the American Academy of Ophthalmology endorse this technology for premature infants.	Add 92227 and 92228 to lines 17, 23, and 278

Straightforward Guideline Note Changes

1) GN33 no longer serves a purpose after GN12 TREATMENT OF CANCER WITH LITTLE OR NO BENEFIT was extensively modified.
    a. HERC staff recommendation: Delete GN33

~~**GUIDELINE NOTE 33, CANCERS OF ESOPHAGUS, LIVER, PANCREAS, GALLBLADDER AND OTHER BILIARY**~~

~~*Lines 319-321,439*~~

~~Retreatment with chemotherapy after failure from the first full course of chemotherapy places the patient in the category of treatment of cancer with little or no benefit. See Guideline Note 12.~~

Back Lines Straightforward Changes

Issue: As HERC staff prepares the new back conditions lines for inclusion on the Prioritized List, several errors and omissions have been identified.

1) Several guidelines need to be associated with the new back lines.
    a. Add lines 351 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS, 366 SCOLIOSIS, 407 CONDITIONS OF THE BACK AND SPINE,532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS to Guideline notes 64 PHARMACIST MEDICATION MANAGEMENT and 65 TELEPHONE AND EMAIL CONSULTATIONS
    b. Add 351, 366, 532 to GL 100 ARTIFICIAL DISC REPLACEMENT and GL 101 ARTIFICIAL DISC REPLACEMENT
    c. Add line 366 to GL 92 ACUPUNCTURE
2) Acupuncture was added to the scoliosis line, but the acupuncture guideline was not modified to reflect this change
3) 62311 (Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal)) was mistakenly not removed from line 407 CONDITIONS OF THE BACK AND SPINE during the discussion of removing epidural steroid injections from the medical back line. The other 2 codes used for ESI were removed. 62311 appears on the dysfunction lines and should remain there for use with antispasmotic medications
4) Changes were made to GN37 in January, 2016. The accepted guideline note did not contain earlier edits made in March 2015.
5) Guideline notes 100 and 101 have not had the appropriate new back conditions lines formally added to them.
6) GN37 needs to be further edited to removed "covered" and replace with "included on this line" to conform with HERC convention

HERC staff recommendations:

EFFECTIVE JULY 1, 2016

1) Remove 62311 (Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal)) from line 407 CONDITIONS OF THE BACK AND SPINE
2) Add lines 351 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS, 366 SCOLIOSIS, 407 CONDITIONS OF THE BACK AND SPINE, 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS to Guideline notes 64 PHARMACIST MEDICATION MANAGEMENT and 65 TELEPHONE AND EMAIL CONSULTATIONS
3) Add lines 351, 366, 532 to GL 100 SMOKING AND SPINAL FUSION and add lines 351 and 532 to GL 101 ARTIFICIAL DISC REPLACEMENT
4) Modify GN92 ACUPUNCTURE as shown below
    a. Provides the same restrictions for acupuncture use for scoliosis as for other back conditions
    b. Correct reference to the coverage guidance
5) Modify GN37 SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS as shown, clarify intent and restore previously approved changes.
6) NOTE: there are changes to the medical back conditions guideline (GN57) in the mechanical traction and TENS portion of the physical therapy modalities review

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,208, 366,407,415,467,543

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

Line 1 PREGNANCY

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

Hyperemesis gravidarum

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

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

Breech presentation

ICD-10-CM: O32.1

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

Back and pelvic pain of pregnancy

ICD-10-CM: O99.89

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

Line 208 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE

Acupuncture is paired with the treatment of post-stroke depression only. Treatments may be billed to a maximum of 30 minutes face-to-face time and limited to 12 total sessions, with documentation of meaningful improvement.

Line 366 SCOLIOSIS

Acupuncture is included on line 366 for pairing with visit limitations as in GUIDELINE NOTE 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE

Line 407 CONDITIONS OF THE BACK AND SPINE

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

Line 415 MIGRAINE HEADACHES

Acupuncture pairs on Line 415 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), for up to 12 sessions.

Line 467 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 467 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions.

*Line 543 TENSION HEADACHES

Acupuncture is included on Line 543 for treatment of tension headaches (ICD-10-CM G44.2), for up to 12 sessions.

The development of this guideline note was informed by a HERC coverage guidance. See See http://www.oregon.gov/oha/herc/Pages/blog-low-back-non-pharmacologic-intervention.aspx

*Below the current funding line.

GUIDELINE NOTE 37, SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS

Lines 351,532

Surgical consultation/consideration for surgical intervention are included on these lines only for patients with neurological complications, defined as showing 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

Spondylolisthesis (ICD-10-CM M43.1, Q76.2) is included on Line 351 only when it results in spinal stenosis with signs and symptoms of neurogenic claudication. Otherwise, these diagnoses are included on Line 532.

Surgical correction of spinal stenosis (ICD-10-CM M48.0) is only included on Line 351 for patients with:

1) MRI evidence of moderate to severe central or foraminal spinal stenosis AND
2) A history of neurogenic claudication, or objective evidence of neurologic impairment consistent with MRI findings.

Otherwise, these diagnoses are included on Line 532. Only decompression surgery is ~~covered~~ included on these lines for spinal stenosis; spinal fusion procedures are not ~~covered~~ included on either line for this diagnosis. ~~Otherwise, these diagnoses are included on Line 532.~~

The following interventions are not ~~covered~~ 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:

- facet joint corticosteroid injection
- prolotherapy
- intradiscal corticosteroid injection
- local injections
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- sacroiliac joint steroid injection
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- radiofrequency denervation
- epidural steroid injections

M99 Diagnoses

Issue: The M99 series of diagnosis codes contains many codes that do not belong on the new back lines, but were placed there during the back line reorganization. HERC staff have worked with Vern Saboe, DC to determine the best placement of these codes.

M99.1 represents an unused diagnosis in modern medicine.

HERC staff recommendation:

1) Remove M99.1 (Subluxation complex (vertebral)) from all current lines and advise DMAP to place on the Undefined List
2) Remove any diagnoses from the M99.8 (Other biomechanical lesions) series from line 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS

ICD-10 Code	Code Description	Current Line	Recommendation
M99.0	Segmental and somatic dysfunction	407 CONDITIONS OF THE BACK AND SPINE	No change
M99.1	Subluxation complex (vertebral)	On various medical lines depending on location	Undefined
M99.2	Subluxation stenosis of neural canal	407 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS	No change
M99.3	Osseous stenosis of neural canal	407, 532	No change
M99.4	Connective tissue stenosis of neural canal	407, 532	No change
M99.5	Intervertebral disc stenosis of neural canal	407, 532	No change
M99.6	Osseous and subluxation stenosis of intervertebral foramina	407, 532	No change
M99.7	Connective tissue and disc stenosis of intervertebral foramina	407, 532	No change
M99.8	Other biomechanical lesions	On various medical lines depending on location Some of these codes also appear on 532	Remove any M99.8 codes from 532
M99.9	Biomechanical lesion, unspecified	663 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	No change

Fitting for Spectacles and Contact Lenses

Question: should the procedure codes for fitting of glasses (spectacles) and contact lenses for general vision purposes be limited to the disorders of refraction and accommodation line?

Question source: HERC staff

Issue: Most of the CPT codes for fitting for spectacles and contact lenses (CPT 92310-92371) are on all the 52 ophthalmology lines. Some of these codes are for fitting glasses and/or contact lenses for specific eye conditions and should be limited to just the line or lines containing that condition. Others are for general issues with refraction and accommodation (near-sightedness, far-sightedness, etc.) and should be limited to the line specific for this condition.

Several of the codes in this series specify use for aphakia, which is the absence of the lens of the eye due to surgical removal, injury, disease or congenital anomaly. Aphakia causes a loss of accommodation and far sightedness (hyperopia). The most common cause of aphakia is cataract removal. Currently aphakia is on line 410 APHAKIA AND OTHER DISORDERS OF LENS.

Several of these codes are for scleral or corneoscleral lenses. These types of contact lenses are used for eye conditions such as keratoconus, or for eyes that have undergone a cornea transplant, and for people with severe dry eyes caused by conditions as the Sjorgren's syndrome or graft-vs-host disease. Keratoconus (ICD-10 H18.6) is on line 315 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA

Specialized glasses are used for the treatment of esotropia and other abnormal eye positioning in children. These diagnoses are found on lines 375 AMBLYOPIA and 399 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN.

A review of paid claims found the vast majority were paired with diagnoses on line 455 DISORDERS OF REFRACTION AND ACCOMMODATION, with some on line 315, 375, 399 and 410. Additionally, some claims were for lenses for cataracts prior to removal, on line 301 CATARACT.

Current ophthalmology lines with contacts and spectacle codes
100 DIABETIC AND OTHER RETINOPATHY
117 CANCER OF EYE AND ORBIT
143 GLAUCOMA, OTHER THAN PRIMARY ANGLE-CLOSURE
159 HERPES ZOSTER; HERPES SIMPLEX AND WITH NEUROLOGICAL AND OPHTHALMOLOGICAL COMPLICATIONS
171 GONOCOCCAL AND CHLAMYDIAL INFECTIONS OF THE EYE; NEONATAL CONJUNCTIVITIS
175 AMEBIASIS
248 PRIMARY ANGLE-CLOSURE GLAUCOMA
249 CORNEAL ULCER; SUPERFICIAL INJURY OF EYE AND ADNEXA
252 RETAINED INTRAOCULAR FOREIGN BODY, MAGNETIC AND NONMAGNETIC
270 ACUTE, SUBACUTE, CHRONIC AND OTHER TYPES OF IRIDOCYCLITIS
274 ADVANCED DEGENERATIVE DISORDERS AND CONDITIONS OF GLOBE

278 RETINOPATHY OF PREMATURITY
284 RETINAL DETACHMENT AND OTHER RETINAL DISORDERS
301 CATARACT
302 AFTER CATARACT
304 VITREOUS DISORDERS
313 CHRONIC INFLAMMATORY DISORDER OF ORBIT
315 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA
323 PURULENT ENDOPHTHALMITIS
324 FOREIGN BODY IN CORNEA AND CONJUNCTIVAL SAC
340 SCLERITIS
341 RUBEOSIS AND OTHER DISORDERS OF THE IRIS
342 WOUND OF EYE GLOBE
353 MILD/MODERATE BIRTH TRAUMA FOR BABY
356 STRABISMUS DUE TO NEUROLOGIC DISORDER
359 PENETRATING WOUND OF ORBIT
365 CHORIORETINAL INFLAMMATION
370 HYPHEMA
372 ENTROPION AND TRICHIASIS OF EYELID
375 AMBLYOPIA
379 RETINAL TEAR
388 CENTRAL SEROUS CHORIORETINOPATHY
399 STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE; LACRIMAL DUCT OBSTRUCTION IN CHILDREN
410 APHAKIA AND OTHER DISORDERS OF LENS
441 RECURRENT EROSION OF THE CORNEA
445 VENOUS TRIBUTARY (BRANCH) OCCLUSION; CENTRAL RETINAL VEIN OCCLUSION
453 DEGENERATION OF MACULA AND POSTERIOR POLE
455 DISORDERS OF REFRACTION AND ACCOMMODATION
456 EXOPHTHALMOS AND CYSTS OF THE EYE AND ORBIT
464 CENTRAL PTERYGIUM AFFECTING VISION
475 ACQUIRED PTOSIS AND OTHER EYELID DISORDERS WITH VISION IMPAIRMENT
476 KERATOCONJUNCTIVITIS
488 ENOPHTHALMOS
499 ECTROPION AND BENIGN NEOPLASM OF EYE
505 CHRONIC CONJUNCTIVITIS, BLEPHAROCONJUNCTIVITIS
564 ALLERGIC RHINITIS AND CONJUNCTIVITIS, CHRONIC RHINITIS
567 HORDEOLUM AND OTHER DEEP INFLAMMATION OF EYELID; CHALAZION
572 BLEPHARITIS
597 EPISCLERITIS
630 CONJUNCTIVAL CYST
636 ACUTE VIRAL CONJUNCTIVITIS
644 HYPERTELORISM OF ORBIT

Fitting for Spectacles and Contact Lenses

OAR concerning glasses and contact lenses:

410-140-0050(2)(a) Benefit Coverage for non-pregnant adults (age 21 and older);

A. Visual services and materials to diagnose and correct disorders of refraction and accommodation are covered only when the client has a covered medical diagnosis or following cataract surgery or a corneal lens transplant as described in OAR 410-140-0140.

410-140-0140(4)(d) Visual services for the purpose of prescribing glasses or contact lenses, fitting fees, or glasses or contact lenses:

A. One complete exam and determination of refractive state is limited to once every 24 months for pregnant adult women;
B. Non-pregnant adults are not covered, except when the client:
    i. Has a medical diagnoses of aphakia, psuedoaphakia, congenital aphakia, keratoconus; or
    ii. Lacks the natural lenses of the eye due to surgical removal (e.g. cataract extraction) or congenital absence; or
    iii. Has had a keratoplasty surgical procedure (e.g. corneal transplant) with limitations described in OAR 410-140-0160 (contact lens services and supplies); and
    iv. Is limited to one complete examination and determination of refractive state once every 24 months.

410-140-0160(2)(b)
The contact lenses are covered for eligible adults only when one of the following conditions exists:

A. Refractive error which is 9 diopters or greater in any meridian;
B. Keratoconus;
C. Anisometropia when the difference in power between two eyes is 3 diopters or greater;
D. Irregular astigmatism;
E. Aphakia; or
F. Post keratoplasty (e.g. corneal transplant) when medically necessary and within one year of procedure.

Fitting for Spectacles and Contact Lenses

HERC staff recommendation:

1) Remove CPT 92310-92371 from all lines on the Prioritized List except the lines shown in the "recommended line" column in the table below
    a. Advise DMAP to remove 92314-92317 from the Ancillary List

CPT code	Code Description	Current Lines/List	Recommended line(s)
92310	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens, both eyes, except for aphakia	ophtho lines	**301** CATARACT **315** CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA **375** AMBLYOPIA **399** STRABISMUS WITHOUT AMBLYOPIA AND OTHER DISORDERS OF BINOCULAR EYE MOVEMENTS; CONGENITAL ANOMALIES OF EYE **455** DISORDERS OF REFRACTION AND ACCOMMODATION
92311	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens for aphakia, 1 eye	ophtho lines	**410** APHAKIA AND OTHER DISORDERS OF LENS
92312	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens for aphakia, both eyes	ophtho lines	**410**
92313	Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneoscleral lens	ophtho lines	**315**
92314	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and direction of fitting by independent technician; corneal lens, both eyes except for aphakia	Ancillary	**301, 315, 375, 399, 455**
92315	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and	Ancillary	**410**

	direction of fitting by independent technician; corneal lens for aphakia, 1 eye		
92316	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and direction of fitting by independent technician; corneal lens for aphakia, both eyes	Ancillary	**410**
92317	Prescription of optical and physical characteristics of contact lens, with medical supervision of adaptation and direction of fitting by independent technician; corneoscleral lens	Ancillary	**315**
92325	Modification of contact lens (separate procedure), with medical supervision of adaptation	ophtho lines	**301, 315, 375, 399, 455**
92326	Replacement of contact lens	ophtho lines	**301, 315, 375, 399, 455**
92340	Fitting of spectacles, except for aphakia; monofocal	ophtho lines	**301, 315, 375, 399, 455**
92341	Fitting of spectacles, except for aphakia; bifocal	ophtho lines	**301, 315, 375, 399, 455**
92342	Fitting of spectacles, except for aphakia; multifocal, other than bifocal	ophtho lines	**301, 315, 375, 399, 455**
92352	Fitting of spectacle prosthesis for aphakia; monofocal	ophtho lines	**410**
92353	itting of spectacle prosthesis for aphakia; multifocal	ophtho lines	**410**
92354	Fitting of spectacle mounted low vision aid; single element system	SNRC	**SNRC**
92355	Fitting of spectacle mounted low vision aid; telescopic or other compound lens system	SNRC	**SNRC**
92358	Prosthesis service for aphakia, temporary (disposable or loan, including materials)	ophtho lines	**410**
92370	Repair and refitting spectacles; except for aphakia	ophtho lines	**301, 315, 375, 399, 455**
92371	Repair and refitting spectacles; spectacle prosthesis for aphakia	ophtho lines	**410**

Biennial Review 2018
Headaches

Question: Should migraine headaches and tension headache lines be combined?

Question source: PK Melethil, LAc

Issue: Mr. Melethil has requested review of placement of tension headaches, and suggested merging the tension and migraine headache lines. He questioned whether there is a clear delineation between these types of headaches and advocated for allowing treatment of both with acupuncture as it is effective for both conditions. He was also concerned that the unfunded position of the tension headache line meant that patients with this condition had access to possibly harmful medications, but not other effective treatments such as acupuncture.

History: There was a Taskforce on the treatment of migraine and non-migraine headaches that met in 1997, and resulted in the merging of these conditions. The Taskforce based this change on the fact that the treatments for these conditions (mainly acupuncture and chiropractic) were equally effective for both conditions. There was some discussion that medications have different effectiveness for the two conditions. It was noted in the Commission discussion of the Taskforce report that the changes were based on weak or unavailable data.

Migraine and tension headaches were later re-split during a reorganization of the Prioritized List due to difference in effectiveness of treatment and on impact on overall health. These differences led to significant differences in the line scoring for these two conditions. The two headache lines were reviewed by the ICD-10 neurology group, but no recommendations made and the review was cursory. The acupuncture review in 2012 found acupuncture effective as a treatment for both migraine and tension headaches. CPT codes for acupuncture were added to both lines.

Evidence

Tension-type headache (TTH)

1) **Banzi 2015**, Cochrane review of SSRI for TTH (not included in packet due to the study's length: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD011681/full)
    a. N=8 studies (412 patients)
    b. Evaluation of SSRIs (citalopram, sertraline, fluoxetine, paroxetine, fluvoxamine) and one SNRI (venlafaxine) on the frequency of TTH
    c. At eight weeks of followup, we found no difference when compared to placebo (two studies, N = 127; mean difference (MD) -0.96, 95% confidence interval (CI) -3.95 to 2.03; I2= 0%) or amitriptyline (two studies, N = 152; MD 0.76, 95% CI -2.05 to 3.57; I2= 44%).
    d. When considering secondary outcomes, SSRIs reduce the symptomatic/analgesic medication use for acute headache attacks compared to placebo (two studies, N = 118; MD -1.87, 95% CI -2.09 to -1.65; I2= 0%). However, amitriptyline appeared to reduce the intake of analgesic more

efficiently than SSRIs (MD 4.98, 95% CI 1.12 to 8.84; I2= 0%). The studies supporting these findings were considered to have an unclear risk of bias.

e. We found no differences compared to placebo or other antidepressants in headache duration and intensity.
f. **Authors' conclusions** Since the last version of this review, the new included studies have not added high quality evidence to support the use of SSRIs or venlafaxine (a SNRI) as preventive drugs for tension-type headache. Over two months of treatment, SSRIs or venlafaxine are no more effective than placebo or amitriptyline in reducing headache frequency in patients with chronic tension-type headache. Our conclusion is that the use of SSRIs and venlafaxine for the prevention of chronic tension-type headache is not supported by the evidence.

2) **Derry 2015**, Cochrane review of ibuprofen for TTH
   a. N=12 studies (3094 patients)
   b. For the IHS-preferred outcome of being pain free at 2 hours the NNT for ibuprofen 400 mg (all formulations) compared with placebo was 14 (95% confidence interval (CI), 8.4 to 47) in four studies, with no significant difference from placebo at 1 hour (moderate quality evidence). The NNT was 5.9 (4.2 to 9.5) for the global evaluation of 'very good' or 'excellent' in three studies (moderate quality evidence). The use of rescue medication was lower with ibuprofen 400 mg than with placebo, with the number needed to treat to prevent one event (NNTp) of 8.9 (5.6 to 21) in two studies (low quality evidence).
   c. **Authors' conclusions** Ibuprofen 400 mg provides an important benefit in terms of being pain free at 2 hours for a small number of people with frequent episodic tension-type headache who have an acute headache with moderate or severe initial pain. There is no information about the lesser benefit of no worse than mild pain at 2 hours.
3) **Fernandez de las Penas 2006**, systematic review of manual therapies for TTH
   a. N=6 studies
   b. These trials evaluated different manual therapy modalities: spinal manipulation (three trials), classic massage (one trial), connective tissue manipulation (two trials), soft tissue massage (one trial), Dr. Cyriax's vertebral mobilization (one trial), manual traction (one trial), and CV-4 craniosacral technique (one trial). Methodologic PEDro quality scores ranged from 2 to 8 points out of a theoretical maximum of 10 points (mean=5.8±2.1). Analysis of the quality and the outcomes of all trials did not provide rigorous evidence that manual therapies have a positive effect in reducing pain from TTH: spinal manipulative therapy showed inconclusive evidence of effectiveness (level 4), whereas soft tissue techniques showed limited evidence (level 3).
   c. Conclusions: The authors found no rigorous evidence that manual therapies have a positive effect in the evolution of TTH.
4) **Posadzki 2012**, systematic review of spinal manipulation for TTH

   a. N=5 RCTs, rated as high methodological quality
   b. Four RCTs suggested that spinal manipulations are more effective than drug therapy, spinal manipulation plus placebo, sham spinal manipulation plus amitriptyline or sham spinal manipulation plus placebo, usual care or no intervention. One RCT showed no difference in daily hours of headache, pain intensity, and daily analgesic use compared to soft tissue therapy plus placebo laser.
   c. *Conclusions:* The evidence that spinal manipulation alleviates tension type headaches is encouraging, but inconclusive. The low quantity of the available data prevent firm conclusion.

5) **Verhagen 2009**, Systematic review of behavioral treatments for TTH
   a. N=44 trials (2618 patients)
      i. only 5 studies (11.4%) were considered to have low risk of bias
   b. Behavioral therapies included relaxation, electromyographic [EMG] biofeedback, and cognitive behavioral training.
   c. Most trials lacked adequate power to show statistical significant differences, but frequently, recovery/improvement rates did not reach clinical relevance. In 8 studies, relaxation treatment was compared with waiting list conditions, and in 11 studies, biofeedback was compared with waiting list conditions, both showing inconsistent results.
   d. Conclusions: On the basis of the available literature, we found no indications that relaxation, EMG biofeedback, or cognitive behavioral treatment is better than no treatment, waiting list, or placebo controls.
6) **Jackson 2012**, meta-analysis of botulinum toxin for migraine and TTH
   a. Pooled analyses suggested that botulinum toxin A was associated with fewer headaches per month among patients with chronic daily headaches (1115 patients,−2.06 headaches per month; 95% CI, −3.56 to −0.56; 3 studies) and among patients with chronic migraine headaches (n=1508, −2.30 headaches per month; 95% CI,−3.66 to −0.94; 5 studies). There was no significant association between use of botulinum toxin A and reduction in the number of episodic migraine (n=1838, 0.05 headaches per month; 95% CI, −0.26 to 0.36; 9 studies) or chronic tension-type headaches (n=675, −1.43 headaches per month; 95% CI, −3.13 to 0.27; 7 studies).
   b. **Conclusion** Botulinum toxin A compared with placebo was associated with a small to modest benefit for chronic daily headaches and chronic migraines but was not associated with fewer episodic migraine or chronic tension-type headaches per month.

Migraine headache

1) Previously reviewed and found to be efficacious:
   a. Botulinum toxin injections
   b. Acupuncture

2) **Derry 2014**, Cochrane review of sumatriptan for acute migraine (all routes of administration)
    a. N=52,236 patients
    b. Subcutaneous administration was the most effective, with pain reduced from moderate or severe to none by two hours in almost 6 in 10 people (59%) taking 6 mg sumatriptan, compared with approximately 1 in 7 (15%) taking placebo; the number needed to treat (NNT) was 2.3 (95% confidence interval 2.1 to 2.4) with 2522 participants in the analysis. The most commonly used doses of oral, rectal, and intranasal sumatriptan also provided clinically useful pain relief, with the oral 50 mg dose providing complete relief of pain in almost 3 in 10 people (28%) compared with about 1 in 10 (11%) after placebo (NNT 6.1 (5.5 to 6.9) in 6447 participants).
    c. Authors' conclusions Sumatriptan is an effective abortive treatment for acute migraine attacks, but is associated with increased adverse events relative to placebo.
3) **Linde 2014,** Cochrane review of valproate for migraine prophylaxis (not included in packet due to study's length): http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010611/epdf
    a. N=10 trials
    b. Analysis of data from two trials (63 participants) showed that sodium valproate reduced headache frequency by approximately four headaches per 28 days as compared to placebo (MD-4.31; 95% confidence interval (CI) -8.32 to -0.30). Data from four trials (542 participants) showed that divalproex sodium (a stable combination of sodium valproate and valproic acid in a 1:1 molar ratio) more than doubled the proportion of responders relative to placebo (RR 2.18; 95% CI 1.28 to 3.72; NNT 4; 95% CI 2 to 11). One study of sodium valproate (34 participants) versus placebo supported the latter findings (RR for responders 2.83; 95% CI 1.27 to 6.31; NNT 3; 95% CI 2 to 9). There was no significant difference in the proportion of responders between sodium valproate versus flunarizine (one trial, 41 participants) or between divalproex sodium versus propranolol (one trial, 32 participants). Pooled analysis of post-treatment mean headache frequencies in two trials (88 participants) demonstrates a slight but significant advantage for topiramate 50 mg over valproate 400 mg (MD -0.90; 95% CI -1.58 to -0.22). For placebocontrolled trials of sodium valproate and divalproex sodium, NNHs for clinically important adverse events ranged from 7 to 14.
    c. Authors' conclusions Valproate is effective in reducing headache frequency and is reasonably well tolerated in adult patients with episodic migraine.

Biennial Review 2018
Headaches

HERC Staff summary

Systematic reviews and meta-analyses find little effective treatment for tension type headache, other than a reduction in pain at 1-2 hours with ibuprofen. Cognitive behavioral therapy, spinal manipulation, prophylactic medications, and botulinum injections all appear to be ineffective at reducing the frequency of headaches. Previous review has found acupuncture to be effective for this condition.

Systematic reviews and meta-analyses as well as prior HERC reviews find various treatments to be effective for treatment of migraine headaches, including acupuncture, botulinum injection, and various medications for treatment of acute migraine or for migraine prophylaxis (e.g. triptans, beta blockers, epileptic medications, etc.).

Line scoring:

Line 415 Migraine headaches (Line 543 Tension headaches)
Category 7 (7)
Impact on healthy life: 4 (2)
Pain/Suffering: 3 (1)
Population effects: 0
Vulnerable population: 0
Tertiary Prevention: 0
Effectiveness: 4 (3)
Need for services: 0.7 (0.5)
Cost: 3 (4)
Score: 392 (90)

HERC staff recommendations:

1) Do not merge the migraine and tension headache lines and do not rescore these lines. Tension headache has little effective treatment, compared to the many effective treatments available for migraine headache.
    a. If rescoring is desired, staff recommend increasing pain/suffering for tension headache to 2 and reducing effectiveness to 1 and need for services to 0.3 and cost to 3. This results in a score of 48 and a line position of approximately 560. Staff recommends no change for the scoring for the migraine line.

Early Childhood Insomnia

Question: Should treatment of early childhood insomnia be prioritized to a higher position on the Prioritized List?

Question source: Early Childhood Workgroup of the Children's System of Care Committee of the Health Systems Division of OHA

Issue: Insomnia is currently on Line 609 DISORDERS OF SLEEP WITHOUT SLEEP APNEA. Insomnia was placed on a very low line with the creation of the Prioritized list, and this placement has never been formally reviewed.

Insomnia is defined as difficulty initiating sleep (considered in children as the difficulty to fall asleep without a caregiver's intervention); maintaining sleep (frequent awakenings during the night and difficulty returning to sleep without a caregiver's intervention); or waking up earlier than the usual schedule with inability to return to sleep.

From the Early Childhood Workgroup:

> Early childhood sleep problems have been linked to a range of adverse health outcomes, including behavioral problems, inattention/hyperactivity, depression/anxiety and impaired cognitive development. Childhood sleep problems may have a major impact on the family, resulting in mood disturbances of parents, decreased effective parenting practices, and increased risk of child abuse.
>
> Given the negative impact on family functioning of sleep deprivation, if the sleep problem is still not improving by 6 months of age with guidance regarding developmentally appropriate sleep hygiene from their primary care provider, and by addressing any medical causes for the sleep problem, specialized services are indicated. These services should focus on increasing the child's regulation and providing support, and training to the caregiver(s).

Evidence

1) **Meltzer 2014**, meta-analysis of behavioral therapy for pediatric insomnia (not included due to length)
   http://jpepsy.oxfordjournals.org/content/early/2014/06/19/jpepsy.jsu041.full.pdf+html
   a. N=16 controlled clinical trials (N=2133) and 12 within subject studies (N=427)
   b. Included studies had a behavioral intervention for insomnia, with or without pharmacologic intervention
   c. Meta-analysis found significant effects for four specified sleep outcomes: sleep-onset latency, number of night wakings, and duration of night wakings, and sleep efficiency, with small to large effect sizes across the controlled clinical trials involving typical children.
   d. Effects in young children
      i. 12 controlled trials (N=1874)

   ii. Four studies assessed sleep-onset latency, with a significant overall effect and small to medium effect size [Z=4.06, p<.001; standard mean deviation (SMD)=0.33] at posttreatment
   iii. Frequency of night wakings was included in seven studies, resulting in a significant overall effect and small to medium effect size (Z=5.99, p<.001; SMD=0.40).
   iv. night waking duration was included in four studies for a significant overall effect and small to medium effect size (Z=5.50, p<.001; SMD=0.44)
- e. Effects on school aged children and adolescents
   i. N=3 controlled trials (N=214 participants 4-13 yrs)
   ii. All three studies included night waking duration which was significant at posttreatment (Z=2.67, p=.008; SMD=0.39)
   iii. sleep efficiency was included in two studies and was found to have an overall significant effect at posttreatment with a large effect size (Z=8.88, p<.001; SMD=2.24).
- f. Conclusions: Moderate-level evidence supports behavioral interventions for pediatric insomnia in young children. Behavioral interventions are effective at reducing sleep onset latency, night waking frequency, and night waking duration in young children. However, insufficient long term evidence for these changes means limited conclusions can be drawn on the durability of these treatments over time.

2) **Trauer 2015**, meta-analysis of behavioral therapy for adult insomnia
   a. N=20 RCTs (1162 participants)
   b. Approaches to CBT-i incorporated at least 3 of the following: cognitive therapy, stimulus control, sleep restriction, sleep hygiene, and relaxation.
   c. At the posttreatment time point, sleep onset latency improved by 19.03 (95% CI, 14.12 to 23.93) minutes, wake after sleep onset improved by 26.00 (CI, 15.48 to 36.52) minutes, total sleep time improved by 7.61 (CI, -0.51 to 15.74) minutes, and sleep efficiency improved by 9.91% (CI, 8.09% to 11.73%). Changes seemed to be sustained at later time points. No adverse outcomes were reported.
   a. **Conclusion:** CBT-i is an effective treatment for adults with chronic insomnia, with clinically meaningful effect sizes

Reviews

1) **Lahorgue Nunes 2015,** review of insomnia in childhood and adolescence
   a. Prevalence: approximately 15-30% of children meet criteria at some time for insomnia, with the higher rates reported in younger children (3 and under)
   b. Psychiatric (anxiety, depression) or neurodevelopmental disorders (attention deficit disorder, autism, epilepsy) frequently occur in association with or as a comorbidity of insomnia.
   c. The therapeutic approach must include sleep hygiene and behavioral techniques and, in individual cases, pharmacological treatment.
      i. Most behavioral techniques can be taught in the primary care setting
      ii. Cognitive behavioral therapy for the caregiver can be useful

Clinical practice guidelines

1) **Schutte-Rodin 2011**, American Academy of Sleep Medicine practice guidelines for insomnia for adults (study not included due to length) http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2576317/pdf/jcsm.4.5.487.pdf
    a. Insomnia symptoms occur in approximately 33% to 50% of the adult population; insomnia symptoms with distress or impairment (i.e., general insomnia disorder) in 10% to 15%; and specific insomnia disorders in 5% to 10%.
    b. Behavioral interventions
        i. Psychological and behavioral interventions are effective and recommended in the treatment of chronic primary and comorbid (secondary) insomnia. (Standard)
        ii. These treatments should be utilized as an initial intervention when appropriate and when conditions permit. (Consensus)
        iii. Initial approaches to treatment should include at least one behavioral intervention such as *stimulus control therapy or relaxation therapy, or the combination of cognitive therapy, stimulus control therapy, sleep restriction therapy with or without relaxation therapy*—otherwise known as cognitive behavioral therapy for insomnia (CBT-I). (Standard)
        iv. Multicomponent therapy (without cognitive therapy) is effective and recommended therapy in the treatment of chronic insomnia. (Guideline)
        v. Other common therapies include *sleep restriction*, *paradoxical intention*, and *biofeedback therapy*. (Guideline)
        vi. Although all patients with chronic insomnia should adhere to rules of good *sleep hygiene*, there is insufficient evidence to indicate that sleep hygiene alone is effective in the treatment of chronic insomnia. It should be used in combination with other therapies. (Consensus)
        vii. When an initial psychological/ behavioral treatment has been ineffective, other psychological/ behavioral therapies, combination CBT-I therapies, combined treatments (see below), or occult comorbid disorders may next be considered. (Consensus)

<u>HERC staff summary</u>:
Insomnia is a very common condition in children and adults. Treatment with cognitive behavioral therapy or other behavioral therapies has moderate evidence of effectiveness. Insomnia in young children may be comorbid with or causal for depression, anxiety, ADHD, and other psychiatric conditions.

HERC staff recommendations:

1) Consider creation of a new line for treatment of early childhood insomnia
    a. May also consider addition of older children, adolescents and adults
    b. If new line is created, adopt a new guideline as shown below

Line: XXX
Condition: EARLY CHILDHOOD INSOMNIA (See Guideline Notes 64,65,XXX)
Treatment: MEDICAL/PSYCHOTHERAPY
ICD-10: F51.01 (Primary insomnia), F51.09 (Other insomnia not due to a substance or known physiological condition), G47.00 (Insomnia, unspecified), G47.09 (Other insomnia)
CPT: 90785,90832-90840,90846-90853 (psychotherapy) 96150-96154 (health and behavior assessment codes), 98966-98969,99051,99060,99184,99201-99216, 99341-99350,99366,99408,99409,99415,99416,99441-99449,99487-99498,99605-99607
HCPCS: G0406-G0408,G0410,G0411,G0425-G0427,G0459,G0463,G0466,G0467,G0469, G0470, H0004

Line scoring:
Line XXX EARLY CHILDHOOD INSOMNIA (Line 609 DISORDERS OF SLEEP WITHOUT SLEEP APNEA)
Category 7 (9)
Impact on healthy life: 3 (0) Note: advocates suggested 5
Pain/Suffering: 3 (2) Note: advocates suggested 4
Population effects: 0 (0)
Vulnerable population: 1 (0) Note: advocates suggested 5
Tertiary Prevention: NA
Effectiveness: 3 (3)
Need for services: 0.3 (0.3)
Cost: 4 (4)
Score: 126 (2.7)
Line 516 (609)

GUIDELINE NOTE XXX, EARLY CHILDHOOD INSOMNIA
Lines XXX, 609
Insomnia (ICD-10 F51.01, F51.09, G47.00, G47.09) is only included on line XXX when all of the following criteria are met:

1) The child is 6 months of age or older, but younger than age 4
2) The sleep pattern or disturbance is significantly out of the range of typical developmental expectations
    a. For age 6-11 months, <10 hours of total sleep and <5 hours for longest duration of sleep
    b. For ages 1-2 years, <9 hours of total sleep and <7 hours for longest duration of sleep

   c. For age 3 years, <8 hours of total sleep and <8 hours for longest duration of sleep
3) Coexisting medical, developmental, or mental disorders do not adequately explain the predominate complaint of insomnia
4) Symptoms have persisted for at least 4 weeks with 4 episodes per week

Otherwise, these conditions are included on line 609.

Appropriate interventions for this problem include: parent training such as infant massage training, behavioral training, dyadic family therapy such as attachment and bio-behavioral catch-up, and family peer support services.

Hypospadia

Question: Where should various types of hypospadias be prioritized?

Question source: Dr. David Lashley, pediatric urologist

Issue: ICD-9 had a single diagnosis code for hypospadias, while ICD-10 has 7 codes differentiating by location of the abnormal urethral opening. Hypospadias is a congenital condition where the urethra exits the phallus in an abnormal location. This defect can result in abnormal urinary streams and sexual dysfunction. Hypospadias is frequently associated with abnormal foreskin development and chordee, an abnormal bending or curving of the penis.

During the ICD-10 review, the all-adult urology review group suggested that 2 of the 7 hypospadias diagnoses should be placed on a lower, uncovered line; however, the final result of the review was to place these two diagnoses on both a covered and an uncovered line with no guideline or other differentiation about when the diagnoses where intended to be covered. Dr. Lashley contacted HERC staff to report that he is having difficulty getting some visits and procedures done for boys with various hypospadias diagnoses since the ICD-10 conversion.

ICD-10 Code	Code Description	Code Placement
Q54.0	Hypospadias, balanic	438 HYPOSPADIAS AND EPISPADIAS 662 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
Q54.1	Hypospadias, penile	438
Q54.2	Hypospadias, penoscrotal	438
Q54.3	Hypospadias, perineal	438
Q54.4	Congenital chordee	438, 662 with guideline
Q54.8	Other hypospadias	438
Q54.9	Hypospadias, unspecified	438, 662

Dr. Lashley provided information and feedback about Q54.0 and Q54.9. He felt that Q54.9 (hypospadias, unspecified) was not required for coverage as urologists should specify the type of hypospadias. He did note that PCPs might use this code as they might be unsure how to classify the type of hypospadias, but use of Q54.9 would still allow one specialist visit after which the specific diagnosis would be determined.

Dr. Lashley felt that Q54.0 (Balanic hypospadias) was a diagnosis that may or may not require treatment. This diagnosis specifically requires treatment in cases of meatal stenosis, significant chordee, abnormal urinary stream or dorsal hood foreskin. However, he felt this diagnosis was rare enough that a guideline would not be required.

Evidence:

1) There was scant literature on this topic. A few papers were identified which compared the outcomes of various surgical techniques for repair of balanic hypospadias

HERC staff recommendations:

1) Remove ICD-10 Q54.9 (Hypospadias, unspecified) from line 438 HYPOSPADIAS AND EPISPADIAS and leave on line 662 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
2) Make no change to placement of ICD-10 Q54.0 (Hypospadias, balanic) on both lines 438 and 662
    a. See separate document with new pediatric urology guideline which will specify placement on line 438 for children and on line 662 for adults

Retractile Testicles

Question: Should the diagnosis code for retractile testicles (Q55.22) be returned to a covered line?

Question source: David Lashley, MD, pediatric urologist

Issue: During the ICD-10 urology review, ICD-9 752.52 and ICD-10 Q55.22 (retractile testicles) were moved from line 98 UNDESCENDED TESTICLE to line 662 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY, as there is no effective treatment for this condition.

Dr. Lashley has raised concerns that this condition needs continued monitoring by the patient's PCP, and in many cases, by a pediatric urologist. The initial consultation for this condition is covered, but not any follow up visits for monitoring. While he agrees that there is no treatment for this condition, he feels that it should be on a covered line to allow monitoring.

Retractile testis is considered as a testis that is located at the upper scrotum or lower inguinal canal and that can be made to descend completely into the scrotum without resistance by manual reduction but returns to its original position. Retractile testis has traditionally been considered as a variant of normal testis because it usually descends into the scrotum during adolescence and shows no difference in testicular volume or childbearing capacity compared with the normal testis. However, retractile testicles have been reported to have a significant rate of testicular ascent out of the scrotum, becoming undescended and requiring surgical correction. The American Urologist Association (AUA 2014) guideline reports that "Studies have reported an extremely broad range of incidence of testicular ascent out of the scrotum (between 2-45%) in boys with retractile testes."

The AUA 2014 guidelines on the diagnosis and management of undescended testes recommends

1) In boys with retractile testes, providers should assess the position of the testes at least annually to monitor for secondary ascent. (Standard; Evidence Strength: Grade B).
2) Providers should not perform ultrasound (US) or other imaging modalities in the evaluation of boys with cryptorchidism prior to referral, as these studies rarely assist in decision making. (Standard; Evidence Strength: Grade B)

From Dr. Lashley:

PCP's send us a lot of kids with a concern about undescended testicle..?25% or more of the time the testicles are retractile and do not require surgery. No problem…they are new patient visits so they get covered regardless of the diagnosis. I tell the family:

Retractile testicles: The family and I talked about treatment options for retractile testicles. Etiologies of retractile testicles were discussed with the family including the

benign nature of this condition, the lack of association with the future development of testicular cancer, and the tendency for the testicles to drop permanently into the scrotum normally between now and puberty. The family and I talked about the fact that surgery in general is not indicated as a treatment of retractile testicles. Alternative treatment options were discussed with the patient in detail. All questions were answered. The family gave fully informed consent to proceed with conservative therapy for their retractile testicles at this time.

On occasion (7-12%) these retractile testicles may "ascend" with the child's linear growth and subsequently require surgical repair. For this reason I recommend that annual genital examinations at his well-child visits continue to document the ability to bring the testicles into the dependant scrotum. I would be happy to see him back if there are ongoing questions or concerns. The patient/family was given instructions to call for incomplete descent of the testicles over time, scrotal/groin/abdominal pain, especially if associated with nausea, vomiting, swelling redness, etc.

so when the pcp checks the next year and can not get the testicle(s) into the scrotum they send them back for re eval. if the testicle is ascended..I am covered as the dx is now above the line. if the testicle is still retractile then i am not covered. it is a total hassle because pcp's will send the kids back to us with undescended testicle diagnosis and thus will not have the follow up visit authorized. i did not realize the retractile code is now BTL so i have a few claims which will not pay. The pcp's want to serve their patients so they often refer BTL diagnosis with ATL codes..which gets them in my door..but then i am often stuck trying to get paid for a BTL visit.

Utilization: For the period 1/1/14-9/30/15, more than >10,000 billings (in any diagnosis position), with 4,402 are in the primary diagnosis position on the billing

HERC staff recommendation:

1) Add ICD-10 Q55.22 (retractile testicle) to line 98 UNDESCENDED TESTICLE and keep on line 662 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
    a. Will allow specialty consultation and monitoring visits
    b. See proposed pediatric urology guideline in separate document which limits inclusion on line 98 to children; this condition in adults in included on line 662

Congenital Urologic Conditions

Question: Should various ICD-10 codes for congenital anomalies of the genitourinary tract be returned to covered lines?

Question source: Dr. David Lashley, pediatric urologist

Issue: During the ICD-10 Urology review, various congenital urinary tract anomaly diagnoses were moved to line 662 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY, due to the reviewers' belief that these conditions do not require any monitoring or treatment. All urologists involved with this review were adult urologists. Previously, all these conditions (or the less specific ICD-9 code from which they were derived) were on covered lines. Dr. Lashley feels that these conditions do require monitoring in infants and children, generally with ultrasounds or with follow up urology visits. He is requesting that these conditions be moved back to their previous covered positions.

Dr. Lashley reports that he may be required to bill for one of these conditions in several situations:

1) Prenatal consultation: Dr. Lashley sees pregnant women with fetuses with moderate to severe genitourinary issues as a prenatal urologic consultation to discuss prognosis and implication of the condition and to set up a post natal treatment plan.
2) Follow up ultrasound at 2 months of age—minimum follow up for any infant with a GU anomaly seen on prenatal ultrasound
3) Serial ultrasound and often nuclear medicine renal scans for most moderate to severe anomalies, to ensure that there is no associated problem such as UPJ or UVJ obstruction or reflux. Once pediatric urology has determined that there is no associated condition requiring surgery, the child is transferred to pediatric nephrology, who normally does annual urine and lab studies to follow the health of the single kidney (in the case of unilateral agenesis) or abnormal kidney. These children also need to have their blood pressure followed closely. Most of these conditions require ultrasounds on varying schedules as well to ensure that the kidneys are growing normally and have no infections (reflux) and to ensure that hydronephrosis is not developing or progressing.
4) Surgeries (procedures may be required depending on the condition/associated condition present). Many of these conditions are billed with covered conditions such as ureteral reflux; however, some require the congenital anomaly diagnosis to be billed as well to allow coverage of more extensive surgeries.
    a. pyeloplasty (repair of UPJ obstruction)
    b. ureter implantation (for reflux or UVJ obstruction)
    c. common sheath reimplantation (for reflux or UVJ obstruction when there is ureteral duplication)
    d. tapered reimplantation (for severe reflux or UVJ obstruction)
    e. uretero-ureterostomy (for reflux or UVJ obstruction when there is ureteral duplication)
    f. cutaneous ureterostomy (for severe uvj obstruction in infants)

g. excision of ureterocele
h. nephrectomy (reflux or obstruction and minimal or no function)
i. nephroureterectomy (reflux or obstruction and minimal or no function)

5) Most of these conditions do not need any follow up after a child is done growing and renal function presumably becomes stable. Unilateral kidney patients may require periodic follow up in nephrology in adulthood.

Previously covered conditions now found only on line 662 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

ICD-10 code	**Code description**	**ICD-9 code equivalent and placement**	**Comments**
Q60.3	Renal hypoplasia, unilateral	753.0 (Renal agenesis and dysgenesis) was on lines 91 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM and 104 ESRD	Q60.4 (bilateral) and Q60.5 (unspecified) are on line 104
Q62.4	Agenesis of ureter	753.4 (Other specified anomalies of ureter) was on line 91	Q62.63 (Anomalous implantation of ureter) and Q62.9 (Anomalous implantation of ureter) are on line 91
Q62.5	Duplication of ureter	753.4	
Q62.60	Malposition of ureter, unspecified	753.4	
Q62.61	Deviation of ureter	753.4	
Q62.62	Displacement of ureter	753.4	
Q63.0	Accessory kidney	753.3 Other specified anomalies of kidney was on line 91	
Q63.1	Lobulated, fused and horseshoe kidney	753.3	
Q63.2	Ectopic kidney	753.3	
Q63.3	Hyperplastic and giant kidney	753.3	
Q63.8	Other specified congenital malformations of kidney	753.3	
Q63.9	Congenital malformation of kidney, unspecified	753.3	

Evidence:

1) **Rodriguez 2014**, review of congenital urologic anomalies

   a. The majority of cases [of duplicated ureter] are asymptomatic in adults; however, in children the risk of renal infection is increased 20-fold… A duplex system can be associatedwith other renal complications such as obstruction, reflux, and infection. If the obstruction is maintained for some time, the kidney can become hydronephrotic. When the infection becomes persistent, it can also lead to a severe chronic pyelonephritis,which ultimately produces chronic renal disease
   b. Horseshoe or fused kidneys: Sometimes the horseshoe kidneys are associated with UPJ obstruction and children can present with urinary tract infections, abdominal mass, and hematuria.
   c. Renal dysplasia: approximately 60% of kidneys affected by renal dysplasia have an obstructive component.

2) **Kerecuk 2008**, review of renal track malformations
   a. Data from the UK Renal Registry62 show that unobstructed and obstructed dysplastic or hypoplastic kidneys together account for about 40% of all children on dialysis
   b. In registries of adults receiving renal replacement therapy, dysplastic or hypoplastic kidneys account for only a small proportion of primary diagnoses; for example, these conditions have a prevalence of 0.6% in the US Renal Data System
   c. there are reports of selected individuals born with solitary functioning kidneys who developed hypertension, proteinuria and renal failure as adults
   d. We lack comprehensive, long-term followup studies in large cohorts of individuals born with different types of renal tract malformations. In addition, the contribution of renal tract malformations to chronic kidney disease and ESRD in adults could be more clearly defined.
   e. Whether prenatal decompression of obstructed renal tracts or initiation of postnatal therapies, such as prophylactic antibiotics or angiotensin blockade, in childhood improve long-term renal outcomes of patients with renal tract malformations is unclear.

3) **Ingraham 2011**, review of congenital urologic malformations
   a. unilateral upper urinary tract obstructive disease rarely results in proteinuria or azotemia, so conservative management of these patients is usually recommended. However, some authors have raised concern about the possibility of increased long-term risk for hypertension as a result of ureteral obstruction. Bilateral upper urinary tract obstruction or obstruction of a solitary functional kidney is far more ominous and often requires prompt surgical intervention and careful medical management to minimize and monitor renal injury.
   b. Unilateral and bilateral hypodysplasia of the kidney, horseshoe kidney, and solitary kidney all have a considerable rate of progression to ESRD requiring dialysis over the first 30 years of life

HERC staff recommendation:

1) Add Q60.3 (Renal hypoplasia, unilateral), Q62.4 (Agenesis of ureter), Q62.5 (Duplication of ureter), Q62.60 (Accessory kidney), Q62.61 (Deviation of ureter), Q62.62 (Displacement of ureter), and Q63 (Other congenital malformations of kidney) to line 91 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM and keep on line 662 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
    a. Would allow periodic specialty visits, labs and imaging. Would also pair with a variety of surgical treatment codes
    b. See proposed pediatric urology guideline in separate document which limits inclusion on the covered line to children

Pediatric Urology Guideline

Question: Should a new guideline be adopted limiting evaluation and treatment of various congenital urologic conditions to children?

Question source: HERC staff

Issue: During the ICD-10 Urology review, the all adult urologist specialty group recommended moving various congenital urologic conditions to uncovered lines, as they felt these conditions did not require treatment. Since that review, Dr. David Lashley, a pediatric urologist, has requested that most of these conditions be returned to covered lines as they need periodic monitoring and possibly imaging, laboratory tests, and in some cases, repair in children. Once a child reaches puberty, most of these conditions stabilize and no longer require monitoring or treatment.

HERC staff recommendation:

1) Adopt the following new guideline to apply to lines 91 CONGENITAL ANOMALIES OF GENITOURINARY SYSTEM, 98 UNDESCENDED TESTICLE, 438 HYPOSPADIAS AND EPISPADIAS and 662 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY

GUIDEINE NOTE XXX CONGENTIAL UROLOGIC CONDITIONS

Lines 91, 98, 438, 662

The following conditions are included on these lines 91, 98, or 438 only for children aged 18 and younger. For adults, these conditions are included on line 662.

1) ICD-10 Q54.0 (Hypospadias, balanic)
2) ICD-10 Q55.22 (Retractile testicle)
3) ICD-10 Q60.3 (Renal hypoplasia, unilateral)
4) ICD-10 Q62.4 (Agenesis of ureter)
5) ICD-10 Q62.5 (Duplication of ureter)
6) ICD-10 Q62.60 (Accessory kidney)
7) ICD-10 Q62.61 (Deviation of ureter)
8) ICD-10 Q62.62 (Displacement of ureter)
9) ICD-10 Q63 (Other congenital malformations of kidney)

Physical Therapy Modalities

Question: Should various physical therapy modalities be removed from the Prioritized List or other list locations, or have other restrictions placed on them?

Question source: HERC staff

Issue: Physical therapy mainly consists of therapeutic exercises. However, there are other, generally passive modalities which are used as part of PT therapy. These other modalities may or may not have evidence to support their use.

Several of these therapies are already not covered or in below the funding line areas of the Prioritized List. There is high utilization of some of these modalities, but nearly all by the CCOs, who are free to cover additional services not paired on the Prioritized List.

Those modalities which underwent evidence review have recommendations in separate documents. The summary of staff recommendations are shown in the table below. CPT code

	Code description	**Line(s)/Lists**	**Paid claims**	**HERC staff recommendation**
97010	Hot or cold packs	**663** MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE…	2268	Not reviewed. No changes.
97012	Mechanical Traction	All PT lines EXCEPT back and neck condition lines	1626	No evidence of effectiveness for back/neck conditions. Modify back guidelines to clarify non-coverage. Review of other indications not justified due to low utilization
97014	Electric Stimulation Therapy	SNRC	10820	Not reviewed. Modify back guidelines to clarify non-coverage
97016	Vasopneumatic Device Therapy	Ancillary	112	Place on lines on PL or make SNRC
97018	Paraffin Bath Therapy	Ancillary	79	Place on lines on PL
97022	Whirlpool Therapy	All PT lines, deep open wound lines, burn lines	847	Remove from wound, burn and back conditions lines
97024	Diathermy	**471** BRACHIAL PLEXUS LESIONS **512** PERIPHERAL NERVE DISORDERS	35	Straightforward remove from PL
97026	Infrared Therapy	Ancillary	753	Evidence found for use in back and neck conditions. Also used for many other conditions. Utilization does not justify extensive review. Continue Ancillary
97028	Ultraviolet Therapy	Ancillary	1	Straightforward remove from PL

Physical Therapy Modalities

97032	Electrical Stimulation	SNRC	1070	Not reviewed. Modify back guidelines to clarify non-coverage
97033	Iontophoresis	Ancillary	137	Used as adjunctive therapy to assist in delivery of topical medications. Remain Ancillary
97034	Contrast Bath Therapy	Ancillary	0	Straightforward add to SNRC
97035	Ultrasound Therapy	SNRC	2510	Not reviewed. No changes.
97036	Hubbard Tank	**212** DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT **384** CHRONIC ULCER OF SKIN **428** COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT	1	Straightforward remove from PL

Physical Therapy Modalities with Little Utilization and Little or No Evidence of Effectiveness

Question: Should various little-used PT modalities with little or no evidence of effectiveness be removed from the Prioritized List?

Question source: OHP Medical Directors, HERC staff

Issue: Several PT services have very little utilization and little evidence to support use. They have been suggested for removal from the Prioritized List.

1) **Diathermy/microwave**
    a. CPT 97024 Application of a modality to 1 or more areas; diathermy (eg, microwave)
    b. Technique by which microwaves are used to deliver heat to areas deep in the body
    c. Currently appears on lines 471 BRACHIAL PLEXUS LESIONS and 512 PERIPHERAL NERVE DISORDERS.
        i. Pairs only with ICD-10 G54.0 (Brachial plexus disorders) above the current funding line
    d. Utilization: 35 paid claims 7/14-6/15 (all payers)
    e. Evidence: literature search on MEDLINE limited to use of diathermy for peripheral nerve injuries and brachial plexus disorders
        i. No literature found
2) **Ultraviolet therapy**
    a. CPT 97028 Application of a modality to 1 or more areas; ultraviolet
    b. Technique in which light waves are used for treatment of a physical condition. There is another type of light therapy used to treat skin conditions such as psoriasis
    c. Currently on the Ancillary List
    d. Utilization: 1 paid claim 7/14-6/15 (all payers)
    e. Evidence:
        i. One article found
        ii. **Chen 2014**, Cochrane review of phototherapy for the treatment of pressure ulcers (study not included due to size) http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD009224.pub2/epdf
            1. N=7 RCTs (403 patients), comparing phototherapy to standard care or sham phototherapy
            2. Overall, there was insufficient evidence to determine the relative effects of phototherapy for healing pressure ulcers.
            3. Among five studies reporting the rate of change in ulcer area, three studies found no statistically significant difference between the two groups.

4. **Authors' conclusions:** We are very uncertain as to the effects of phototherapy in treating pressure ulcers. The quality of evidence is very low due to the unclear risk of bias and small number of trials available for analysis. The possibility of benefit or harm of this treatment cannot be ruled out. Further research is recommended.

3) Hubbard Tank

a. CPT 97036 Application of a modality to 1 or more areas; Hubbard tank, each 15 minutes
b. A form of hydrotherapy in which the patient is immersed in a full body tank
    i. Does not include aquatic exercise therapy (CPT 97113)
c. Currently appears on lines 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT, 384 CHRONIC ULCER OF SKIN,428 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
d. Utilization: 1 paid claim 7/14-6/15 (all payers)
e. Evidence
    i. **White 2015**, PT association recommendations for Choosing Wisely (study not included due to length: http://ptjournal.apta.org/content/ptjournal/95/1/9.full.pdf
        1. Don't use whirlpool for wound management.
        2. The concern with whirlpool and other large open tanks of water is increased risk of infection for open wounds. Other wound care strategies have been found to be more effective for wound care, such as directed wound irrigation or a pulsed lavage with suction.

4) Contrast baths

a. CPT 97034 Application of a modality to 1 or more areas; contrast baths, each 15 minutes
b. A form of hydrotherapy in which a body part (normally a limb) is placed in alternately hot and cold baths
c. Currently is on the Ancillary List
d. Utilization: 0 paid claims 7/14-6/15 (all payers)
e. Evidence
    i. **Bregor Stanton 2009**, systematic review and meta-analysis of use of contrast baths
        1. N=28 studies (1938 onward)
        2. Subjects had diagnosis of rheumatoid arthritis, diabetes, or foot/ankle injuries.
        3. The diversity of conditions, protocols, and outcomes limited the ability to make definitive conclusions on efficacy.
        4. Conclusions: The contrast bath procedure may increase superficial blood flow and skin temperature, though the evidence on the impact on edema is conflicting. No relationship between

physiologic effects and functional outcomes has been established. Level of Evidence: 2A

ii. NCOR 2012

1. Found evidence for improved exercise performance, mainly in high level athletes
2. Contraindications include open wounds, poorly controlled epilepsy, infection wounds, hypertension, diabetes, and fear of water

<u>HERC staff recommendations</u>:

1) Remove CPT 97024 (Application of a modality to 1 or more areas; diathermy (eg, microwave)) from lines 471 BRACHIAL PLEXUS LESIONS and 512 PERIPHERAL NERVE DISORDERS
    a. Add 97024 to the Services Recommended for Non-Coverage Table due to lack of evidence of effectiveness
2) Add CPT 97028 (Application of a modality to 1 or more areas; ultraviolet) to the Services Recommended for Non-Coverage Table due to lack of evidence of effectiveness
    a. Advise HSD to remove 97028 from the Ancillary List
3) Add CPT 97034 (Application of a modality to 1 or more areas; contrast baths, each 15 minutes) to the Services Recommended for Non-Coverage Table due to lack of evidence of effectiveness
    a. Advise HSD to remove 97034 from the Ancillary List
4) Remove CPT 97036 Application of a modality to 1 or more areas; Hubbard tank, each 15 minutes from lines 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT, 384 CHRONIC ULCER OF SKIN, 428 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
    a. Add 97036 to the Services Recommended for Non-Coverage Table due to evidence of harm

Paraffin Wax Therapy

Question: Should paraffin wax therapy coverage be clarified?

Question source: HERC staff

Issue: Paraffin wax therapy (CPT 97018) is currently Ancillary. This therapy involves the submersion of an extremity, normally a hand, into a bath of hot wax to improve circulation, increase flexibility, and reduce pain. The majority of use of this modality is for hand conditions, with some treatment of foot conditions.

Utilization: 79 paid claims 7/1/14-6/30/15. All 8 diagnoses paired with 97018 were hand conditions (osteoarthritis, carpal tunnel syndrome, contractures, fractures).

Evidence:

1) **Chang 2014**, RCT of paraffin therapy vs ultrasound for carpal tunnel syndrome
    a. N=47
    b. Statistical analysis revealed significant improvements in symptom severity scores in both groups. After adjusting for age, gender and baseline data, the analysis of covariance revealed a significant difference in the functional status score between two groups.
    c. Conclusions: The combination of ultrasound therapy with a wrist orthosis may be more effective than paraffin therapy with a wrist orthosis.
2) **Dilec 2013**, RCT of paraffin therapy for hand osteoarthritis
    a. N=57 (29 paraffin, 27 control)
    b. After treatment, the paraffin group exhibited significant improvement in pain at rest and during ADL, ROM of the right hand, and pain and stiffness dimensions of the AUSCAN (P<.05). There was no significant improvement in functional dimension of the AUSCAN and the DFI (P>.05). The control group showed a significant deterioration in right hand grip and bilateral lateral pinch and right chuck pinch strength (P<.05). When the 2 groups were compared, pain at rest, both at 3 and 12 weeks, and the number of painful and tender joints at 12 weeks significantly decreased in the paraffin group (P<.05). Bilateral hand-grip strength and the left lateral and chuck pinch strength of the paraffin group were significantly higher than the control group at 12 weeks (P<.05).
    c. Conclusions: Paraffin bath therapy seemed to be effective both in reducing pain and tenderness and maintaining muscle strength in hand osteoarthritis. It may be regarded as a beneficial short-term therapy option, which is effective for a 12-week period.

Summary: There are few studies on the effectiveness of paraffin wax therapy. Based on limited evidence, paraffin wax therapy is likely effective for treatment of hand arthritis and carpal tunnel syndrome.

HERC staff recommendation:

1) Advise HSD to remove paraffin wax therapy (CPT 97018) from the Ancillary List
2) Add paraffin wax therapy (CPT 97018) to the following lines, which contain hand arthritis, contracture, and fracture diagnoses
    a. 297 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
    b. 358 CLOSED FRACTURE OF EXTREMITIES (EXCEPT MINOR TOES)
    c. 359 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE
    d. 362 DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS
    e. 420 PERIPHERAL NERVE ENTRAPMENT; PALMAR FASCIAL FIBROMATOSIS
    f. 468 OSTEOARTHRITIS AND ALLIED DISORDERS

Vasopneumatic devices

Question: Should vasopneumatic device coverage be clarified?

Question source: HERC staff

Issue: Vasopneumatic device therapy (CPT 97016) is currently Ancillary. This therapy involves the use of device to apply pressure to a part of the body. This device is used for reducing swelling (edema) after acute injury and for the treatment of lymphedema.

Utilization: 112 paid claims 7/1/14-6/30/15. The top 10 diagnoses paired with 97016 were injuries to the joints of the lower leg. It was also paired with diagnoses of neck and back conditions.

Evidence:
No articles were found

Summary: There is minimal evidence concerning the effectiveness of vasopneumatic device therapy.

HERC staff recommendation:

1) Advise HSD to remove vasopneumatic device therapy (CPT 97016) from the Ancillary List
2) Option 1:
    a. Add vasopneumatic device therapy (CPT 97016) to the following lines, which contain limb arthritis, sprain, and other injury diagnoses as well as lymphedema. This allows use for conditions generally considered treatable by this therapy and not other conditions, such as back and neck pain.
        i. 359 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE
        ii. 380 DISRUPTIONS OF THE LIGAMENTS AND TENDONS OF THE ARMS AND LEGS, EXCLUDING THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT
        iii. 435 INTERNAL DERANGEMENT OF KNEE AND LIGAMENTOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT
        iv. 468 OSTEOARTHRITIS AND ALLIED DISORDERS
        v. 579 LYMPHEDEMA
        vi. 616 SPRAINS AND STRAINS OF ADJACENT MUSCLES AND JOINTS, MINOR
3) Option 2:
    a. Add vasopneumatic device therapy (CPT 97016) to the Services Recommended for Non-Coverage Table due to lack of evidence of effectiveness

Whirlpool Therapy

Question: Should whirlpool therapy be removed from wound and burn care lines?

Question source: HERC staff

Issue: Whirlpool therapy (CPT 97022 (Application of a modality to 1 or more areas; whirlpool) is an adjunctive PT therapy in which a part of the body is placed into a whirlpool bath. This reportedly increases circulation, decreases pain and swelling, and increasing mobility. It is also used for found care, as a method of debriding wounds through the shearing action of the water. CPT 97022 appears on many lines on the Prioritized List, including lines 61 BURN, FULL THICKNESS GREATER THAN 10% OF BODY SURFACE, 76 BURN, PARTIAL THICKNESS GREATER THAN 30% OF BODY SURFACE OR WITH VITAL SITE; FULL THICKNESS, LESS THAN 10% OF BODY SURFACE, 200 BURN, PARTIAL THICKNESS WITHOUT VITAL SITE REQUIRING GRAFTING, UP TO 30% OF BODY SURFACE, and 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT.

CPT 97022 is also found on all 4 new back lines which are planned for implementation shortly.

Utilization: 847 paid claims (7/1/14-6/30/15). The top 10 diagnoses associated with 97022 were injuries of the extremities and low back pain. There were no wound or burn diagnoses in the top 10 diagnoses submitted for this procedure. There were 161 claims for CPT 97022 coded with lumbago as the diagnosis.

Evidence—wound care

1) **White 2015**, PT association recommendations for Choosing Wisely (not included in the packet due to study's length)
   http://ptjournal.apta.org/content/ptjournal/95/1/9.full.pdf
   a. Don't use whirlpool for wound management.
   b. Whirlpools are a nonselective form of mechanical debridement. Utilizing whirlpool to treat wounds predisposes the patient to risks of bacterial cross-contamination, damage to fragile tissue from high turbine forces, and complications in extremity edema when arms and legs are treated in a dependent position in warm water. Other, more selective forms of hydrotherapy should be utilized, such as directed wound irrigation or a pulsed lavage with suction.

Evidence—back conditions

No articles were identified in MedLine using whirlpool, hydrotherapy, or related terms for the treatment of low back pain. There is a robust literature on the use of aquatic therapy (pool exercises) for the treatment of back pain.

HERC staff recommendations:

1) Effective October 1, 2016: Remove CPT 97022 (Application of a modality to 1 or more areas; whirlpool) from the following lines due to evidence of harm:
    a. 61 BURN, FULL THICKNESS GREATER THAN 10% OF BODY SURFACE
    b. 76 BURN, PARTIAL THICKNESS GREATER THAN 30% OF BODY SURFACE OR WITH VITAL SITE; FULL THICKNESS, LESS THAN 10% OF BODY SURFACE
    c. 200 BURN, PARTIAL THICKNESS WITHOUT VITAL SITE REQUIRING GRAFTING, UP TO 30% OF BODY SURFACE
    d. 212 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT
2) Effective July 1, 2016: Remove CPT 97022 (Application of a modality to 1 or more areas; whirlpool) from all of the new back conditions lines due to lack of evidence of efficacy
    a. 351 CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS
    b. 366 SCOLIOSIS
    c. 407 CONDITIONS OF THE BACK AND SPINE
    d. 532 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS

Implantable Cardiac Event Monitors

Question: Should implantable cardiac event monitors be a covered service?

Question source: Tracy Muday, MD, OHP Medical Director

Issue: Implantable cardiac event monitors (CPT 33282 and HCPCS C1764) are currently Excluded. Dr. Muday received a request for placement of this device for evaluation of cryptogenic stroke. The HSC reviewed this device in 2000 and placed it on the Excluded List; the rationale and documentation for this decision is not available. The minutes note that this decision was made with the input of specialty groups familiar with the procedure. This device has not been reviewed since 2000.

An insertable cardiac monitor, also referred to as an implantable loop recorder (ILR), is a small insertable device that continuously monitors heart rhythms and records them either automatically or when a hand-held patient assistant is used. Unlike Holter monitors (monitor for 1-7 days) or external cardiac loop recorders (monitor for 3-4 weeks), the ILR's record for about 3 years. They are most commonly used to evaluate fainting spells/transient loss of consciousness that remain unexplained after initial evaluation. ILRs are also used for evaluation of seizures, recurrent palpitations, lightheadedness and dizziness.

Cryptogenic ischemic stroke, one in which the origin of the emboli cannot be determined after full evaluation (e.g. ECG, 24 hours of telemetry, echocardiogram, carotid ultrasound), make up nearly a quarter of all ischemic strokes. There is growing interest in the use of ICLRs to identify occult paroxysmal atrial fibrillation in patients with cryptogenic stroke (MED 2015).

Code	Code description	Placement
33282	Implantation of patient-activated cardiac event recorder	Services recommended for non-coverage table
33284	Removal of an implantable, patient-activated cardiac event recorder	290 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
C1764	Event recorder, cardiac (implantable)	Ancillary

Evidence

1) **MED 2015**, Implantable Loop Recorders for the Evaluation of Cryptogenic Stroke
   a. There is no high-quality comparative evidence on the use of implantable cardiac loop records or other ambulatory monitoring modalities on the initiation of oral anticoagulation or stroke recurrence in patients diagnosed with occult atrial fibrillation.
   b. In the past two years, four systematic reviews found increased detection of occult atrial fibrillation by ILCRs compared to other ambulatory monitoring efforts. However, these reviews do not report on change in management nor impact on stroke recurrence (Afzal et al., 2015; Dussault et al., 2015; Kishore et

al., 2014; Sposato et al., 2015). None of the systematic reviews identified head-to-head comparative trials of different ICLR devices or extended monitoring devices. The limited data available for inclusion in the reviews were based on observational trials with short follow up periods.

c. In a small, poor-quality cohort study of 61 patients receiving ICLRs, all received weeklong serial ECGs as well. The authors reported that within the first week of use, ILCR compared to serial ECG detected cases of intermittent atrial fibrillation at a 3:1 ratio. The authors did not discuss the potential clinical significance of this finding. This study did not observe any recurrent stroke or TIAs in their short follow-up period.
d. In a fair-quality, industry funded, RCT of 441 patients, higher rates of stroke and lower use of oral anticoagulation were observed in those randomized to conventional monitoring compared to ICLRs (i.e. baseline and serial ECGs every 6 months, thus not meeting strict inclusion criteria). At 6-and 12-months follow-up, the ICM group compared to controls had statistically significantly higher percentages of participants that received anticoagulation (6 months: 10.1% vs. 4.6%, P=0.04 and 12 months: 14.7% vs. 6.0%, P=0.007).
e. Among the included studies, adverse events were rare and included site infection, pocket erosion, pain, and irritation. A single patient experienced device failure from sub-optimal placement preventing rhythm detection.
f. Summary: Patients with ischemic stroke found to have atrial fibrillation on initial evaluation experience decreased risk of recurrent stroke with the use of oral anticoagulation therapy. In patients with cryptogenic stroke, despite an extensive initial evaluation without detection of atrial fibrillation, the use of prolonged monitoring demonstrates increased detection of paroxysmal or occult atrial fibrillation. The current literature is limited on the impact of the detection of occult atrial fibrillation through prolonged monitoring and subsequent initiation of anticoagulation on stroke recurrence. Clinicians and researchers are advocating for more comparative research to be conducted on ICLRs and their use in cryptogenic stroke, as well as the clinical impact of detecting occult atrial fibrillation in those with cryptogenic stroke.

2) **Parry 2010**, review of ILR for evaluation of unexplained syncope
   a. Conclusion: The ILR has entered routine clinical practice over the last 15 years with surprisingly few rigorous data. In this era of evidence-based practice, this requires to be addressed with a focus on high quality trials of up-to-the minute technology. In the interim, the ILR offers a useful adjunct in the investigation of unexplained syncope, particularly where an arrhythmic cause is suspected. Further controlled data are required to inform clinical practice with attention focused on empowering ILR-guided diagnosis, establishing the optimal timing of ILR use in syncope and embracing new technological advancements

Expert groups

1) **European Society of Cardiology 2009**, (http://europace.oxfordjournals.org/content/11/5/671 study not included in packet due to length) ILR position statement
    a. For management of transient loss of consciousness (TLoC)
        i. Class I. ILR is indicated:
            1. In an early phase of evaluation of patients with recurrent syncope of uncertain origin who have:
                a. absence of high-risk criteria that require immediate hospitalization or intensive evaluation and
                b. a likely recurrence within battery longevity of the device (Level of evidence A)
            2. In high-risk patients in whom a comprehensive evaluation did not demonstrate a cause of syncope or lead to specific treatment (Level of evidence B)
        ii. Class II A. ILR may be indicated:
            1. To assess the contribution of bradycardia before embarking on cardiac pacing in patients with suspected or certain neurally mediated syncope presenting with frequent or traumatic syncopal episodes (Level of evidence B)
        iii. Class II B. ILR may be indicated:
            1. In patients with T-LOC of uncertain syncopal origin in order to definitely exclude an arrhythmic mechanism (Level of evidence C)
    b. For diagnosis of undocumented palpitations
        i. Class IIA: ILRs may be indicated in selected cases with severe infrequent symptoms when ELRs and other ECG monitoring systems fail to document the underlying cause (Level of evidence B). The outcome of asymptomatic arrhythmias remains uncertain.
    c. For diagnosis of atrial fibrillation
        i. Continuous monitoring by implantable devices further increases the detection of AF, but it is hampered by misdetections and artefacts.
        ii. Technological improvements are required for significant reduction of maldetection. Manual analysis can improve diagnostic yield if stored electrograms are provided. The results of some on-going studies with new generation devices are awaited
        iii. The clinical relevance of Loop Recorders to guide medical and device therapy has yet to be demonstrated
    d. For risk stratification after MI
        i. The clinical usefulness of ILR to guide medical and device therapy in patients surviving myocardial infarction has yet to be demonstrated
        ii. ILRs have a potential role in identifying the correlation between symptoms and suspected ventricular tachyarrhythmia in selected high-risk patients affected by Brugada ECG pattern, long or short QT, hypertrophic cardiomyopathy, and arrhythmogenic right ventricular dysplasia.

Other policies

1) **NICE 2010** http://guidance.nice.org.uk/cg109 (Study not included in packet due to length)
    - **a.** For evaluation of transient loss of consciousness (TLoC) in adults: For people with a suspected cardiac arrhythmic cause of syncope, offer an ambulatory ECG and do not offer a tilt test as a first-line investigation. The type of ambulatory ECG offered should be chosen on the basis of the person's history (and, in particular, frequency) of TLoC. For people who have TLoC infrequently (less than once every 2 weeks), offer an implantable event recorder.
2) **Aetna 2015 (not included due to length**
   http://www.aetna.com/cpb/medical/data/1_99/0073.html
    a. Aetna considers an implantable loop recorder (e.g., Reveal Insertable Loop Recorder by Medtronic, Inc.) medically necessary for evaluation of recurrent unexplained episodes of pre-syncope, syncope, "seizures", palpitations, or dizziness when both of the following criteria are met:
        i. A cardiac arrhythmia is suspected as the cause of the symptoms; *and*
        ii. Either of the following criteria is met:
            1. For persons with heart failure, prior myocardial infarction or significant ECG abnormalities (see appendix), noninvasive ambulatory monitoring, consisting of 30-day presymptom external loop recordings or MCT, fails to establish a definitive diagnosis; *or*
            2. For persons without heart failure, prior myocardial infarction or significant ECG abnormalities (see appendix), symptoms occur so infrequently and unpredictably (less frequently than once per month) that noninvasive ambulatory monitoring (MCT or external loop recorders) are unlikely to capture a diagnostic ECG.

    b. Aetna considers implantable loop recorders experimental and investigational for all other indications because their effectiveness for indications other than the ones listed above has not been established.
3) **Cigna 2015 (not included due to length)**
   http://s-rm3.cigna.com/assets/docs/health-care-professionals/coverage_positions/mm_0085_coveragepositioncriteria_cardiac_event_monitors.pdf
    a. Cigna covers the use of an implantable loop recorder (CPT codes 33282, 33284, 93285, 93291, 93297, 93298, 93299, C1764, E0616) as medically necessary for the evaluation of recurrent unexplained episodes of fainting when ALL of the following criteria are met:
        i. cardiac arrhythmia is suspected to be the cause of fainting
        ii. noninvasive ambulatory monitoring failed to establish a definitive diagnosis because the symptoms occur so infrequently and unpredictably that the length of the monitoring period may have been inadequate to capture a diagnostic electrocardiogram (ECG) rhythm disorder

iii. tilt-table testing is negative or nondiagnostic

HERC staff summary:
The use of implantable loop recorders (ILRs) appears to have evidence to support and expert recommendations for use for evaluation of recurrent transient loss of consciousness in patients in whom a comprehensive evaluation including noninvasive ambulatory monitoring did not demonstrate a cause of the TLoC or lead to specific treatment, and in whom a cardiac cause is suspected, and in whom an event is expected to recur within the battery life of the ILR.

The use of ILRs for evaluation for possible atrial fibrillation as the cause of cryptogenic stroke appears to be an area of active research and controversy.

HERC staff recommendations:

1) Add coverage for the use of implantable loop recorders (ILRs) for the evaluation of recurrent transient loss of consciousness in selected patients. Do not add coverage for other indications due to their experimental nature
    a. Advise HSD to add CPT 33282 (Implantation of patient-activated cardiac event recorder) to the Diagnostic Procedures File and remove from the Services Recommended for Non-Coverage Table
    b. Advise HSD to add HCPCS C1764 (Event recorder, cardiac (implantable)) to the Diagnostic Procedures File and remove from the Ancillary List
    c. Adopt the following Diagnostic Guideline Note

DIAGNOSTIC GUIDELINE DX, IMPLANTABLE LOOP RECORDERS
Use of an implantable cardiac loop recorder (ILR) is a covered service only when the patient meets all of the following criteria:

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

ILRs are not a covered service for evaluation of cryptogenic stroke or any other indication.

Electric Tumor Treatment Fields for Glioblastoma

Question: Should electric tumor treatment field therapy be covered for initial treatment of glioblastoma?

Question source: Andy Luther, MD, OHP medical director

Issue: Electric tumor treatment field therapy (ETTF) involves a portable device which delivers low-intensity, intermediate frequency electric fields via non-invasive, transducer arrays. It is thought to physically interfere with tumor cell division. Glioblastoma is a very difficult to treat cancer of the brain with a typical life expectancy with current therapy of 1-2 years. Standard treatment involves surgical resection, radiation therapy, and chemotherapy.

ETTF therapy was reviewed for treatment of recurrent glioblastoma in May, 2014. At that time, little evidence was found to support its effectiveness and it was found to be less cost effective than conventional therapy for recurrent glioblastoma. The HCPCS codes for this therapy (HCPCS A4555 and E0766) were placed on the Services Recommended for Non-Coverage Table.

ETTF recently received FDA approval for initial treatment of glioblastoma. This approval was based on the results of a single trial of 695 participants.

A4555	Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only
E0766	Electrical stimulation device used for cancer treatment, includes all accessories, any type

From Dr. Luther:

> … had a request for the Optune "tumor treating fields" system for treatment of glioblastoma in conjunction with temozolomide. It was FDA approved in October for certain patients, but Up-To-Date is fairly cautious about it's use given data available so far. We have an unfortunate patient that it might be appropriate for, and of course it is very expensive, OHP coverage not clear. There is now (as of October) an indication for treatment for newly diagnosed glioblastoma, after rad/chemo, in conjunction with ongoing temozolomide. I think the ancillary GL only addresses recurrent glioblastoma, so this may deserve another look, as it seems likely to keep coming up.

Originally approved entry in the Services Recommended for Non-Coverage Table
ELECTRONIC TUMOR TREATMENT FIELDS
Most recent review date: May, 2014
Electronic tumor treatment field therapy (ETTF; HCPCS A4555 and E0766) has been found to have significantly lower cost effectiveness compared to conventional chemotherapy for treatment of recurrent glioblastoma. See VBBS/HERC minutes from 5/8/14 for details [link].

Current entry in the Services Recommended for Non-Coverage Table

HCPCS A4555, E0766	Electronic tumor treatment field (ETTF) therapy	June, 2014	Found to have comparable effectiveness to conventional treatments, but significantly higher cost[3]

Evidence

Stupp 2015 (http://www.ncbi.nlm.nih.gov/pubmed/?term=26670971 Study not included due to length)

1) Randomized, non-controlled trial, open label trial of temozolomide chemotherapy alone vs temozolomide chemotherapy followed by TTF therapy for initial treatment of glioblastoma
2) N=695 patients (466 TTF+chemo, 229 chemo alone)
    a. Trial stopped after analysis of 315 patients (280 actually included in analysis after exclusions)
    b. Excluded patients who progressed rapidly after initial diagnosis and thus had the poorest prognoses
3) Intention to treat trial, endpoint was progression free survival
4) Median follow up 38 months (range, 18-60 months).
5) Median progression-free survival in the intent-to-treat population was 7.1 months (95%CI, 5.9-8.2 months) in the TTFields plus temozolomide group and 4.0 months (95%CI, 3.3-5.2 months) in the temozolomide alone group (hazard ratio [HR], 0.62 [98.7%CI, 0.43-0.89]; *P* = .001). Median overall survival in the per-protocol population was 20.5 months (95%CI, 16.7-25.0 months) in the TTFields plus temozolomide group (n = 196) and 15.6 months (95%CI, 13.3-19.1 months) in the temozolomide alone group (n = 84) (HR, 0.64 [99.4%CI, 0.42-0.98]; *P* = .004).
6) Further data analysis and follow up will be done; however, control patients were allowed to cross over to the ETTF group after official study termination and therefore future study results will be difficult to interpret
7) Significant differences in chemotherapy received by the TFF and control groups
    a. Number of cycles of temozolomide in the TTF group until disease progression=6 vs 4 cycles in the control group
    b. Second line chemotherapy received in 67% of the TTF group vs 57% of the temozolomide alone group
    c. Unclear if due to benefit of TTF (longer healthy life) or whether the additional chemotherapy explains some or all of the observed TTF benefit
    d. Question about whether the open-label use of TTF impacted provider or patient decision making regarding additional therapies (see **Sampson 2015** critique)
8) No increase in adverse events seen in the TTF group compared to the temozolomide alone group
9) CONCLUSIONS AND RELEVANCE In this interim analysis of 315 patients with glioblastoma who had completed standard chemoradiation therapy, adding TTFields to maintenance temozolomide chemotherapy significantly prolonged progression-free and overall survival.
10) Industry sponsored trial

Major guidelines:

NCCN 2015 (study not included due to length)

1) ETTF mentioned as a possible therapy option for treating recurrent glioblastoma
    a. "Consider alternating electric field therapy for glioblastoma (category 2B)"
    b. No change from recommendation reviewed by HERC in 2014
2) No mention of ETTF as possible therapy for treatment of initial treatment of glioblastoma

European Society for Medical Oncology 2014

(http://annonc.oxfordjournals.org/content/early/2014/04/29/annonc.mdu050 Guideline not included due to length)

1) Reviewed ETTF as treatment for recurrent glioblastoma and did not find evidence to support its use
2) Use for initial treatment of glioblastoma was not reviewed

HERC staff summary:

The current evidence to support the use of electric tumor treatment fields in the initial treatment of glioblastoma is based on a single trial, which had questions regarding the trial methodology. No major specialty group is currently including ETTF as a recommended treatment for initial glioblastoma treatment. However, this does appear to be a rapidly evolving field and a promising treatment.

HERC staff recommendations:

1) Do not add ETTF (HCPCS A4555 and E0766) as an initial treatment for glioblastoma
2) Amend the entry to the Services Recommended for Non-Coverage as shown below

HCPCS A4555, E0766	Electronic tumor treatment field (ETTF) therapy	June, 2014 (Affirmed March 2016) March, 2016	For recurrent glioblastoma: Found to have comparable effectiveness to conventional treatments, but significantly higher cost[3] For initial treatment of glioblastoma: Experimental[2]

Footnotes 2 and 3 refer to OARs

Incontinentia Pigmenti

Question: Should incontinentia pigmenti (ICD-10 Q82.3) be moved to a higher priority line and paired with ophthalmologic treatment codes?

Question source: Casey Eye Institute

Issue: Dr. Pete Campbell, an ophthalmologist at OHSU, has requested review of incontenentia pigmenti. He feels that this condition should be paired with several ophthalmology treatment CPT codes.

The ICD-10 code Q82.3 (Incontinentia pigmenti) is on line 660 DERMATOLOGICAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY. The equivalent ICD-9 code was generic [ICD-9 757.33 (Congenital pigmentary anomalies of skin)] and was also this line.

From Dr. Campbell:

> Incontientia pigmenti (Q82.3) is a genetic disorder that can cause problems in many different body parts and organ systems including hair, skin, bones, brain, and the eye. Approximately 30% of patients with IP will develop ocular complications and 20% will develop vision threatening disease. As a result, the standard of care is to perform examinations under anesthesia, ocular imaging including fluorescein angiography, and laser panretinal photocoagulation to reduce the risk of blindness.

Dr. Campbell is requesting the Q82.3 be moved to a covered line on the Prioritized List and pair with CPT codes 92002-92014, 99201-99215, 92018, 92235, 92250, 92134, and 67228.

O'Doherty et al (2010) reviewed incontinentia pigmenti ophthalmologic manifestations and treatment. This is a very rare disorder, so few children were included in the case review (N=11). Reported ocular complications include nystagmus, strabismus, microphthalmos, ptosis, blue sclera, pigmentation of the conjunctiva, corneal changes, cataract, optic atrophy, vitreous hemorrhage and myopia. However, the most typical abnormality is fibroblastic retinal detachment secondary to an ischemic vasculopathy not dissimilar in appearance to retinopathy of prematurity. Expert recommendation is for examination under anesthesia, with laser photocoagulation if needed. Fluorescein angiography has been found to be useful to identify neovascularization and allow earlier treatment and reduce the risk of retinal detachment.

This condition can also result in seizures, structural brain abnormalities, developmental delay, and dental issues.

Dr. Campbell reports that Casey Eye Institute has seen 38 cases of incontinentia pigmenti in the past 4 years, most of which required only office visits.

Incontinentia Pigmenti

HERC staff recommendation:

1) Add Q82.3 (Incontinentia pigmenti) to line 278 RETINOPATHY OF PREMATURITY Treatment: CRYOSURGERY and remove from line 660 DERMATOLOGICAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
    a. Allows pairing with CPT 92002-92014, 99201-99215, 92018, 92235, 92250, 92134, and 67228 (Ophthalmologic visits and treatments)
    b. Expert literature describes presentation, treatment, etc. as similar to retinopathy of prematurity
    c. Neurologic and developmental delay complications can be treated by using the specific dysfunction diagnosis, which would likely be found on one of the dysfunction lines
    d. Seizures can be treated by using a seizure diagnosis code

Sacroiliac Joint Fusion for Sacroiliitis

Question: Should sacroiliac joint fusion be added as a treatment for sacroiliitis?

Question source: Andy Kranenburg, MD and Adam Cabala, MD, surgeons

Issue: Drs. Kranenburg and Cabala have requested that the HERC consider pairing sacroiliac joint fusion (CPT 27279) with sacroiliitis (ICD-10 M46.1). They report that this procedure can reduce pain and increase function and quality of life. Please see their letter for full details.

Currently, sacroiliac joint fusion (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) is on line 187 FRACTURE OF PELVIS, OPEN AND CLOSED. M46.1 (Sacroiliitis, not elsewhere classified) which includes sacroiliitis and sacroiliac arthritis is currently on line 532 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT (LINE 545 FROM THE OCT. 1, 2015 PRIORITIZED LIST†) and will be only included on the medical back line when the back line revisions are implemented.

Evidence

Note: none of the articles in the surgeon-provided bibliography were available in MEDLINE.

1) **Ahmad Al-khayer 2008**
    a. Case series N=9, percutaneous SIJ arthrodesis technique for patients with intractable SIJ pain. Preoperative
    b. 2 year follow up
    c. Results: The mean Oswestry Disability Index value dropped from 59 (range: 34 to 70) preoperatively to 45 (range: 28 to 60) postoperatively (Pr0.005). The mean Visual Analog Scale value dropped from 8.1 (range: 7 to 9) preoperatively to 4.6 (range: 3 to 7) postoperatively (Pr0.002). The mean patients' satisfaction was 6.8 (range: 5 to 8).
    d. Conclusions: This new technique may offer a safe and effective treatment for intractable SIJ pain.
2) **Rashbaum 2016**, review of treatments for sacroiliac joint dysfunction
    a. There have been multiple reports from various countries reporting good outcomes of minimally invasive SIJ fusion.
    b. Reported on two studies that were not locatable in MEDLINE:
        i. Whang et al (2015): There is level I evidence available from a recent prospective, randomized study comparing SIJ fusion to nonoperative care. The follow-up for the study period reported was 6 months. Patient selection criteria for the study included SIJ localized pain, positive findings on at least 3 of 5 established manual examinations, and at least 50% improvement in SIJ pain 30–60 minutes after image-guided anesthetic injection into the joint. The SIJ fusion group had a significantly higher success rate (based on improvement in SIJ pain scores and lack of device-related complications, revision surgery, or neurological

complications) as well as a statistically significantly greater improvement in Oswestry Disability Index scores, and quality of life assessment.

ii. Rudolf et al (2014): Five-year follow-up was available for a small series of patients. Five-year follow-up was available for 17 of 21 patients (80.9%) who underwent SIJ fusion 5 years before the analysis. Plain radiographs and CT scans were performed on 15 of these patients. Imaging showed increased bone density adjacent to all implants with intraarticular osseous bridging in 87% of patients and no evidence of implant loosening or migration.

iii. Both articles were reported to have at least 1 author who was an employee of a manufacturer and one or more of the other authors had a potential conflict most often as a consultant or stockholder

Other policies:

1) Aetna 2015 does not cover sacroiliac joint fusion

HERC staff recommendation:

1) Do not add sacroiliac joint fusion (CPT 27279) to 532 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT or the new surgical back line
    a. No evidence of effectiveness
    b. Appears experimental

Non-Contact, Low-Intensity Ultrasound for Chronic Wound Healing

Question: Is non-contact, low-intensity ultrasound for chronic wound healing effective either as sole or adjuvant therapy compared to other modalities?

Question source: Alliqua Biomedical, company which produces MIST Therapy® (a non-contact, low-frequency ultrasound technology)

Issue: Non-contact, low-frequency ultrasound is not currently covered for wound healing treatment. Suspected deep tissue injury (SDTI) was excluded.

Low frequency ultrasound (CPT 97610) was reviewed in October, 2013 when the new CPT code for this procedure was released. At that time, it was placed on the Services Recommended for Non-Coverage table due to being experimental.

The manufacturer of MIST therapy has requested that the HERC re-review this procedure, as "there is significant data demonstrating a reduction in healing times and increase in complete healing rates compared to standard of care treatment."

Evidence:

Systematic Reviews:

1) **NICE 2011,** Medical Technology Guidance of MIST Therapy system for the promotion of wound healing (not included due to length) https://www.nice.org.uk/guidance/mtg5/resources/the-mist-therapy-system-for-the-promotion-of-wound-healing-1788114109381
    a. N=10 studies
        i. N=2 RCTs (203 patients total).
            1. Kavros et al. 2007: 70 patients with non-healing wounds and chronic critical limb ischemia comparing standard wound care (daily dressing changes and weekly debridement) with standard wound care + MIST Therapy system 3x/week for 12 weeks. 63% of wounds healed (defined as >50% reduction in volume) in intervention compared with 29% in control group ($p<0.01$).
            2. Ennis et al. 2005: 133 patients with diabetic foot ulcers comparing MIST Therapy system with sham device 3x/week for 10 weeks. Standard wound care for both groups as well. Intention to treat analysis: 26% of wounds healed in intervention group compared to 22% in control group (not statistically significant.)

        ii. N=8 observational studies: "Overall the Committee recognised that the quality of evidence in the area of wound care is generally low and heterogeneity of chronic wounds poses a challenge...[but] evidence supporting the clinical effectiveness of the MIST Therapy system was equal to or better than evidence for many other wound care interventions in current use in the NHS."

b. **Authors' conclusions:** "Evidence suggested real potential for the MIST Therapy system to enhance the healing of chronic wounds, but that overall the quality of the evidence was limited by small patient numbers and lack of appropriate comparison groups."
c. **Technology coverage conclusions:** The amount and quality of published evidence on the relative effectiveness of the MIST Therapy system is not sufficient, at the time of writing, to support the case for routine adoption of the MIST Therapy system in the NHS.

2) Cullum 2011: Cochrane Systematic Review on Therapeutic Ultrasound for venous leg ulcers

a. N=8 RCTs (6 high frequency ultrasound, 2 low frequency ultrasound)
    i. Low frequency RCTs: Peschen 1997, Weichenthal 1997
        1. Peschen 1997 N=24 people with one venous ulcer each, larger than 2 cm x 2 cm of > three months' duration. Everyone received standard treatment of hydrocolloid dressing + compression bandage. Intervention arm also received low-freq ultrasound 3x/wk for 12 weeks while the control group received sham ultrasound. Outcome: RR for ulcer healing at 12 weeks is 5.00, 95% CI 0.27-94.34.
        2. Weichenthal 1997 N=37 people with a venous ulcer > three months' duration and no e/o arterial dz or diabetes. Everyone received conventional treatment (fibrinolytics, antibiotics, antiseptics, and occlusive dressings) but 19 also received low-frequency ultrasound in a footbath (not saline mist.) Unknown frequency or duration of ultrasound treatments. One person from intervention group excluded at the end for having evidence of arterial vascular disease. Outcomes: At eight weeks one ulcer healed completely in ultrasound group and none in control. RR 2.85, 95% CI 0.12 - 65.74. Not statistically significant. German study.
    ii. Pooled both studies using fixed effect model: RR 3.91, 95% CI 0.47 - 32.85, not statistically significant difference in healing.
    iii. Limitations: Both RCTs are underpowered.
    iv. **Authors' conclusions**: "There is no evidence to support the routine use of therapeutic ultrasound (US) as a treatment for venous leg ulcers. The evidence that exists is of low quality and volume, and a beneficial effect cannot be ruled out."

3) Akbari 2009: Cochrane Systematic Review Therapeutic Ultrasound for Pressure Ulcers

a. N=3 RCTs (146 people.)
    i. McDiarmid 1985: N=40. Compared low-frequency ultrasound 3x/wk for unclear duration with sham treatment for patients with pressure ulcers. 48% pressure ulcers healed in intervention group compared with 42% in sham group. RR 1.13, 95% CI 0.57 to 2.26.

ii. ter Riet 1995: 88 nursing home patients with pressure ulcers > stage I, randomized to receive low-frequency ultrasound 5x/wk for 12 weeks. 40% wounds healed in intervention group compared with 44% in sham group. RR 0.91, 95% CI 0.55 to 1.48.
iii. Nussbaum 1994: Compared a combination of ultrasound and laser treatment with standard wound care, so this study is not relevant to this inquiry.
iv. ter Riet + McDiarmid pooled using fixed effects model: RR 0.97, 95% CI 0.65 to 1.45.

c. **Authors' conclusions**: Pooled analysis from 2 available RCTs "found no evidence of a benefit of ultrasound on the healing rates of pressure ulcers."

Meta-analysis:

1) **Driver 2011**: meta-analysis of low frequency ultrasound for treatment of chronic wounds
    a. N=8 studies (1 RCT—not blinded, 5 retrospective of which only 1 had a control group receiving standard care, and 2 prospective nonrandomized)
        i. Patients=444.
    b. Results:
        i. 4/8 studies (N=278) had data on reduction in wound volume. Ultrasound was associated with 79.7% reduction over approx 12 wks, no significant evidence of heterogeneity or study bias.
        ii. 7/8 studies (N=429) had data on proportion of wounds healed by end of study period. Average time to healing was 8.2 wks, median 6.8 wks all with ultrasound.
        iii. 4/8 studies (N=188) reported on wound area change from baseline, with ultrasound intervention arms suggesting a pooled estimate of 85.2% reduction with 95% CI of 64.7%-97.6% over the study period (undefined.)
    c. Limitations:
        i. The meta-analysis looked at studies with historical controls in order to compare to standard of care, rather than directly compare ultrasound to standard wound care. This meta analysis noted that the 62% wound area reduction in the historical controls was lower than the lower limit of the CI in this pooled analysis (CI 65%-98%). There was concern from the reviewer that the meta analysis misreports some data from these historical studies
        ii. Standard of care varied across studies.
        iii. Wound etiology varied across studies.
        iv. All but one of the eight studies were observational, non-randomized, non-blinded studies.

   v. This meta-analysis does not describe funding sources or any conflicts of interest, but a subsequent RCT (Olyaie 2013) refers to it as an "industry-sponsored meta-analysis."
- d. Authors' Conclusions: "Remarkable consistency of reductions in wound area, wound volume, and wound pain were observed...Future research on this noncontact, low-frequency ultrasound therapy should focus on larger, randomized clinical trials."

2) **Voight 2011**: Meta-analysis of low frequency ultrasound as adjunctive therapy for wound healing
   a. N=5 RCTs (1 included in Cullum 2011)
      i. only two pairings of 2 studies were able to be pooled for outcomes.
   b. Two studies dealing specifically with venous ulcers (Peschen 1997 and Weichenthal 1997) pooled for % wound size reduction. N=61. Mean difference 25.97%, CI 11.09%-40.86%, P=0.0006.
   c. Two studies were pooled for outcome of nonhealed wounds at 3 months comparing ultrasound vs sham events (Ennis 2005 and Peschen 1997.) N=60. Pooled Risk Ratio 0.74 [0.58, 0.95]
   d. Limitations: Significant differences between the five studies meant that the authors could only pool two studies for two different outcomes. One study was industry funded, issues in the protocol of another was criticized.
   e. Authors' conclusions: "Although it appears...that [low-frequency, low intensity, noncontact ultrasound] is more effective at complete healing than standard of care, the quality of the evidence as it relates to biases was poor...Although the quality of the evidence is in general of lower quality for both types of ultrasound, the evidence does demonstrate a short-term clinically beneficially effect of [low-frequency, low intensity, noncontact ultrasound]...used as an adjunctive therapy on the clinical end points of complete healing and reduction in wound area size for patients presenting with venous stasis and diabetic foot ulcers."

Guidelines**:** none identified

Other coverage policies: Aetna and Anthem BCBS do not cover due to investigational nature of the therapy

HERC staff summary

Systematic reviews from trusted sources (NICE and Cochrane) and well-conducted meta-analyses failed to find evidence to support significant improvement in wound healing with low frequency ultrasound compared to usual wound care. The one meta-analysis submitted by the manufacturer (Driver 2011) supporting this technology had significant methodological flaws.

HERC staff recommendations:

1) Do not add overage for low frequency ultrasound for any type of chronic wound. Keep CPT 97610 (Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day) on the Services Recommended for Non-Coverage table

Posterior Tibialis Tendinopathy

Question: Should surgical correction of flat foot (posterior tibialis tendinopathy) be reprioritized higher on the Prioritized List?

Question source: Dr. Richard Owens, orthopedic surgery

Issue: Flatfoot diagnoses are generally on uncovered lines, and the diagnoses on the Prioritized List used for this condition generally do not pair with the most used repair codes. Dr. Owens has requested that the HERC consider coverage for flat foot due to posterior tibialis tendonopathy. Dr. Owens feels that lack of coverage for the early forms of this disorder results in patients developing more severe stages and finally getting coverage for an ankle fusion surgery for the late states, when earlier care might have prevented the need for such extensive surgery.

Flatfoot (hyperpronation and flattening-out of the longitudinal arch) (also known as pes planus or pes planovalgus) is a common deformity among children and adults. It may be congenital, or be acquired due to various conditions including posterior tibial tendon dysfunction. Lack of a functional arch affects the biomechanics of the lower leg and can result in pain. Flat feet are very common in children, and may resolve as the child grows. Flat feet can also develop as an adult ("adult acquired flatfoot") due to injury, illness, unusual or prolonged stress to the foot, faulty biomechanics, or as part of the normal aging process.

If a youth or adult appears flatfooted while standing in a full weight bearing position, but an arch appears when the person plantar flexes, or pulls the toes back with the rest of the foot flat on the floor, this condition is called flexible flatfoot. Most flexible flat feet are asymptomatic, and do not cause pain. In these cases, there is usually no cause for concern. In some patients, lower leg pain results from the flat foot, which can be treated with the use of shoes with properly fitting, arch-supporting orthotics.

Rigid flatfoot, a condition where the sole of the foot is rigidly flat even when a person is not standing, often indicates a significant problem in the bones of the affected feet, and can cause pain in about a quarter of those affected. Other flatfoot-related conditions, such as various forms of tarsal coalition (two or more bones in the midfoot or hindfoot abnormally joined) or an accessory navicular (extra bone on the inner side of the foot) should be treated promptly, usually by the very early teen years, before a child's bone structure firms up permanently as a young adult. Both tarsal coalition and an accessory navicular can be confirmed by X-ray. Rheumatoid arthritis can destroy tendons in the foot (or both feet) which can cause this condition, and untreated can result in deformity and early onset of osteoarthritis of the joint. Such a condition can cause severe pain and considerably reduced ability to walk, even with orthoses. Ankle fusion is usually recommended.

There are 4 stages of acquired flat foot deformity. Stage I is an inflammation of the tendon and normally is treated conservatively with braces. Stage II has the foot remaining flexible, with arch collapse and mild sinus tarsi pain. Stage III is a rigid fore and hindfoot, with severe sinus

tarsi pain and subtalar arthritis. Stage IV involves ankle pain, deltoid ligament compromise, and subtalar arthritis and talar tilt in ankle mortise are seen on xray. Acquired flat foot deformity is typically seen in middle aged patients with conditions such as diabetes.

Treatment of asymptomatic flat feet is not required. Foot or leg pain due to flat feet is treated with orthotics for arch support, NSAIDs, and/or foot exercises. Surgery may be done for more severe stages of flat foot or when conservative therapy fails.

From Dr. Rich Owen

> I am sending a review article from our orthopedic review journal. It discusses the four stages of adult acquired flatfoot deformity. Patients predictably progress from Stage 1 to at least Stage 3 and sometimes Stage 4 without treatment. Currently, OHP doesn't cover surgical or nonsurgical options. The condition is severely debilitating, and gets worse with time. Many times nonsurgical treatment does not work.

Dr. Owens recommended the following coverage for acquired flatfoot:

1) Stage 1: braces or orthotics to prevent progression.
2) Stage 2: braces or orthotics. Repair for patients less than 70 years of age (CPT 20902, 27687, 27690, 28090, 28300, 28306, 28307, 28715)
3) Stage 3: surgical repair (CPT 27605, 27687, 28715)
4) Stage 4: surgery-total ankle replacement (CPT 27702)

Posterior Tibialis Tendinopathy

Current Prioritized List status

ICD-10 Code	Code description	Current Line(s)
M19.07	Primary osteoarthritis, ankle and foot	**361** RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE **467** OSTEOARTHRITIS AND ALLIED DISORDERS
M21.4	Flat foot [pes planus] (acquired))	**580** CAVUS DEFORMITY OF FOOT; FLAT FOOT; POLYDACTYLY AND SYNDACTYLY OF TOES
M21.6	Other acquired deformities of foot	**382** DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF- DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION **530** DEFORMITIES OF UPPER BODY AND ALL LIMBS
*M21.961	Unspecified acquired deformity of right lower leg	**382** **545** DEFORMITIES OF FOOT
*M66.9	Spontaneous rupture of unspecified tendon	**506** OTHER DISORDERS OF SYNOVIUM, TENDON AND BURSA, COSTOCHONDRITIS, AND CHONDRODYSTROPHY
M76.82	Posterior tibial tendinitis	**490 and 508** ERIPHERAL ENTHESOPATHIES
Q66.5	Congenital pes planus	**545**
Q66.9	Congenital deformity of feet, unspecified	**545**

*identified by Dr. Owens as appropriate diagnosis code

CPT code	Code Description	Current Line(s)
*20902	Bone graft, any donor area; major or large	**164** TRAUMATIC AMPUTATION OF ARM(S), HAND(S), THUMB(S), AND FINGER(S) (COMPLETE)(PARTIAL) WITH AND WITHOUT COMPLICATION **447** MALUNION AND NONUNION OF FRACTURE **488** ENOPHTHALMOS **587** ATROPHY OF EDENTULOUS ALVEOLAR RIDGE
*27605	Tenotomy, percutaneous, Achilles tendon (separate procedure); local anesthesia	**297** NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS **364** DEFORMITY/CLOSED DISLOCATION OF MAJOR JOINT AND RECURRENT JOINT DISLOCATIONS

		392 DEFORMITY/CLOSED DISLOCATION OF MINOR JOINT AND RECURRENT JOINT DISLOCATIONS
*27687	Gastrocnemius recession (eg, Strayer procedure)	**297**, **364**, **392** **530** DEFORMITIES OF UPPER BODY AND ALL LIMBS
*27690	Transfer or transplant of single tendon (with muscle redirection or rerouting); superficial (eg, anterior tibial extensors into midfoot)	**297,364,392,530** **545** DEFORMITIES OF FOOT
27700-27703	Arthroplasty, ankle	**361** RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE
*28090	Excision of lesion, tendon, tendon sheath, or capsule (including synovectomy) (eg, cyst or ganglion); foot	**361,364,392, 545** **596** GANGLION
28238	Reconstruction (advancement), posterior tibial tendon with excision of accessory tarsal navicular bone (eg, Kidner type procedure)	**364, 392, 545**
*28300	Osteotomy; calcaneus (eg, Dwyer or Chambers type procedure), with or without internal fixation	**297,364,392,530,545**
*28306	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal	**545**
*28307	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal with autograft (other than first toe)	**297,364,392,545**
*28715	Arthrodesis; triple	**290** COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT **297,361,364,392,545**
28735	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (eg, flatfoot correction)	**364,392,545**

29907	Arthroscopy, subtalar joint, surgical; with subtalar arthrodesis	**297** NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS **361,364,392** **447** MALUNION AND NONUNION OF FRACTURE **545**
HCPCS Code		
S2117	Arthroereisis, subtalar	**382** DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION

*identified by Dr. Owens as appropriate procedure code
Other codes identified through literature and other insurer policy statements
Note: S2117 is a controversial procedure

Evidence

1) **Rome 2012**, Cochrane review of non-surgical treatments for pediatric flatfoot (study not included due to length)
   http://www.bcu.ac.uk/cmsproxyimage?path=/_media/docs/cd006311.pdf
   a. N=3 trials (305 children)
   b. Data from one trial (40 children with juvenile arthritis and foot pain) indicated that use of custom-made orthoses compared with supportive shoes alone resulted in significantly greater reduction in pain intensity (mean difference (MD) -1.5 points on a 10-point visual analogue scale (VAS), 95% CI -2.8 to -0.2; number need to treat to benefit (NNTB) 3, 95% CI 2 to 23), and reduction in disability (measured using the disability subscale of the Foot Function Index on a 100mm scale (MD -18.65mm, 95% CI -34.42 to -2.68mm).
   c. The second trial of seven to 11 year old children with bilateral flat feet (n = 178) found no difference in the number of participants with foot pain between custom-made orthoses, prefabricated orthoses and the control group who received no treatment.
   d. A third trial of one to five year olds with bilateral flat feet (n=129) did not report pain at baseline but reported the subjective impression of pain reduction after wearing shoes. No adverse effects were reported in the three trials.
   e. **Authors' conclusions** The evidence from randomised controlled trials is currently too limited to draw definitive conclusions about the use of non-surgical interventions for paediatric pes planus. Future high quality trials are warranted in this field. Only limited interventions commonly used in practice have been studied and there is much debate over the treatment of symptomatic and asymptomatic pes planus
2) **MacKenzie 2012**, review of treatment of pediatric flatfoot
   a. N=13 studies, generally poor quality
   b. Conclusions: evidence for efficacy of nonsurgical interventions for flexible pediatric flat feet is very limited. Future research needs validated foot type assessment, applicable outcome measures for the intervention, the use of control groups, allowance for independent effects of footwear, age range comparisons, larger samples, and prospective, longer follow-up.
3) **Bouchard 2014**, review of flatfoot in children and adolescents
   a. Most flexible flatfoot deformities are asymptomatic, will not lead to future pain or disability, and do not require treatment.
   b. Scant convincing evidence exists to support the use of inserts or shoe modifications for effective relief of symptoms, and there is no evidence that those devices change the shape of the foot.
   c. Surgery is rarely indicated, and in nearly all cases, an associated contracture of the heel cord is present
   d. Indications for flatfoot surgery are strict: failure of prolonged nonsurgical attempts to relieve pain that interferes with normal activities and occurs under the medial midfoot and/or in the sinus tarsi.

e. Osteotomies with supplemental soft-tissue procedures are the best proven approach for management of rigid flatfoot.

4) **Stegeman 2015**, review of outcomes after tarsal joint fusion
   a. Only one study was considered to have best evidence for flatfoot treatment by subtalar fusion
      i. An increase in the AOFAS score from 46 preoperatively to 70 points postoperatively was observed without concomitant use of low-intensity ultrasound (US) bone growth stimulation, and this score had increased from 50 to 84 when low-intensity US stimulation was used.
   b. Flatfoot treated using triple arthrodesis was described in 2 of the studies (12.5%); however, no best evidence could be deduced from those reports, and no study was found with flatfoot treated using talonavicular arthrodesis.
   c. van der Krans et al described 20 patients with posterior tibial tendon disease and calcaneocuboid distraction arthrodesis and noted improvement in the AOFAS score from a mean of 46 preoperative to a mean of 79 postoperatively, along with structural improvement in the alignment of the foot as measured radiographically, with the talar–first metatarsal angle decreasing from 15 deg preoperatively to 4.1 deg postoperatively.

<u>Submitted literature</u>

1) **Deland 2008**, acquired flatfoot deformity in adults
   a. Stage 1 should be treated conservatively with NSAIDs, orthotics, or immobilization with a cast or brace
      i. No study has been done to document whether these devices slow or prevent the progression of deformity
   b. Reviewed various surgical options for treating various stages of flatfoot deformity

HERC staff recommendations:

1) Add ICD-10 M21.6 (Other acquired deformities of foot) to line 545 DEFORMITIES OF FOOT and remove from line 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS
    a. More appropriate placement
2) Add ICD-10 Q66.5 (Congenital pes planus) to line 580 CAVUS DEFORMITY OF FOOT; FLAT FOOT; POLYDACTYLY AND SYNDACTYLY OF TOES and remove from line 545
    a. More appropriate placement
3) Add CPT codes for surgical treatment of flatfoot to line 580
    a. Will allow pairing and limited coverage through the exceptions process
    b. Add CPT 28735 (Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (eg, flatfoot correction)) to line 580 and remove from lines 364, 392, 545
    c. Add the following CPT codes to line 580
        i. 20902, 27605, 27687, 27690, 27700-27703, 28090, 28238, 28300, 28306, 28307, 28715, 29907
        ii. See table above for procedure descriptions
4) Do not change current prioritization/placement of flatfoot; maintain on line 580.
    a. Generally does not require treatment. If progresses to ankle arthritis, can have surgical and non-surgical treatment of that condition. Severe flat foot deformity treatment can be pursued through the exceptions process
    b. No evidence identified on rate of progression of early stages to later stages or on the ability of orthotics or braces to prevent such progression
    c. If coverage is considered, only acquired flat foot should be considered (not congenital) with guideline

Opioid Guideline Taper Deadline

Question: Should the opioid guideline for back conditions be modified to allow more time for the taper off of chronic opioids for those patients already on long term opioid therapy?

Question source: HERC staff, OHP Medical Directors/CCOs, HSD

Issue: The implementation of the back line changes was delayed from its planned implementation on January 1, 2016. The new implementation date is July 1, 2016. However, the deadline for tapering patients off chronic opioid therapy remains the end of 2016. There needs to be clarification about whether this date should be changed given the changed implementation date.

The initial Taskforce recommendation was for a 1 year timeframe for taper, due to patients and providers needing to be educated, other systems to be brought into place to allow for other care such as comprehensive pain clinic care.

The CCOs generally feel that 12 months will be required to get systems in place to ensure that all chronic patients are tapered off. At the May QHOC meeting of the CCOs, there was a suggestion to change the wording to allow a continued slow taper if such a taper was successfully progressing, without having a hard time limit. Proposed wording from this group was "By the end of 2016, all patients currently treated with long term opioid therapy for diagnoses on these lines must be ~~tapered off of long term opioids~~ on an opioid taper plan, with the taper reassessed every 3 months and coverage continued only if tapering is successfully proceeding ~~for diagnoses on these lines~~.

The Oregon Pain Management Commission met on April 28, 2016 and discussed a preference for beginning to offer and implement the non-pharmacologic modalities for treatment of back pain prior to starting a taper on opioid medications. The Pain Commission members were concerned that the recommended 10% per week taper was abrupt and difficult, and would result in increased fear and anxiety, concern about "taper failures" and illegal narcotic use. The proposed wording for this section from the Pain Commission was "By the end of 2016, all patients currently treated with long term opioid therapy must be ~~tapered off of long term opioids~~ re-evaluated including psychosocial factors and plan of care to include multidisciplinary treatment options for diagnoses on these lines." The Pain Commission also noted that criteria #3 in the guideline was unrealistic to allow only an additional 7 days when there was also a 38 day exception allowed.

Additionally, QHOC members requested that the guideline be modified to clarify what validated tools should be used to document improvement in function.

HERC staff recommendations:

1) Add in specific information about the "validated tools" required for documentation of improvement in function
    a. Proposed wording matches the medical back pain guideline
2) Discuss possible changes to the opioid guideline to push back the date for ending chronic opioid therapy for those patients already on such therapy. Several possible options have been identified:
    a. Keep the opioid deadline at the end of 2016 (6 month tapers at most), OR
    b. Push back the opioid deadline from end of 2016 to July 2017 (conforms with the original intent of 1 year taper time and CCO preferred), OR
    c. Consider alternative wording removing a hard time limit
        i. QHOC proposed wording: "By the end of 2016, all patients currently treated with long term opioid therapy for diagnoses on these lines must be ~~tapered off of long term opioids~~ on an opioid taper plan, with the taper reassessed every 3 months and coverage continued only if tapering is successfully proceeding ~~for diagnoses on these lines.~~"
            1. Consider adding wording clarifying that the intent is to eventually taper off completely. Possible additional wording: "The goal of this taper must be a complete taper off opioids."
        ii. Pain Commission proposed wording: "By the end of 2016, all patients currently treated with long term opioid therapy must be ~~tapered off of long term opioids~~ re-evaluated including psychosocial factors and plan of care to include multidisciplinary treatment options for diagnoses on these lines."
3) Discuss the HERC's intent that moving back conditions to a covered line was not intended to cover medications previously denied by a CCO, but rather to provide a wider range of services for these conditions

GUIDELINE NOTE 60, OPIOID PRESCRIBING FOR CONDITIONS OF THE BACK AND SPINE

Lines 351, 366, 407, 532

The following restrictions on opioid treatment apply to all diagnoses included on these lines.

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

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

   e. There is documented lack of current or prior opioid misuse or abuse.
2) Treatment with opioids after 6 weeks, up to 90 days, requires the following
   a. Documented evidence of improvement of function of at least thirty percent as compared to baseline based on a validated tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
   b. Must be prescribed in conjunction with therapies such as spinal manipulation, physical therapy, yoga, or acupuncture.
   c. Verification that the patient is not high risk for opioid misuse or abuse. Such verification may involve
      i. Documented verification from the state's prescription monitoring program database that the controlled substance history is consistent with the prescribing record
      ii. Use of a validated screening instrument to verify the absence of a current substance use disorder (excluding nicotine) or a history of prior opioid misuse or abuse
      iii. Administration of a baseline urine drug test to verify the absence of illicit drugs and non-prescribed opioids.
   d. Each prescription must be limited to 7 days of treatment and for short acting opioids only
3) Further opioid treatment after 90 days may be considered ONLY when there is a significant change in status, such as a clinically significant verifiable new injury or surgery. In such cases, use of opioids is limited to a maximum of an additional 7 days. In exceptional cases, use up to 28 days may be covered, subject to the criteria in #2 above.

For patients with chronic pain from diagnoses on these lines currently treated with long term opioid therapy, opioids must be tapered off, with a taper of about 10% per week recommended. By the end of 2016, all patients currently treated with long term opioid therapy must be tapered off of long term opioids for diagnoses on these lines. If a patient has developed dependence and/or addiction related to their opioids, treatment is available on line 4 SUBSTANCE USE DISORDER.

Tobacco smoking and surgical procedures

Question: Tobacco smoking and elective surgeries

Question source: Medical Directors from CCOs

Issue: At the November 2015 and January 2016 VbBS meetings, a new guideline on tobacco cessation and elective surgeries was proposed. Members debated a guideline that would require intensive smoking cessation counseling prior to elective surgery versus a guideline requiring tobacco cessation prior to elective surgery. CCO and FFS medical directors were consulted. In general, implementation of the behavioral intervention was thought to be quite challenging and several members preferred requiring cessation. Concerns about equity and addiction were also raised. Additionally, there were concerns raised about the acceptability of other nicotine replacement strategies, what the definition of elective entails, presence of severe psychiatric comorbidity interfering with cessation, and which specific surgeries might be included or excluded. Members asked HERC staff to return with further details that would assist with implementation.

The following questions thus need to be addressed:

1) Should the guideline note require intensive smoking cessation interventions or require smoking cessation to occur prior to elective surgeries?
2) How should elective versus urgent/emergent surgical procedures be defined?
3) Which types of surgeries should be included? Should they be by general body system and/or specialty or specifically defined by code?
4) What other procedures should be excluded from the guideline note?
5) Are there certain underlying health conditions such as people with severe and persistent mental illness who should be excluded from the guideline?
6) Should there continue to be a discrepancy between these elective surgeries requiring 1 month of cessation (if this is chosen) versus other surgeries such as bariatric and spinal fusion surgery which have 6 month abstinence requirements?

Evidence on specific surgeries

MED, 2015 report

1. Key findings:
    a. Smoking is associated with greater morbidity across a wide range of surgeries
    b. Smoking cessation initiated at least four weeks before surgery was associated with reduced complications for certain types of surgeries
    c. The longer the abstinence the greater the benefit
2. General elective surgeries

a. Moderate strength of evidence that smokers have an increased risk of general morbidity, wound complications, general infections, pulmonary complications, neurological complications, and admission to the intensive care unit (ICU) after undergoing various types of elective surgery.

3. Specific surgeries
    a. Dental
        i. Moderate strength of evidence that smokers experience greater dental implant failure rates
        ii. Low strength of evidence that smokers have a higher risk of developing postoperative complications for:
            1. Subepithelial connective tissue grafts
            2. Guided tissue regeneration
            3. Periodontal flap surgery.
    b. Orthopedic
        i. Rotator cuff repair – more postoperative complications (moderate SOE). smokers experience worse functional outcomes, greater pain, and lower quality of life scores up to two years following surgery.
        ii. Glenoid labrum surgery – higher failure rates (very low SOE)
        iii. Total hip arthoplasty – greater general postoperative complications
        iv. Total knee arthroplasty – higher risk of general postoperative complications; but conflicting results in current and former smokers for function, need for revision, cardiac and pulmonary complications, prosthetic loosening, and infection.
    c. Cardiovascular - moderate strength of evidence that smokers have significantly worse postoperative outcomes following cardiac and arterial surgery
        i. Coronary artery bypass graft: smokers experience higher rates of general pulmonary complications and worse functional outcomes.
        ii. Non-specific elective cardiac surgery: smokers experience greater rates of general pulmonary complications, ICU hours and readmission, infection rates, and mean mechanical ventilations hours.
        iii. Heart transplant: smokers have lower survival outcomes.
        iv. Lower extremity bypass graft: smokers are more likely to have graft failure; smokers were more likely to have graft failure (odds ratio [OR] =2.35 [95% CI 1.98 to 2.78], P<0.00001, 21 trials, 2,792 participants). Difference in graft patency in former smokers compared with current smokers was significantly better (P=0.003) and graft patency rates in former smokers were comparable with the never smokers group (specific rates not reported). There were

no differences noted between studies with a follow-up period of less or greater than two years.

Additional types of surgeries

1. Sinus surgery (review upon request of QHOC medical director)
    a. *Reh, 2012* (study not included due to length http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3443524/pdf/nihms372192.pdf)
        i. Literature review of impact of active smoking and second hand smoke on chronic rhinosinusitis
        ii. 31 papers on exposure to smoke and sinusitis
        iii. 29 papers to evaluate impact of smoking on sinus surgery
        iv. Smoke exposure increases risk of asthma, otitis media
        v. Retrospective studies in the 1990s found association with poorer, symptom scores, worse patient reported outcomes, and possibly higher revision rates. More recent prospective studies have found equivalence in endoscopy scores, health related quality of life, although higher rates of revision. One larger prospective study 784 patients found worse endoscopic scores, but similar QOL outcomes. A small study in children showed poorer ciliary regrowth when exposed to second hand smoke and less symptom improvement.
        vi. Authors Conclusion: There is clear evidence in the literature that cigarette smoke, either through active smoking or passive exposure to SHS, contributes to CRS. Recent prospective studies suggest that active smoking is not a contraindication to ESS while the impact of smoking volume and longterm smoking after ESS has not been sufficiently evaluated.
    b. *Rudmik, 2011* (study not included due to length: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3124774/pdf/nihms-258797.pdf)
        i. Prospective cohort study of patients with rhinosinusitis electing endoscopy sinus surgery
        ii. N= 784
        iii. Tertiary academic medical center
        iv. **RESULTS:** Smokers (heavy or light) and nonsmokers experienced similar improvement in health related quality of life following surgery. While overall changes in endoscopy scores did not differ between smokers and nonsmokers, there was a significant difference in the prevalence of worsening postoperative endoscopy scores between heavy smokers, light smokers, and nonsmokers (100%, 33%, and 20%, respectively; p = 0.002).
        v. Patient oriented outcomes appear similar, but markedly worse postoperative endoscopy scores vary by smoking intensity

2. Vaginoplasty and phalloplasty
    a. At the last VbBS meeting there was expert testimony that vaginoplasty is associated with poorer outcomes, and the one surgeon who does this in Portland requires a 6 week cessation prior to surgery.
    b. Chesson, 1996
        i. Expert review and case series, 20 phalloplasty procedures after instituting a new technique
        ii. In female-to-male reassignment, smoking and other addictions carry an unacceptable complication rate and are relative contraindications to hormonal and surgical reassignment. Microsurgical vascular techniques necessary for this procedure are not successful in heavy smokers, and therefore smoking is an absolute contraindication to phalloplasty.
        iii. Smoking associated with severe vascular problems
    c. WPATH is silent
    d. University of Michigan http://www.med.umich.edu/1libr/Surgery/PlasticSurgery/GenderReassignment/SRS-PenileInversion-Preop.pdf
        i. requires 6 weeks smoking cessation prior to penile inversion vaginoplasty
    e. Gender surgery Amsterdam http://www.gendersurgeryamsterdam.com/operation-female-male/phalloplasty/smoking-weight/
        i. requires smoking cessation 12 weeks prior to phalloplasty
    f. Vancouver Health Guideline Care of the Patient undergoing sex reassignment surgery http://www.amsa.org/wp-content/uploads/2015/04/CareOfThePatientUndergoingSRS.pdf
        i. MTF patients are strongly encouraged to stop smoking. This is an absolute requirement if a free flap phalloplasty will be performed in the future.

<u>Evidence on timing of smoking cessation</u>

Thomsen, 2014

1. Cochrane systematic review of RCTs looking at interventiosn for preoperative smoking cessation
2. 13 trials including 2010 participants
3. Smoking cessation at least 4 weeks prior to surgery results in improved morbidity
4. Smoking cessation counseling
    a. Brief interventions ineffective for either complication reduction or long term smoking cessation
    b. Intensive interventions, defined as weekly face to face for 4-8 weeks with telephonic support, and with pharmacotherapy (NRT) are effective

5. Optimal period unclear
6. Conclusion: There is evidence that preoperative smoking interventions providing behavioural support and offering NRT increase short-termsmoking cessation and may reduce postoperative morbidity. Based on indirect comparisons and evidence from two small trials, interventions that begin four to eight weeks before surgery, include weekly counselling and use NRT are more likely to have an impact on complications and on long-term smoking cessation.

Evidence on nicotine replacement and elective surgery

Sorenson, 2012

1. Systematic review of nicotine and nicotine replacement therapy (NRT) on pathophysiology of wound healing
    a. Nicotine used to be considered responsible for effects of smoking on wound healing
    b. Nicotine infusion increased tissue oxygen tension, but smoking decreases
    c. Animal and cell studies show transient mixed effects
    d. "In summary, the effect of nicotine on wound healing processes is complex and as of yet not fully understood. Nicotine appears to attenuate inflammatory wound healing mechanisms, compared to proliferative wound healing mechanisms including angiogenesis and collagen synthesis. Clinically, there is no evidence to suggest that nicotine administered as nicotine replacement drugs to abstinent smokers has a detrimental or beneficial effect on postoperative outcome of wound or tissue healing."
2. *Thomsen, 2014* Cochrane systematic review
    a. Of the 10 RCTs examining behavioral support for cessation, nicotine replacement therapy (NRT) offered or recommended to some or all patients in 8 trials.
    b. 1 trial – varenicline given 1 week preoperatively, continued 11 weeks postoperatively
        i. No increase in smoking cessation
        ii. No surgical morbidity benefit
    c. 1 trial – nicotine lozenges from night before surgery + brief counseling
        i. No increase in smoking cessation

Definition of elective surgical procedures:

1. MedicineNet.com - Surgery that is subject to choice (election). The choice may be made by the patient or doctor. For example, the time when a surgical procedure is performed may be elective. The procedure is beneficial to the patient but does not need be done at a particular time. As opposed to urgent or emergency surgery.
2. http://www.surgeryencyclopedia.com/Ce-Fi/Elective-Surgery.html

   a. An elective surgery is a planned, non-emergency surgical procedure. It may be either medically required (e.g., cataract surgery), or optional (e.g., breast augmentation or implant) surgery.
3. http://www.health.wa.gov.au/electivesurgery/docs/Elective_Surgery_Patient_Information_ENGLISH.pdf
   a. Elective surgery is a term used for non-emergency surgery which is medically necessary, but which can be delayed for at least 24 hours. Patients requiring emergency surgery will not be placed on the elective surgery list.
4. http://medical-dictionary.thefreedictionary.com/elective+surgery
   a. Elective surgery
      i. Any operation that can be performed with advanced planning–eg, cholecystectomy, hernia repair, colonic resection, coronary artery bypass
      ii. Surgery a patient chooses to undergo although its need is neither vital nor urgent.
      iii. Non-emergency surgery, taking place at a predetermined date
   b. Urgent surgery
      i. Surgery required within < 48 hrs Examples Kidney stone, stomach obstruction or ulcer, bleeding hemorrhoids, ectopic pregnancy
5. Merriam Webster
   a. Urgent = calling for immediate attention
6. Oxford http://www.oxforddictionaries.com/us/definition/american_english/urgent
   a. (Of a state or situation) requiring immediate action or attention
   b. (Of action or an event) done or arranged in response to a pressing or critical situation

<u>Information on cotinine testing in nicotine replacement therapy</u>

1. *Thomsen 2012,* Cochrane review
   a. Most RCTs used exhaled carbon monoxide (CO) testing
      i. Self reported smoking cessation (Andrews, 2006; Lindstrom, 2008; Wolfenden, 2005)
      ii. Exhaled CO (≤ 10 ppm) (Lee, 2013; Moller, 2002, Ratner, 2004; Shi, 2013; Thomsen, 2010; Warner, 2012)
      iii. Urine cotinine (Ratner, 2004)
      iv. Expired CO and Sputum cotinine (Sorenson, 2007, Ostroff, 2013)
      v. Exhaled CO and urinary cotinine (Sorenson, 2003a; Wong 2012)

2. *Jacob, 2002*
   a. Validation study of Anabasine and anatabine in users of nicotine replacement therapy compared to smokers
   b. 99 cigarette smokers and 205 smokeless tobacco users

   c. Objective: to evaluate the use of urine concentrations of the minor tobacco alkaloids anabasine and anatabine as outcome measures for persons undergoing NRT.
   d. Results: Subjects abstaining from smokeless tobacco and using nicotine gum did not excrete measurable amounts of anabasine or anatabine.
3. Mayo Clinic laboratories http://www.mayomedicallaboratories.com/test-catalog/Clinical+and+Interpretive/82510
   a. In addition to nicotine and metabolites, tobacco products also contain other alkaloids that can serve as unique markers of tobacco use. Two such markers are anabasine and nornicotine. Anabasine is present in tobacco products, but not nicotine replacement therapies. Nornicotine is present as an alkaloid in tobacco products and as a metabolite of nicotine. The presence of anabasine >10 ng/mL or nornicotine >30 ng/mL in urine indicates current tobacco use, irrespective of whether the subject is on nicotine replacement therapy. The presence of nornicotine without anabasine is consistent with use of nicotine replacement products. Heavy tobacco users who abstain from tobacco for 2 weeks exhibit urine nicotine values <30 ng/mL, cotinine <50 ng/mL, anabasine <2 ng/mL, and nornicotine <2 ng/mL.
   b. Passive exposure to tobacco smoke can cause accumulation of nicotine metabolites in nontobacco users. Urine cotinine has been observed to accumulate up to 20 ng/mL from passive exposure. Neither anabasine nor nornicotine accumulates from passive exposure.
4. NV Public Employee Benefits Program, "through consultation with their lab"
   a. Heavy smoker, cotinine will be positive for 7-10 days
   b. Average pack a day smoker, cotinine will be positive for 4-5 days
   c. Second hand smoke exposure would not result in a clinically significant positive cotinine

<u>Relevant codes for specific procedures</u>

a. Orthopedic
   i. Rotator cuff

Code	Code Description	Line
23412	Repair of ruptured musculotendinous cuff (eg, rotator cuff) open; chronic	423
23420	Reconstruction of complete shoulder (rotator) cuff avulsion, chronic (includes acromioplasty)	423
29827	Arthroscopy, shoulder, surgical; with rotator cuff repair	423

   ii. Glenoid labrum

29807	Arthroscopy, shoulder, surgical; repair of SLAP lesion	364,392,423

   iii. Total hip

27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	85,204,205,290, 360,361,447
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft	85,290,361,428
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft	290,428
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft	290,428
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft	290,364,392,428

iv. Total knee

27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)	361,364,392

b. Dental

Dental implants

Code	Code Description	Prioritized List Status
D6010	SURGICAL PLACEMENT OF IMPLANT BODY: ENDOSTEAL IMPLANT	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6011	Second stage implant surgery	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6012	SURGICAL PLACEMENT OF INTERIM IMPLANT BODY FOR TRANSITIONAL PROSTHESIS: ENDOSTEAL IMPLANT	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6013	Surgical placement of mini implant	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6040	SURGICAL PLACEMENT: EPOSTEAL IMPLANT	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6050	SURGICAL PLACEMENT: TRANSOSTEAL IMPLANT	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6051	Interim abutment - includes placement and removal. A healing cap is not an interim abutment	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6052	Semi-precision attachment abutment-includes placement of keeper assembly	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6055	CONNECTING BAR - IMPLANT SUPPORTED OR ABUTMENT SUPPORTED	622 DENTAL CONDITIONS (EG. MISSING TEETH)

Code	Code Description	Prioritized List Status
D6056	Prefabricated abutment - includes modification and placement. Modification of a prefabricated abutment may be necessary	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6057	Custom fabricated abutment - includes placement – Created by a laboratory process specific for an individual application	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6058	ABUTMENT SUPPORTED PORCELAIN/CERAMIC CROWN	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6059	ABUTMENT SUPPORTED PORCELAIN FUSED TO METAL CROWN (HIGH NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6060	ABUTMENT SUPPORTED PORCELAIN FUSED TO METAL CROWN (PREDOMINANTLY BASE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6061	ABUTMENT SUPPORTED PORCELAIN FUSED TO METAL CROWN (NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6062	ABUTMENT SUPPORTED CAST METAL CROWN (HIGH NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6063	ABUTMENT SUPPORTED CAST METAL CROWN (PREDOMINANTLY BASE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6064	ABUTMENT SUPPORTED CAST METAL CROWN (NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6065	IMPLANT SUPPORTED PORCELAIN/CERAMIC CROWN	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6066	IMPLANT SUPPORTED PORCELAIN FUSED TO METAL CROWN (TITANIUM, TITANIUM ALLOY, HIGH NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6067	IMPLANT SUPPORTED METAL CROWN (TITANIUM, TITANIUM ALLOY, HIGH NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6068	ABUTMENT SUPPORTED RETAINER FOR PORCELAIN/CERAMIC FPD	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6069	ABUTMENT SUPPORTED RETAINER FOR PORCELAIN FUSED TO METAL FPD (HIGH NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6070	ABUTMENT SUPPORTED RETAINER FOR PORCELAIN FUSED TO METAL FPD (PREDOMINANTLY BASE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)

Code	Code Description	Prioritized List Status
D6071	ABUTMENT SUPPORTED RETAINER FOR PORCELAIN FUSED TO METAL FPD (NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6072	ABUTMENT SUPPORTED RETAINER FOR CAST METAL FPD (HIGH NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6073	ABUTMENT SUPPORTED RETAINER FOR CAST METAL FPD (PREDOMINANTLY BASE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6074	ABUTMENT SUPPORTED RETAINER FOR CAST METAL FPD (NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6075	IMPLANT SUPPORTED RETAINER FOR CERAMIC FPD	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6076	IMPLANT SUPPORTED RETAINER FOR PORCELAIN FUSED TO METAL FPD (TITANIUM, TITANIUM ALLOY, OR HIGH NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6077	IMPLANT SUPPORTED RETAINER FOR CAST METAL FPD (TITANIUM, TITANIUM ALLOY, OR HIGH NOBLE METAL)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6080	IMPLANT MAINTENANCE PROCEDURES WHEN PROSTHESES ARE REMOVED AND REINSERTED, INCLUDING CLEANSING OF PROSTHESES AND ABUTMENTS	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6090	REPAIR IMPLANT SUPPORTED PROSTHESIS BY REPORT	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6091	REPLACEMENT OF SEMI-PRECISION OR PRECISION ATTACHMENT (MALE OR FEMALE COMPONENT) OF IMPLANT/ABUTMENT SUPPORTED PROSTHESIS, PER ATTACHMENT	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6092	RE-CEMENT OR RE-BOND IMPLANT/ABUTMENT SUPPORTED CROWN	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6093	RE-CEMENT OR RE-BOND IMPLANT/ABUTMENT SUPPORTED FIXED PARTIAL DENTURE	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6094	ABUTMENT SUPPORTED CROWN - (TITANIUM)	622 DENTAL CONDITIONS (EG. MISSING TEETH)
D6095	REPAIR IMPLANT ABUTMENT, BY REPORT	622 DENTAL CONDITIONS (EG. MISSING TEETH)

Subepithelial connective tissue grafts

Code	Code Description	Prioritized List Line number
D4270	PEDICLE SOFT TISSUE GRAFT PROCEDURE	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4273	SUBEPITHELIAL CONNECTIVE TISSUE GRAFT PROCEDURES, PER TOOTH	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4274	DISTAL OR PROXIMAL WEDGE PROCEDURE (WHEN NOT PERFORMED IN CONJUCTION WITH SURGICAL PROCEDURES IN THE SAME ANATOMICAL AREA)	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4275	SOFT TISSUE ALLOGRAFT	Services recommended for non-coverage table,496
D4276	COMBINED CONNECTIVE TISSUE AND DOUBLE PEDICLE GRAFT, PER TOOTH	Services recommended for non-coverage table,496
D4277	Free soft tissue graft procedure (including donor site surgery) - first tooth or edentulous tooth site in graft	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4278	Free soft tissue graft procedure (including donor site surgery) -each additional contiguous tooth position in same graft site	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4283	Autogenous connective tissue graft procedure (including donor and recipient surgical sites) – each additional contiguous tooth, implant or edentulous tooth position in same graft site	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4285	Non-autogenous connective tissue graft procedure (including recipient surgical site and donor material) – each additional contiguous tooth, implant or edentulous tooth position in same graft site	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)

Guided tissue regeneration

Code	Code Description	Prioritized List Status
D4266	Guided tissue regeneration -- resorbable barrier, per site This procedure does not include flap entry or closure, or, when indicated, wound debridement, osseous contouring, bone replacement grafts, and placement of biologic materials to aid in osseous reg	Services recommended for non-coverage table
D4267	Guided tissue regeneration -- non-resorbable barrier, per site (includes membrane removal) This procedure does not include flap entry or closure, or, when indicated, wound debridement, osseous contouring, bone replacement grafts, and placement of biologic	Services recommended for non-coverage table

Periodontal flap surgery

Code	Code Description	Prioritized List Status
D4240	GINGIVAL FLAP PROCEDURE, INCLUDING ROOT PLANING - FOUR OR MORE CONTIGUOUS TEETH OR TOOTH BOUNDED SPACES PER QUADRANT	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4241	GINGIVAL FLAP PROCEDURE, INCLUDING ROOT PLANING - ONE TO THREE CONTIGUOUS TEETH OR TOOTH BOUNDED SPACES PER QUADRANT	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)
D4245	APICALLY POSITIONED FLAP	496 DENTAL CONDITIONS (EG. PERIODONTAL DISEASE)

c. Cardiovascular

CABG (33510-33536)

Code	Code Description	Current Prioritized List Status
33510	Coronary artery bypass, vein only; single coronary venous graft	49,73,103,193,290
33511	Coronary artery bypass, vein only; 2 coronary venous grafts	73,103,193,290
33512	Coronary artery bypass, vein only; 3 coronary venous grafts	73,103,193,290
33513	Coronary artery bypass, vein only; 4 coronary venous grafts	73,103,193,290
33514	Coronary artery bypass, vein only; 5 coronary venous grafts	73,103,193,290
33516	Coronary artery bypass, vein only; 6 or more coronary venous grafts	73,103,193,290
33517	Coronary artery bypass, using venous graft(s) and arterial graft(s); single vein graft (List separately in addition to code for primary procedure)	73,103,193,290
33518	Coronary artery bypass, using venous graft(s) and arterial graft(s); 2 venous grafts (List separately in addition to code for primary procedure)	73,103,193,290
33519	Coronary artery bypass, using venous graft(s) and arterial graft(s); 3 venous grafts (List separately in addition to code for primary procedure)	73,103,193,290
33521	Coronary artery bypass, using venous graft(s) and arterial graft(s); 4 venous grafts (List separately in addition to code for primary procedure)	73,103,193,290

Code	Code Description	Current Prioritized List Status
33522	Coronary artery bypass, using venous graft(s) and arterial graft(s); 5 venous grafts (List separately in addition to code for primary procedure)	73,103,193,290
33523	Coronary artery bypass, using venous graft(s) and arterial graft(s); 6 or more venous grafts (List separately in addition to code for primary procedure)	73,103,193,290
33530	Reoperation, coronary artery bypass procedure or valve procedure, more than 1 month after original operation (List separately in addition to code for primary procedure)	49,73,74,86,90,103,110,115 and 7 other lines.
33533	Coronary artery bypass, using arterial graft(s); single arterial graft	73,193,290
33534	Coronary artery bypass, using arterial graft(s); 2 coronary arterial grafts	73,193,290
33535	Coronary artery bypass, using arterial graft(s); 3 coronary arterial grafts	73,193,290
33536	Coronary artery bypass, using arterial graft(s); 4 or more coronary arterial grafts	73,193,290

Lower extremity bypass graft

Code	Code Description	Prioritized List Status
35533	Bypass graft, with vein; axillary-femoral-femoral	240,290,354
35537	Bypass graft, with vein; aortoiliac	240,258,289,290,310,330,452
35538	Bypass graft, with vein; aortobi-iliac	240,258,289,290,310,330,452
35539	Bypass graft, with vein; aortofemoral	240,258,289,290,310,330,354,452
35540	Bypass graft, with vein; aortobifemoral	240,258,289,290,310,330,354,452
35556	Bypass graft, with vein; femoral-popliteal	240,290,354
35558	Bypass graft, with vein; femoral-femoral	240,290,354
35563	Bypass graft, with vein; ilioiliac	240,289,290,310,330,452
35565	Bypass graft, with vein; iliofemoral	240,290,354
35566	Bypass graft, with vein; femoral-anterior tibial, posterior tibial, peroneal artery or other distal vessels	240,290,354
35570	Bypass graft, with vein; tibial-tibial, peroneal-tibial, or tibial/peroneal trunk-tibial	240,290,354
35571	Bypass graft, with vein; popliteal-tibial, -peroneal artery or other distal vessels	240,290,354

Code	Code Description	Prioritized List Status
35583	In-situ vein bypass; femoral-popliteal	240,290,354
35585	In-situ vein bypass; femoral-anterior tibial, posterior tibial, or peroneal artery	240,290,354
35587	In-situ vein bypass; popliteal-tibial, peroneal	240,290,354
35621	Bypass graft, with other than vein; axillary-femoral	240,290,330,354
35623	Bypass graft, with other than vein; axillary-popliteal or -tibial	240,258,290,330,354
35637	Bypass graft, with other than vein; aortoiliac	240,258,289,290,310,330,452
35638	Bypass graft, with other than vein; aortobi-iliac	240,258,289,290,310,330,452
35646	Bypass graft, with other than vein; aortobifemoral	240,258,289,290,310,330,354,452
35647	Bypass graft, with other than vein; aortofemoral	240,258,289,290,330,354,452
35654	Bypass graft, with other than vein; axillary-femoral-femoral	240,258,290,330,354,452
35656	Bypass graft, with other than vein; femoral-popliteal	240,290,330,354
35661	Bypass graft, with other than vein; femoral-femoral	240,290,330,354
35663	Bypass graft, with other than vein; ilioiliac	240,289,290,310,330,452
35665	Bypass graft, with other than vein; iliofemoral	240,290,330,354
35666	Bypass graft, with other than vein; femoral-anterior tibial, posterior tibial, or peroneal artery	240,290,330,354
35671	Bypass graft, with other than vein; popliteal-tibial or -peroneal artery	240,290,330,354

HERC staff summary

Smoking cessation at least 4 weeks prior to surgery results in morbidity improvements for a wide range of elective surgeries. Intensive smoking cessation interventions that often included NRT showed improvements in postoperative morbidity. NRT is therefore an acceptable practice as part of intensive smoking cessation interventions to reduce perioperative morbidity when the surgery is planned in the following 4-8 weeks.

With regard to the following questions

1) *Should the guideline note require intensive smoking cessation interventions or* require smoking cessation to occur prior to elective surgeries?
    a. The group seemed to lean toward requiring cessation to occur. QHOC medical directors definitely preferred requiring cessation to make this an implementable requirement.
2) *How should elective versus urgent/emergent surgical procedures be defined?*

   a. General literature suggests a high acuity definition (e.g. within 48 hours) however, there are many surgeries, including those for cancer, subacute cardiovascular disease, etc, that may easily be pushed off for a few days to a week or two due to access issues, but postponing them until cessation occurs (or doesn't) may not be clinically appropriate nor ethically acceptable. Having the same definition of the time period of cessation as the need for surgery makes some sense. Recommend 1 month as the time period.

3) *Which types of surgeries should be included? Should they be by general body system and/or specialty or specifically defined by code?*
   a. Including all "elective" surgeries may be fraught with issues. Recommend listing specific surgeries for which we know that smoking worsens outcomes. The challenge with this is that some other related surgeries, for example, shoulder replacement surgery may not have identified studies but outcomes may fair equally poorly among active smokers.
4) *What other procedures should be excluded from the guideline note?*
   a. At least, cancer-related, diagnostic, and reproductive services. But by listing specific types of surgeries and including specific codes, these (and many others) would naturally be excluded.
   b. The codes for those specific surgeries for which there is information about worse perioperative morbidity fall on many lines on the Prioritized List. Consider not applying the guideline to the following lines:
      i. Orthopedic - *lines 85* (hip fracture), *204* (cancer of soft tissue), *205* (cancer of bones), *290* (complications of a procedure always requiring treatment), *360* (closed fracture of extremities), *447* (malunion and nonunion of fracture)
      ii. Cardiovascular - *Line 73* (acute and subacute ischemic heart disease); *Line 103* (cardiomyopathy); exclude life and limb threatening lines
5) *Are there certain underlying health conditions such as people with severe and persistent mental illness who should be excluded from the guideline?*
   a. Proposed language included
6) *Should there continue to be a discrepancy between these elective surgeries requiring 1 month of cessation (if this is chosen) versus other surgeries such as bariatric and spinal fusion surgery which have 6 month abstinence requirements?*
   a. It is reasonable to have different requirements given the invasiveness, potentially for delayed healing and complications associated with specific surgeries (e.g. fusion, bariatric).
   b. However, those with a requirement for shorter term smoking cessation (i.e 1 month) use of NRT would be considered acceptable, whereas those surgeries using a 6 month requirement would entail complete cessation, including of NRT products.
   c. Different objective testing would need to be used in elective surgeries for which NRT is acceptable compared to when it is not.

HERC STAFF RECOMMENDATIONS

1. Discussion adoption of a new guideline note:

GUIDELINE NOTE XXX, SMOKING CESSATION AND ELECTIVE SURGICAL PROCEDURES

Lines 193, 317, 354, 361, 364, 392, 423, 469, 496, 622

Smoking cessation is required prior to elective surgical procedures for active tobacco users. Cessation is required at least 1 month prior to the procedure and requires objective evidence of abstinence from smoking.

The well-studied tests for confirmation of smoking cessation include cotinine levels and exhaled carbon monoxide testing. However, cotinine level may be positive in nicotine replacement therapy (NRT) users (which is not a contraindication to elective surgery coverage). In patients using NRT the following alternatives to urine cotinine to demonstrate smoking cessation may be considered:

- Exhaled carbon monoxide testing (well studied)
- Anabasine or anatabine testing

Elective surgical procedures in this guideline are defined as surgical procedures which are flexible in their scheduling because they do not pose an imminent threat nor require immediate attention within 1 month.

The specific surgical procedures that fall under this guideline include elective:

- Orthopedic - rotator cuff *(Line 423),* glenoid labrum (*Lines 364, 392, 423*), total hip (*Line 361*) and total knee arthroplasty *(Line 361*)
- Cardiovascular
  - CABG (*Line 193* = chronic ischemic heart disease)
  - Lower extremity bypass graft – *Line 354* (NON-LIMB THREATENING PERIPHERAL VASCULAR DISEASE)
- Invasive dental procedures – implants, subepithelial connective tissue grafts, ~~guided tissue regeneration,~~ periodontal flap surgery (*Lines 496, 622*)
- Vaginoplasty and phalloplasty (*Line 317*)
- Chronic sinusitis surgery (*Line 469*)

For patients with severe and persistent mental illness (e.g. schizophrenia) smoking cessation for any duration may be an insurmountable barrier, and adherence to this guideline may be waived.

Certain procedures, such as lung volume reduction surgery, bariatric surgery, erectile dysfunction surgery, and spinal fusion have 6 month tobacco abstinence requirements. See Guideline Notes 8, 100, and 112.

Additional issues:

Modify guideline notes 8, 100, and 112:

A) to be consistent in requiring cotinine level testing, and

B) consider adding language about the frequency of testing.

GUIDELINE NOTE 100, SMOKING AND SPINAL FUSION

Lines 51,154,204,258,374,412,484,533,588

Non-emergent spinal arthrodesis (CPT 22532-22634) is limited to patients who are non-smoking for 6 months prior to the planned procedure, as shown by negative cotinine levels (at least one level within one month of the quit date and one level within one month of surgery). Patients should be given access to appropriate smoking cessation therapy.

GUIDELINE NOTE 8, BARIATRIC SURGERY

Lines 30,594

…Excerpt

Must remain free of abuse of or dependence on alcohol during the six-month period immediately preceding surgery. No current use of nicotine or illicit drugs and must remain abstinent from their use during the six-month observation period. Testing will, at a minimum, be conducted within one month of the surgery to confirm abstinence from ~~nicotine and~~ illicit drugs. Tobacco abstinence to be confirmed in active smokers by negative cotinine levels (at least one level within one month of the quit date and one level within one month of surgery).

GUIDELINE NOTE 112, LUNG VOLUME REDUCTION SURGERY

Line 288

Lung volume reduction surgery (LVRS, CPT 32491, 32672) is included on Line 288 only for treatment of patients with radiological evidence of severe bilateral upper lobe predominant emphysema (diagnosis code ICD-10-CM J43.9/ICD-9-CM 492.0, 492.8) and all of the following:

1. BMI ≤31.1 kg/m2 (men) or ≤32.3 kg/m 2 (women)
2. Stable with ≤20 mg prednisone (or equivalent) dose a day
3. Pulmonary function testing showing
   a. Forced expiratory volume in one second (FEV 1) ≤ 45% predicted and, if age 70 or older, FEV 1≥ 15% predicted value
   b. Total lung capacity (TLC) ≥ 100% predicted post-bronchodilator
   c. Residual volume (RV) ≥ 150% predicted post-bronchodilator
4. PCO 2, ≤ 60 mm Hg (PCO 2, ≤ 55 mm Hg if 1-mile above sea level)

5. PO 2, ≥ 45 mm Hg on room air (PO 2, ≥ 30 mm Hg if 1-mile above sea level)
6. Post-rehabilitation 6-min walk of ≥ 140 m
7. Non-smoking for 6 months prior to surgery, as shown by negative cotinine levels (at least one level within one month of the quit date and one level within one month of surgery).

The procedure must be performed at an approved facility (1) certified by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) under the LVRS Disease Specific Care Certification Program or (2) approved as Medicare lung or heart-lung transplantation hospitals. The patient must have approval for surgery by pulmonary physician, thoracic surgeon, and anesthesiologist post-rehabilitation. The patient must have approval for surgery by cardiologist if any of the following are present: unstable angina; left-ventricular ejection fraction (LVEF) cannot be estimated from the echocardiogram; LVEF <45%; dobutamine radionuclide cardiac scan indicates coronary artery disease or ventricular dysfunction; arrhythmia (>5 premature ventricular contractions per minute; cardiac rhythm other than sinus; premature ventricular contractions on EKG at rest).

2) Add a new guideline about surgical treatment of erectile dysfunction based on the November VbBS discussion.

GUIDELINE NOTE XXX SMOKING AND SURGICAL TREATMENT OF ERECTILE DYSFUNCTION

Line 526

Surgical treatment of erectile dysfunction is only included on this line when patients are non-smoking for 6 months prior to surgery, as shown by negative cotinine levels (at least one level within one month of the quit date and one level within one month of surgery).

Acupuncture for Tobacco Cessation

Question: Should limits be placed on the use of acupuncture for tobacco cessation?

Question source: HERC staff

Issue: Acupuncture (CPT 97810-97814) is included on line 5 TOBACCO DEPENDENCE but currently has no mention/limits in the acupuncture guideline. The ACA does not require coverage for acupuncture treatment for smoking cessation.

Line: 5
Condition: TOBACCO DEPENDENCE (See Guideline Notes 4,64,65)
Treatment: MEDICAL THERAPY/BEHAVIORAL COUNSELING
ICD-10: F17.200-F17.228,F17.290-F17.299,Z71.6
CPT: 96150-96154,97810-97814,98966-98969,99078,99201-99215,99224,99324-99350, 99366,99406,99407,99415,99416,99441-99449,99487-99498,99605-99607
HCPCS: D1320,G0425-G0427,G0436,G0437,G0459,G0463,G0466,G0467,G0469,G0470, G9016,H0038,S9453

Current guideline

GUIDELINE NOTE 92, ACUPUNCTURE (ADAPTED FROM THE OCT. 1, 2015 PRIORITIZED LIST†)
Lines 1,208,351,415,467,532,543 (Lines 351 and 532 represent lines 374 and 545 from the Oct. 1, 2015 Prioritized List†)
Inclusion of acupuncture (CPT 97810-97814) on the Prioritized List has the following limitations:
Line 1 PREGNANCY
Acupuncture pairs on Line 1 for the following conditions.

Hyperemesis gravidarum
ICD-10-CM: O21.0, O21.1
Acupuncture pairs with hyperemesis gravidarum when a diagnosis is made by the maternity care provider and referred for acupuncture treatment for up to 12 sessions of acupressure/acupuncture.

Breech presentation
ICD-10-CM: O32.1
Acupuncture (and moxibustion) is paired with breech presentation when a referral with a diagnosis of breech presentation is made by the maternity care provider, the patient is between 33 and 38 weeks gestation, for up to 6 visits.

Back and pelvic pain of pregnancy
ICD-10-CM: O99.89
Acupuncture is paired with back and pelvic pain of pregnancy when referred by maternity care provider/primary care provider for up to 12 sessions.

Line 208 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE

Acupuncture is paired with the treatment of post-stroke depression only. Treatments may be billed to a maximum of 30 minutes face-to-face time and limited to 12 total sessions, with documentation of meaningful improvement.

Line 351 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT (Line 374 from the Oct. 1, 2015 Prioritized List†)

Acupuncture is included on Line 351 (Line 374 from the Oct. 1, 2015 Prioritized List†) only for pairing with disorders of the spine with myelopathy and/or radiculopathy represented by ICD-10-CM G83.4, M47.2, M50.0, M50.1, M51.0, M51.1, M54.1), for up to 12 sessions.

Line 415 MIGRAINE HEADACHES

Acupuncture pairs on Line 415 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), for up to 12 sessions.

Line 467 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 467 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions.

*Line 532 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT (Line 545 from the Oct. 1, 2015 Prioritized List†)

Acupuncture pairs on Line 532 (Line 545 from the Oct. 1, 2015 Prioritized List†) with the low back diagnoses appearing on this line (ICD-10-CM M51.36, M51.86, M54.5, M99.03, S33.5, S33.9, S39.092, S39.82, S39.92). Acupuncture pairs with chronic (>90 days) neck pain diagnoses on this line (ICD-10-CM M53.82, M54.2, S13.4, S13.8), for up to 12 sessions.

*Line 543 TENSION HEADACHES

Acupuncture is included on Line 543 for treatment of tension headaches (ICD-10-CM G44.2), for up to 12 sessions.

The development of this guideline note was informed by a HERC evidence-based guideline. See http://www.oregon.gov/oha/herc/Pages/blog-low-back-non-pharmacologic-intervention.aspx

Acupuncture for Tobacco Cessation

Evidence:

1) **White 2014**[i]**,** Cochrane review of acupuncture for smoking cessation
    a. N=38 studies
        i. N=3 studies (393 patients) comparing acupuncture to waiting list control
        ii. N=19 studies (1,588 patients) comparing active acupuncture to sham acupuncture
    a. Based on three studies, acupuncture was not shown to be more effective than a waiting list control for long-term abstinence, with wide confidence intervals and evidence of heterogeneity (n = 393, risk ratio [RR] 1.79, 95% confidence interval [CI] 0.98 to 3.28, I^2 = 57%). Compared with sham acupuncture, the RR for the short-term effect of acupuncture was 1.22 (95% CI 1.08 to 1.38), and for the long-term effect was 1.10 (95% CI 0.86 to 1.40). Acupuncture was less effective than nicotine replacement therapy (NRT). There was no evidence that acupuncture is superior to psychological interventions in the short- or long-term.
    b. Moderate quality of evidence of no long term benefit for acupuncture on smoking cessation, although evidence of short term effect
    c. Wide variety of acupuncture protocols. Details of included studies' intervention frequency/duration as well as adjunct therapy, if any (studies only listed here if full articles were available):
    i. Bier 2002: 20 sessions over 4 wks. Three arms: true acupuncture, true acupuncture + intensive ed program, sham acupuncture + intensive ed program
    ii. Clavel 1985: single session. *Adjunct therapy: 3 one-hour sessions of group therapy in first month
    iii. Clavel 1992: 3 sessions over one month
    iv. Cottraux 1983: 3 weekly sessions
    v. Fritz 2013: 5 weekly 20 min sessions of b/l auriculotherapy
    vi. He 1997: Both groups received combination of body electroacupuncture, ear acupuncture and ear acupressure (genuine vs sham points), 6 treatments over 3 wks + 6 plant seeds taped to "correct" or "incorrect" points on the ear and subjects instructed to press on each seed 100x on 4 occasions daily
    vii. Lagrue 1980: facial acupuncture vs sham acupuncture, day 0 and day 7. *Adjunct therapy: "standardised advice"
    viii. Waite 1998: lung point in ear vs control patella point. *Both groups received one 20-minute session of acupuncture w electrical stimulation followed by placement of seed on needle site. Instructed to press seed with desire to smoke.ix. White 1998: acupuncture with electrical stim to lung points in both ears vs sham acupuncture to mastoid bone. Days 1,3, 7. *Adjunct therapy: counseling by a nurse
    x. Wu 2007: indwelling auricular needles in active vs sham points, 4 points retained for one week, then replaced. 8 wk tx period. *Adjunct therapy: counseling from nurse
    d. **Authors' conclusions** Although pooled estimates suggest possible short-term effects there is no consistent, bias-free evidence that acupuncture, acupressure, or laser therapy have a sustained benefit on smoking cessation for six months or

more. However, lack of evidence and methodological problems mean that no firm conclusions can be drawn.

2) **Patnode 2015[ii]: USPSTF Review of Reviews.** (article not included in meeting materials due to length)
   a. Includes all types of behavioral and pharmacotherapy interventions. In total, reviewed 638 abstracts and 114 full-text reviews for possible inclusion, narrowing down to 54 systematic reviews which met eligibility criteria. Identifies 2 reviews on acupuncture (White 2014 and Di 2014) and classifies them both as "good." Additionally, it evaluates Cheng 2012's review of acupoint stimulation as "fair." No other reviews regarding acupuncture or acupressure identified.
   b. Authors' conclusions: Concluded that "evidence on the use of...complementary and alternative therapies was limited and not definitive."

3) **McRobbie 2007[iii]: NICE Rapid Review of Non NHS Treatments for Smoking Cessation** (Study not included in meeting materials due to length)
   a. 19 reviews narrowed to 9 reviews after further exclusion based on poor quality, no systematic method, or review of reviews. Included White's Cochrane review from 2006. Additionally, 21 studies were narrowed to 14 studies after exclusion for not being an RCT. Further, of those 14 studies, 13 were included in the Cochrane Review. Only one new RCT (Docherty 2003) was included, but it was examining laser therapy and thus is not relevant to this lit review.
   b. Since this NICE Review relied heavily on an old Cochrane review, this is less relevant to HERC's current lit review.
   c. **Authors' conclusion**: Marginal effect compared to placebo in short-term but no evidence of efficacy in long-term abstinence rates. Level 1+ evidence "well-conducted meta-analyses, systematic reviews of RCTs, or RCTs (including cluster RCTs) with a low risk of bias."

4) **Cheng 2012[iv]** Systematic Review and Meta-Analysis in American Journal of Chinese Medicine.
   a. n = 20 studies total
      n = 9 studies evaluating smoking cessation rate at 3,6 months
      n = 3 studies evaluating daily cigarette consumption
   b. Includes 13 of same acupuncture studies as White 2014 Cochrane.
   c. Combined all types of acupoint stimulation (acupuncture, acupressure, laser therapy) and all types of controls into single analysis. White 2014 comments that this likely explains the differences in the reviews.
   d. Smoking cessation RR 1.24 (95% CI 1.07,1.43) immediately after tx, 1.70 (1.17,2.46) at 3 months, 1.79 (1.13,2.82) at 6 months compared to control or sham interventions.
   d. Authors' conclusions: "Acupoint stimulation increases smoking cessation rate and reduces daily cigarette consumption. Multi-modality treatment,

especially acupuncture combined with smoking cessation education..., can help."

5) **Di 2014**[v] (Drug and Alcohol Dependence Journal) "A Meta-Analysis of Ear-Acupuncture, Ear-Acupressure and Auriculotherapy for Cigarette Smoking Cessation"

a. Did not take body acupuncture or laser therapy into account.
b. n = 25 RCTs, two pools: 1) comparing to inactive control and 2) comparing to other smoking cessation specific treatment.
c. Pool 1) immediate RR = 1.77 (1.39, 2.25), 3 months RR = 1.54 (1.14, 2.08), 6 months RR = 2.01 (1.23, 3.28), insufficient data for 12 months. Pool 2) "no superiority or inferiority...[immediately] or at 3 and 6 month follow-ups." Small trials.
d. Authors' conclusions: Ear acupuncture, ear acupressure and auriculotherapy is superior to inactive controls for smoking cessation immediately and at 3 months and 6 months.

6) **Tahiri 2012**[vi] Meta-analysis in American Journal of Medicine (not included due to size) http://bscw.rediris.es/pub/bscw.cgi/d5001225/Tahiri-Alternative_smoking_cessation_aids.pdf

a. n = 6 acupuncture trials (823 patients). All 6 were included in Di 2014 meta-analysis and 5 of them included in White 2014. The sixth RCT (Kerr 2008) was classified as laser therapy and excluded from White 2014.
b. OR = 3.53 (1.03,12.07)
c. Very wide confidence interval.
d. Authors' conclusions: "acupuncture...may help smokers quit."

Expert input:
From Laura Ocker, Lac

February 18 2016

I think 12 acupuncture treatments is a good starting point for pain / chronic pain conditions. For smoking cessation, more treatment would be warranted (assuming the patient is truly making progress). For smoking cessation, my recommendation to patients is 2-3 visits per week the first two or three weeks and then 1-2 times per week for several weeks following. Then I am available for a few follow-up appointments throughout the year when stressors trigger the urge to start smoking again. **So, I'd say 18 treatments would be better.** For the person who is truly making progress. If I treat them 3-5 times and they show no signs of cutting down or quitting, I suggest they pursue other options or come back when they feel more ready.

Would be great to combine acupuncture with CBT or other therapies, but I wouldn't necessarily make it a requirement. If someone is doing really well with acupuncture alone, they may not need the additional support. Or vice versa. Also, there are times when medications are not appropriate, such as pregnancy or for patients who are medication-adverse, and this is another good area for acupuncture.

I'd say 18 treatments is a good number for private practice. Although in community health center / community acupuncture settings where a patient can come in more easily and more often for a drop-in treatment (and where you're more likely to be seeing Medicaid patients and people with multiple chronic health conditions and other significant life stressors) up to 24-30 treatments (IF MAKING PROGRESS) would be completely reasonable.

I would recommend 18. I would expect my colleagues to be ethical enough to not treat past the first couple of weeks if the patient has not quit or substantially reduced the number of cigarettes per day.

March 2015

I think that smoking cessation may be one of those conditions, like so many others, for which we see a high degree of efficacy in clinical practice, but for which there may not adequate evidence to support the use of acupuncture as a treatment option from a coverage standpoint. My colleagues and I find that acupuncture and Oriental medicine is a helpful therapy for smoking cessation - in that it reduces cravings and withdrawal symptoms and reduces associated symptoms such as anxiety, rage, nervousness, frustration, etc. Acupuncture alone, or often combined with other therapies, such as CBT or use of nicotine products gradually weaned under a physician's guidance, is very helpful to people who would like to quit smoking. I would like to see acupuncture remain an option for smoking cessation.

HERC staff summary

Four meta-analyses (White 2014, Di 2014, Cheng 2012, and Tahiri 2012) came to varying conclusions, either finding superiority of acupuncture over control/sham at 0-6 months or inconclusive. The differences between the meta-analyses was most attributable to differing methods of pooling. In general, the widely varying acupuncture techniques and protocols used in RCTs let to the inability to draw firm conclusions on effectiveness.

The general staff conclusion is that acupuncture may be helpful for smoking cessation, and is definitely not harmful. The number of visits used in study protocols ranged from 3-20, but were generally fewer than recommended by experts. There is insufficient evidence about the need to pair acupuncture with other therapies for smoking cessation.

HERC staff recommendation:

1) Modify GN92 Acupuncture as shown below
    a. 18 visits maximum
    b. Wording in purple includes wording proposed in the Straightforward Back Line Changes document

GUIDELINE NOTE 92, ACUPUNCTURE (ADAPTED FROM THE OCT. 1, 2015 PRIORITIZED LIST†)

Lines 1,208,351,415,467,532,543 (Lines 351 and 532 represent lines 374 and 545 from the Oct. 1, 2015 Prioritized List†)

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

Line 1 PREGNANCY

Acupuncture pairs on Line 1 for the following conditions.

Hyperemesis gravidarum

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

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

Breech presentation

ICD-10-CM: O32.1

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

Back and pelvic pain of pregnancy

ICD-10-CM: O99.89

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

Line 5 TOBACCO DEPENDENCE

Acupuncture is included on this line for a maximum of 18 sessions.

Line 208 DEPRESSION AND OTHER MOOD DISORDERS, MILD OR MODERATE

Acupuncture is paired with the treatment of post-stroke depression only. Treatments may be billed to a maximum of 30 minutes face-to-face time and limited to 12 total sessions, with documentation of meaningful improvement.

Line 351 DISORDERS OF SPINE WITH NEUROLOGIC IMPAIRMENT (Line 374 from the Oct. 1, 2015 Prioritized List†)

Acupuncture is included on Line 351 (Line 374 from the Oct. 1, 2015 Prioritized List†) only for pairing with disorders of the spine with myelopathy and/or radiculopathy represented by ICD-10-CM G83.4, M47.2, M50.0, M50.1, M51.0, M51.1, M54.1), for up to 12 sessions.

Line 366 SCOLIOSIS

Acupuncture is included on line 366 for pairing with visit limitations as in GUIDELINE NOTE 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE

Line 415 MIGRAINE HEADACHES

Acupuncture pairs on Line 415 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), for up to 12 sessions.

Line 467 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 467 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions.

*Line 532 ACUTE AND CHRONIC DISORDERS OF SPINE WITHOUT NEUROLOGIC IMPAIRMENT (Line 545 from the Oct. 1, 2015 Prioritized List†)

Acupuncture pairs on Line 532 (Line 545 from the Oct. 1, 2015 Prioritized List†) with the low back diagnoses appearing on this line (ICD-10-CM M51.36, M51.86, M54.5, M99.03, S33.5, S33.9, S39.092, S39.82, S39.92). Acupuncture pairs with chronic (>90 days) neck pain diagnoses on this line (ICD-10-CM M53.82, M54.2, S13.4, S13.8), for up to 12 sessions.

*Line 543 TENSION HEADACHES

Acupuncture is included on Line 543 for treatment of tension headaches (ICD-10-CM G44.2), for up to 12 sessions.

The development of this guideline note was informed by a HERC evidence-based guideline. See http://www.oregon.gov/oha/herc/Pages/blog-low-back-non-pharmacologic-intervention.aspx

[i] White, Adrian R., et al. "Acupuncture and related interventions for smoking cessation." *Cochrane Database Syst Rev* 1 (2014).

[ii] Patnode, Carrie D., et al. "Behavioral Counseling and Pharmacotherapy Interventions for Tobacco Cessation in Adults, Including Pregnant Women: A Review of Reviews for the US Preventive Services Task Force." *Annals of internal medicine* 163.8 (2015): 608-621.

[iii] McRobbie, Hayden, et al. "Rapid Review of Non NHS Treatments for Smoking Cessation." NICE (2007).

[iv] Cheng, Hsiao-Min, et al. "Systematic review and meta-analysis of the effects of acupoint stimulation on smoking cessation." *The American journal of Chinese medicine* 40.03 (2012): 429-442.

[v] Di, Yuan Ming, et al. "A meta-analysis of ear-acupuncture, ear-acupressure and auriculotherapy for cigarette smoking cessation." *Drug and alcohol dependence* 142 (2014): 14-23.

[vi] Tahiri, Mehdi, et al. "Alternative smoking cessation aids: a meta-analysis of randomized controlled trials." *The American journal of medicine* 125.6 (2012): 576-584.

Hyperbaric Oxygen Guideline

Question: Should the hyperbaric oxygen guideline be clarified/simplified?

Question source: HERC staff; CCO medical directors; Dr. Alejandro Perez, Providence hyperbaric oxygen medical director

Issue: The current hyperbaric oxygen guideline is confusing to many readers. HERC staff has worked to clarify language for this guideline.

Dr. Carl Stevens, a medical director with CareOregon, has suggested modifications to the guideline to clarify language. One specific request was to apply the requirement for re-evaluation of the wound healing to all conditions listed in the guideline, as all may or may not respond to hyperbaric oxygen therapy.

Review of the CMS National Coverage Determination wording found that it was unclear whether CMS intended that the 30 day re-evaluation requirement be applied to diabetic wounds, or to all wounds. Dr. Alejandro Perez, the Providence Hyperbaric Oxygen program medical director, has recommended to HERC staff that the wording only apply to diabetic wounds and ulcers. Specifically, many of the post-radiation wounds or osteoradionecrosis conditions need specific numbers of treatments which do not correspond well to a 30 day limit. Other conditions need specialized follow up evaluations such as cystoscopy or colonoscopy, which might not be appropriate to do every 30 days.

From Dr. Perez

> For jaw osteoradionecrosis and for soft tissue radiation injuries, however, this is not appropriate. For jaw osteoradionecrosis, for most protocols used, one would do some treatments (20) before surgery and 10 after. This would not fit into a 30 day cycle because of the break needed for surgery and because most hyperbaric centers only are active 5 days per week. Assessment and completion of treatment is appropriate after 30 treatments, not 30 days. For radiation injuries like radiation cystitis, radiation colitis, radiation related ulcerations the process for healing and to see impact is often measured clinically and not by some objective measure. One would not do a cystoscopy or colonoscopy every 30 days for example. Additionally the treatment can take >60 treatments before clinical effect seen. 30 day evaluation would only prove that 30 days is insufficient to see improvement in many patient, but yet by this measure a patient may never get to therapeutic benefit (a self fulfilling prophecy).

On review of the guideline, staff identified that the current guideline note is confusing regarding whether other ICD-10 codes included on the line are actually covered when they are not specifically mentioned in the guideline. Clarification is needed, as there are many conditions included in this line (such as carbon monoxide poisoning, air embolism, etc.) which

are not included in the guideline as the guideline is just a list of limitations for certain ICD-10 codes or restrictions on certain conditions.

Staff identified that the code for osteoradionecrosis of the jaw was possibly incorrect. However, Dr. Perez recommended continuing to use M27.8 (Other specified diseases of jaws) is included on this line, as this is the CMS recommended code for this condition. Additionally, Dr. Perez identified that L59.9 (Disorder of the skin and subcutaneous tissue related to radiation, unspecified) was missing from this line and should be added. The coverage guidance for hyperbaric oxygen therapy recommended coverage of radiation injury. Currently L59.9 appears only on line 536 CONTACT DERMATITIS AND OTHER ECZEMA.

Guideline history

1) 2011, reviewed osteomyelitis and determined no evidence to support coverage
2) 2013, modified guideline wording to improve readibility
3) 2014, coverage guidance on hyperbaric oxygen was adopted and a modified guideline was adopted to reflect the coverage guidance recommendations. The diabetic wound portions of the guideline note were adopted with exact wording from the coverage guidance, except the addition of the requirement for re-evaluation every 30 days. This requirement was added to address medical director concerns and was based on the CMS coverage determination.

Current guideline note:

GUIDELINE NOTE 107, HYPERBARIC OXYGEN

Line 337

Hyperbaric oxygen is a covered service only under the following circumstances:

- when paired with ICD-10-CM codes E11.5x and E11.621, E11.622 and E11.623 for diabetic wounds with gangrene OR diabetic wounds of the lower extremities in patients who meet the all of the following criteria:
    - Patient has Type 1 or Type 2 diabetes and has a lower extremity wound that is due to diabetes, AND
    - Patient has a wound classified as Wagner grade III or higher, AND
    - Patient has failed an adequate course of standard wound therapy including arterial assessment, with no measurable signs of healing after at least thirty days, AND
    - Wounds must be evaluated at least every 30 days during administration of hyperbaric oxygen therapy. Continued treatment with hyperbaric oxygen therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.
- when paired with ICD-10-CM codes M27.8 for osteoradionecrosis of the jaw only
- when paired with ICD-10-CM codes O08.0, M60.000-M60.09 only if the infection is a necrotizing soft-tissue infection
- when paired with ICD-10 CM codes S07.xxx,S17.xxx,S38.xxx,S47.1xxA-S47.1xxD,S47.2xxA-S47.2xxD,S47.9xxA-S47.9xxD, S57.xxx,S67.xxx,

S77.xxx,S87.xxx,S97.xxx, T79.Axx only for posttraumatic crush injury of Gustilo type III B and C

- when paired with ICD-10--CM codes T66.xxxA only for osteoradionecrosis and soft tissue radiation injury
- when paired with ICD-10-CM codes T86.820-T86.829,T82.898A/T82.898D, T82.9xxA/T82.9xxD, T83.89xA/T83.89xD, T83.9xxA/T83.9xxD, T84.89xA/T84.89xD, T84.9xxA/T84.9xxD, T85.89xA/T85.89xD, T859xxA/T859xxD only for compromised myocutaneous flaps

HERC staff recommendations:

1) Add L59.9 (Disorder of the skin and subcutaneous tissue related to radiation, unspecified) to line 337
2) Modify GN107 as shown below

[easier to read format]

GUIDELINE NOTE 107, HYPERBARIC OXYGEN

Line 337

Hyperbaric oxygen therapy is included on this line, subject to the following limitations:

1. Codes appearing on this line from ICD-10-CM E08-E13 are included only when they are diabetic wound ulcers of the lower extremities which are Wagner grade 3 or higher (that is, involving bone or gangrenous) and show no measurable signs of healing after 30 days of adequate standard wound therapies including arterial assessment. Courses of treatment for wounds or ulcers are limited to 30 days after the initial treatment; additional 30 day treatment courses are only covered for patients with incomplete wound/infection resolution AND measurable signs of healing
2. ICD-10-CM M27.8 is included on this line for osteoradionecrosis of the jaw only
3. ICD-10-CM O08.0 and M60.0 are included on this line only if the infection is a necrotizing soft-tissue infection
4. ICD-10-CM S07, S17, S38, S47.1, S47.2, S47.9, S57, S67, S77, S87, S97, T79.A are included on this line only for posttraumatic crush injury of Gustilo type III B and C
5. ICD-10-CM T66.XXXA-T66.XXXD are included on this line only for osteoradionecrosis and soft tissue radiation injury
6. ICD-10-CM T86.82, T82.898, T82.9, T83.89, T83.9, T84.89, T84.9, T85.89, T85.9 are included on this line only for compromised myocutaneous flaps

[edited guideline format]

GUIDELINE NOTE 107, HYPERBARIC OXYGEN

Line 337

A course of ~~H~~hyperbaric oxygen treatment is included on this line ~~a covered service~~ subject to the following limitations: ~~only under the following circumstances~~:

~~when paired with ICD-10-CM codes E11.5x and E11.621, E11.622 and E11.623 for diabetic wounds with gangrene OR diabetic wounds of the lower extremities in patients who meet the all of the following criteria:~~

~~a. Patient has Type 1 or Type 2 diabetes and has a lower extremity wound that is due to diabetes, AND~~

~~b. Patient has a wound classified as Wagner grade III or higher, AND~~

~~c. Patient has failed an adequate course of standard wound therapy including arterial assessment, with no measurable signs of healing after at least thirty days, AND~~

~~d. Wounds must be evaluated at least every 30 days during administration of hyperbaric oxygen therapy. Continued treatment with hyperbaric oxygen~~

~~therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.~~

2) Codes appearing on this line from ICD-10-CM E08-E13 are included only when they are diabetic wound ulcers of the lower extremities which are Wagner grade 3 or higher (that is, involving bone or gangrenous) and show no measurable signs of healing after 30 days of adequate standard wound therapies including arterial assessment. Courses of treatment for wounds or ulcers are limited to 30 days after the initial treatment; additional 30 day treatment courses are only covered for patients with incomplete wound/infection resolution AND measurable signs of healing

1) ~~when paired with~~ ICD-10-CM M27.8 is included on this line for osteoradionecrosis of the jaw only
2) ~~when paired with~~ ICD-10-CM O08.0 and M60.0 are included on this line only if the infection is a necrotizing soft-tissue infection
3) ~~when paired with diagnosis codes included on this line from~~ ICD-10-CM S07, S17, S38, S47.1, S47.2, S47.9, S57, S67, S77, S87, S97, T79.A are included on this line only for posttraumatic crush injury of Gustilo type III B and C
4) ~~when paired with~~ ICD-10-CM T66.XXXA-T66.XXXD are included on this line only for osteoradionecrosis and soft tissue radiation injury
5) ~~when paired with~~ ICD-10-CM T86.82, T82.898, T82.9, T83.89, T83.9, T84.89, T84.9, T85.89, T85.9 are included on this line only for compromised myocutaneous flaps

Disorders of Bilirubin Metabolism

Issue: at the March, 2016 meeting, the VBBS approved moving 4 diagnoses from line 106 HEMOLYTIC DISEASE DUE TO ISOIMMUNIZATION, ANEMIA DUE TO TRANSPLACENTAL HEMORRHAGE, AND FETAL AND NEONATAL JAUNDICE and added to line 64 METABOLIC DISORDERS, as the conditions are not neonatal conditions. However, on further examination, all but one of these conditions are all benign and do not require treatment. Criglar-Najjar syndrome is actually a neonatal condition and should be returned to a neonatal line. These conditions all had a single ICD-9 code (277.4 Disorders of bilirubin metabolism) which was on line 106.

E80.4 is Gilbert syndrome, a hereditary disorder in bilirubin metabolism. Gilbert syndrome results in mild anemia and mild elevations in bilirubin levels but has no clinical significance.

E80.5 is Criglar-Najjar syndrome, a rare inherited disorder affecting the metabolism of bilirubin. The disorder results in a form of nonhemolytic jaundice, which results in high levels of unconjugated bilirubin and often leads to brain damage in infants. Treatment is phototherapy, medications, and exchange transfusion in infancy, with liver transplant as the definitive therapy. Type II Criglar-Najjar is a less serious form of the condition that can normally be managed with medications. The 2014 American Association for the Study of Liver Diseases, the American Society of Transplantation and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition practice guideline for pediatric liver transplant (**Squires 2014**) (study not included due to length https://www.aasld.org/sites/default/files/guideline_documents/EvaluationPediatricLT2014.pdf) recommends all infants with Criglar-Najjar syndrome type 1 be evaluated as soon as possible, before irreversible brain damage occurs, for liver transplantation. Liver transplant is noted to be the only effective treatment for this disease.

E80.6 (Other disorders of bilirubin metabolism) has a few subdiagnoses including Dubin-Johnson syndrome, which is an autosomal recessive disorder that causes an increase of conjugated bilirubin in the serum without elevation of liver enzymes (ALT, AST). This condition is associated with a defect in the ability of hepatocytes to secrete conjugated bilirubin into the bile, and is similar to Rotor syndrome. It is usually asymptomatic. E80.6 is also used for Rotor's syndrome, which is an inherited autosomal recessive disorder characterized by the presence of mild jaundice due to abnormalities in the bilirubin transportation from the liver parenchyma to the biliary system. It is rare and considered benign.

E80.7 is Disorders of bilirubin metabolism, unspecified.

HERC staff recommendations:

1) Remove E80.4-E80.8 from line 64 METABOLIC DISORDERS
2) Add E80.4 (Gilbert syndrome), E80.6 (Other disorders of bilirubin metabolism), and E80.7 (Disorders of bilirubin metabolism, unspecified) to line 656 ENDOCRINE AND METABOLIC CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
3) Add E80.5 (Crigler-Najjar syndrome) to line 106 HEMOLYTIC DISEASE DUE TO ISOIMMUNIZATION, ANEMIA DUE TO TRANSPLACENTAL HEMORRHAGE, AND FETAL AND NEONATAL JAUNDICE and to line 246 ACUTE AND SUBACUTE NECROSIS OF LIVER; SPECIFIED INBORN ERRORS OF METABOLISM (EG. MAPLE SYRUP URINE DISEASE, TYROSINEMIA) Treatment: LIVER TRANSPLANT

Pectus Excavatum and Pectus Carinatum
May 2016

Question: Should pectus excavatum and pectus carinatum be moved to a higher priority line on the Prioritized List?

Question source: Kimberly Ruscher, MD, pediatric surgeon; Garret Zallen, MD surgeon from PeaceHealth

Issue: Currently, pectus excavatum (ICD-10 Q67.6) and pectus carinatum (Q67.7) are on line 665 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY. There are no surgical repair codes on line 665.

A large body of literature was reviewed at the March, 2016 VBBS meeting. The staff summary of this literature review is below:

> *Pectus excavatum*: The literature is conflicting regarding whether surgical repair of pectus excavatum improves cardiac or pulmonary function or exercise tolerance, based on large case series and case-control studies. At best, there is a modest improvement in cardiopulmonary function long term, with short term decreases in pulmonary function after surgery. The vast majority of the literature reports on intermediate outcomes such as cardiac ejection fraction or forced expiratory volume, rather than patient oriented outcomes such as exercise tolerance. Cases with severe deformities causing measurable cardiac or pulmonary impairment or patients with certain co-morbidities may benefit more from surgical intervention than less impacted individuals.
>
> *Pectus carinatum*: There is no evidence that surgical correction or bracing of this condition improves cardiac or pulmonary outcomes or improves other health outcomes. Correction of this condition appears to be solely cosmetic.

Drs. Ruscher and Zollen testified about the resulting cardiac impairment and exercise intolerance caused by pectus excavatum (PE). They requested coverage of treatment for PE for more severely affected patients. The group who respond best from treatment are adolescents. Significant harms including death can result from the surgical treatment of this condition.

The surgeons testified that pectus caravatum (PC) has major physical appearance issues, and treatment involves bracing, which requires a surgery consult, and PT consult and brace fitting. Bracing at a 90+% success rate.

Coverage of PE with a guideline was discussed. The surgical experts argued against using the Haller index to determine severity, as this requires 3D imaging and allowing expert opinion is more cost effective. The staff guideline required cardiac or pulmonary impediments; the surgical experts recommended coverage for severe body image disturbance as well. The experts proposed an alternate guideline, which included atypical chest pain and paradoxical chest pain as possible criteria for coverage.

Pectus Excavatum and Pectus Carinatum
May 2016

HERC staff was directed to work with the OHP medical directors and Dr. Ruscher and Zellen to rework the proposed guideline for treatment of PE and PC. The VBBS generally felt that PE should be included on a covered line, and also left on an uncovered line, with a guideline to distinguish when it is intended to be covered. Staff was directed to review other insurance coverage policies.

<u>Current Prioritized List status</u>
Q67.6 (pectus excavatum) is on line 665 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
Q67.7 (pectus carinatum) is on line 665
Q76.6-Q76.9 (congential malformation of ribs/sternum/bony thorax) are on line 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS

21740 Reconstructive repair of pectus excavatum or carinatum; open
21742 minimally invasive approach (Nuss procedure), without thoracoscopy
21743 minimally invasive approach (Nuss procedure), with thoracoscopy
All appear on line 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS

Other policies (all documents appeared in the March, 2016 VBBS meeting packet)

1) **NICE 2009**
    a. Current evidence on the safety and efficacy of placement of pectus bar for pectus excavatum (also known as MIRPE [minimally invasive repair of pectus excavatum] or the Nuss procedure) is adequate to support its use
    b. Key efficacy outcomes in the review were cosmetic appearance and patient satisfaction
        i. Outcomes listed in review were improved quality of life, self-esteem and cosmetic appearance scores
2) **Cigna 2009**
    a. Under many benefit plans, surgery for chest wall deformities is not covered when performed solely for the purpose of improving or altering appearance or self-esteem or to treat psychological symptomatology or psychosocial complaints related to one's appearance.
    b. If coverage for surgical repair of chest wall deformities is available, the following conditions of coverage apply.
        i. CIGNA covers surgical repair of severe pectus excavatum as medically necessary when imaging studies (e.g., computerized tomography [CT] scans, radiographs) confirm a pectus index (i.e., Haller index) greater than 3.25 and EITHER of the following criteria is met:
            1. Pulmonary function studies demonstrate at least a moderately severe restrictive lung defect.
            2. Cardiac imaging (e.g., echocardiography, stress echocardiography, magnetic resonance imaging [MRI]) demonstrates findings consistent with external compression.
    c. CIGNA covers surgical repair of pectus carinatum as medically necessary when there is documented evidence of significant physical functional impairment (e.g., cardiac or respiratory insufficiency), and the procedure is expected to correct the impairment
    d. CIGNA covers the surgical repair of a chest deformity associated with Poland syndrome as medically necessary when rib formation is absent.
3) **Aetna 2015** Aetna considers surgical repair of severe pectus excavatum deformities that cause functional deficit medically necessary when done for medical reasons in members who meet all of the following criteria:
    a. Well-documented evidence of complications arising from the sternal deformity. Complications include but may not be limited to:
        i. Asthma
        ii. Atypical chest pain
        iii. Cardiopulmonary impairment documented by respiratory and/or cardiac function tests
        iv. Exercise limitation
        v. Frequent lower respiratory tract infections; *and*

b. An electrocardiogram or echocardiogram has been done if a heart murmur or known heart disease is present to define the relationship of the cardiac problem to the sternal deformity; a*nd*
c. A CT scan of the chest demonstrates a pectus index, derived from dividing the transverse diameter of the chest by the anterior-posterior diameter, greater than 3.25.
d. Aetna considers surgical repair of pectus excavatum cosmetic when criteria are not met.
e. Aetna considers the following interventions for the treatment of pectus excavatum experimental and investigational because their effectiveness has not been established;
    i. The magnetic mini-mover procedure
    ii. The vacuum bell
    iii. Dynamic Compression System
f. Aetna considers surgical reconstruction of musculo-skeletal chest wall deformities associated with Poland's syndrome that cause functional deficit medically necessary
g. Aetna considers bracing and surgical procedures to correct pectus carinatum cosmetic because this deformity does not cause physiologic disturbances from compression of the heart or lungs.

4) **<u>United Indications for Coverage</u>**
    a. Surgical repair of pectus excavatum is considered reconstructive and medically necessary when the following criteria has been met:
        i. Pectus Excavatum
            1. Imaging studies confirm Haller index greater than 3.25; and
            2. The functional impairment is defined by one or more of the following:
                a. For restrictive lung capacity the total lung capacity is documented in the physician current office notes as <80% of the predicted value; or
                b. There is cardiac compromise as demonstrated by decreased cardiac output on the echocardiogram; or
                c. There is objective evidence of exercise intolerance as documented by:
                    i. Cardiopulmonary exercise testing that is below the predicted values; or
                    ii. Exercise pulmonary function tests that are below the predicted values and show restrictive lung disease
        ii. Pectus Carinatum
            1. It is extremely uncommon that pectus carinatum will cause a functional/physiological deficit. Pectus carinatum is not a congenital anomaly; it is a developmental condition of the

cartilage that generally occurs during an adolescents growth spurt. (Goretsky, 2004) Requests for coverage of repair of pectus carinatum will be reviewed by a UHC Medical Director on a case by case basis.

5) **<u>HealthPartners Indications for Coverage</u>**
   a. Pectus Excavatum:
      i. All of the following criteria must be met for coverage of repair of pectus excavatum:
         1. A Pectus/ Haller Index greater than 3.25 (calculated by using chest measurements from a CT scan of the area of the chest with the greatest depression.)
         2. Exercise limitation with symptoms OR chest pain related to pectus excavatum present for more than six months and unresponsive to more conservative treatment. Documentation of either of these is required.
         3. Diminished cardiopulmonary function during exercise, documented by lung/cardiac function tests (i.e. 20% depression of cardiopulmonary function.); and
         4. Cardiologist/pulmonologist concurs with need for surgical correction.
      ii. Pectus Carinatum repair is not covered unless there is documentation in the medical record of related functional problems.
      iii. Repairs for cosmetic reasons are not covered.

Pectus Excavatum and Pectus Carinatum
May 2016

HERC staff recommendations:

1) Keep Q67.7 (pectus carinatum) on line 665 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
    a. Treatment is cosmetic
    b. Severe cases can be reviewed through the exceptions process
2) Move pectus excavatum to a covered line for severe cases
    a. Remove Q67.6 (pectus excavatum) from line 665 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY and add to lines 406 BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS and 530 DEFORMITIES OF UPPER BODY AND ALL LIMBS
    b. Add CPT codes for the Nuss procedure and other repair procedures (CPT 21740-21743) to line 406. These codes are already present on line 530.
    b. Add Q79.8 (Other congenital malformations of musculoskeletal system) to line 406 and keep on line 530.
    c. Add a new guideline note to lines 406 and 530 as shown below
        i. Require a Haller index, as all private insurance plans require this measurement
        ii. Do not include atypical chest pain or paradoxical chest wall movement as these are difficult to relate directly to the PE
        iii. Do not include significant body image disturbance as other conditions on the PL are not covered when only body image disturbance is present
        iv. Do not include exercise limitation as a criteria because this is difficult and expensive to objectively determine

GUIDELINE NOTE XXX PECTUS EXCAVATUM
Lines 406, 530
Pectus excavatum (ICD-10 Q67.6) is included on line 406 only for patients with all of the following:

1) severe deformity (Haller index >3.25) AND
2) documented pulmonary or cardiac dysfunction demonstrated by either
    a. Cardiac effects to include cardiac compression or displacement, bundle branch block or other cardiac pathology secondary to compression of the heart, OR
    b. Pulmonary function studies demonstrating at least a moderately severe restrictive lung defect, AND
3) cardiologist/pulmonologist concurs with need for surgical correction AND
4) these conditions are reasonably expected to be relieved with surgery.

Otherwise, this condition is included on line 530.

ICD-10 Q79.8 is included on line 406 only for Poland syndrome. Other diagnoses using this code are on line 530. Surgical reconstruction of musculo-skeletal chest wall deformities associated with Poland's syndrome are only included on line 406 when causing functional deficits.

Section 4.0

Multisector evidence reviews

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE AND MULTISECTOR INTERVENTION REPORT: TOBACCO CESSATION DURING PREGNANCY

For illustration—HERC meeting materials 5/19/16

HERC Coverage Guidance

For women who use tobacco during pregnancy, the following interventions to aid in smoking cessation are recommended for coverage:

- Behavioral interventions (*strong recommendation*)
- Financial incentives (contingent) (*weak recommendation)*
- Prenatal ultrasound with high feedback around smoking impacts on the fetus *(weak recommendation)*

The following interventions are not recommended for coverage:

- Electronic nicotine delivery systems *(weak recommendation)*
- Counseling-based interventions to reduce secondhand smoke exposure (*weak recommendation)*
- Partner support for smoking cessation (*weak recommendation)*

No recommendation is being made regarding the coverage of pharmacotherapy:
Federal law requires coverage of tobacco cessation services, including FDA-approved pharmacotherapy to be covered by some plans (including Medicaid). Even so, based on the evidence, the Commission cannot make a coverage recommendation in favor of pharmacotherapy for smoking cessation for pregnant women.

Note: Definitions for strength of recommendation are provided in Appendix A *GRADE Informed Framework Element Description*.

Multisector Interventions

To reduce the use of tobacco during pregnancy and improve associated outcomes, the evidence supports the following interventions:

- Financial incentives (contingent most effective)
- Smoke-free legislation
- Tobacco excise taxes

No or insufficient evidence is available for:

- Internet or text messaging based interventions
- Mass media campaigns specific to pregnant women

Note: Statements on multisector interventions are designed to recommend effective interventions which impact health outcomes and that occur outside the clinical setting. Policy settings include community-based programs as well as policy changes by private and public organizations.

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for coverage guidances to guide public and private payers based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon. They are based on a review of the relevant research, which is evaluated using an adaptation of the GRADE methodology. For more information on methodology, see Appendix A.

GRADE-INFORMED FRAMEWORK

The 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 carrying out the steps involved in developing recommendations. There are several elements that determine the strength of a recommendation, as listed in the table below. The 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. The level of confidence in the estimate is determined by the Commission based on assessment of two independent reviewers from the Center for Evidence-based Policy. Unless otherwise noted, estimated resource allocation, values and preferences, and other considerations are assessments of the Commission.

Coverage question: Should pharmacotherapy or electronic nicotine delivery systems be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Pregnancy complications *(Critical outcome)*	Miscarriage and spontaneous abortion: 7/923 (0.7%) in NRT groups vs. 4/859 (0.4%) in control groups RR 1.47 (95% CI 0.45 to 4.77) ●●●○ *(Moderate certainty of equivalence)* Preterm birth (<37 weeks) 101/1053 (9.5%) in NRT groups vs. 104/995 (10.4%) in control groups RR 0.87 (95% CI 0.67 to 1.14) ●●●● *(High certainty of equivalence)*	The costs of medications for smoking cessation are moderate, but there are no projected savings given the lack of proven effectiveness and lack of impact on health outcomes.	Pregnancy can be a motivating time for many women who wish to quit using cigarettes. However, they may be concerned about the use of medications which have not been proven safe, or effective during pregnancy. There is likely significant variability in women's interest in	The only pharmacotherapies for which studies were found were nicotine replacement therapies. Bupropion is considered relatively low risk in pregnancy (pregnancy class B), varenicline has some potential level of risk and it is unclear if risk
Low birth weight *(Critical outcome)*	<2500 grams: 107/1043 (1.0%) in NRT groups 112/994 (1.1%) in control groups RR 0.74 (95% CI 0.41 to 1.34) ●●●● *(High certainty of equivalence)*			

Coverage question: Should pharmacotherapy or electronic nicotine delivery systems be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Perinatal/infant death *(Critical outcome)*	Stillbirth: 14/920 (1.5%) in NRT groups vs. 10/857 (1.1%) in control groups RR 1.24 (95% CI 0.54 to 2.84) ●●●○ *(Moderate certainty of equivalence)* Neonatal death: 4/898 (0.4%) in NRT groups vs. 5/848 (0.5%) in control groups RR 0.66 (95% CI 0.17 to 2.62) ●●●○ *(Moderate certainty of equivalence)*		using medications to assist smoking cessation.	outweighs benefit (pregnancy class C), and nicotine and nortriptyline have evidence of risk (pregnancy class D).
Tobacco abstinence during pregnancy *(Important outcome)*	All trials: 143/1133 (12.6%) in NRT groups vs. 91/1066 (8.5%) in control groups (RR 1.41, 95% CI 1.03 to 1.93) ●●●● *(High certainty that NRT is better than no treatment or placebo)* Placebo controlled trials: 118/965 (12.2%) in NRT groups vs. 90/961 (9.3%) in control groups (RR 1.28, 95% CI 0.99 to 1.66) ●●●● *(High certainty that NRT is equivalent to or better than placebo)*			

Coverage question: Should pharmacotherapy or electronic nicotine delivery systems be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Tobacco abstinence after pregnancy *(Important outcome)*	At 3 to 6 months post-partum: 61/346 (17.6%) in the NRT groups vs. 40/279 (14.3%) in the control groups RR 1.22 (95% CI 0.84 to 1.77) ●●●● *(High certainty of equivalence)*			
Balance of benefits and harms:				
Rationale: There is moderate to high certainty that pharmacotherapy is ineffective at reducing bad maternal/fetal outcomes. There is high certainty ~~and~~ that it is equivalent to or better than placebo~~ineffective~~ for tobacco abstinence during and after pregnancy. Given a ~~proven~~ lack of proven benefit, a possibility of harm, associated costs, and mixed values and preferences, a ~~potentially strong~~ recommendation against coverage would be considered. Federal law requires some payers (including Medicaid) to cover pharmacotherapy for pregnant women who smoke tobacco. There are no studies on electronic nicotine delivery systems in pregnant women.~~.~~ Given the lack of proven benefit, unknown harms, and costs, they are recommended for noncoverage.				
Recommendation: No recommendation about pharmacotherapy given federal law.~~.~~ Electronic nicotine delivery systems are not recommended for coverage *(strong~~weak~~ recommendation).*				

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

Coverage question: Should behavioral interventions be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Pregnancy complications *(Critical outcome)*	Preterm birth (<37 weeks) 251/3992 (6.3%) in intervention groups vs. 307/3860 (7.9%) in control groups RR 0.82 (95% CI 0.70 to 0.96) ●●●○ *(Moderate certainty that behavioral interventions are better than usual care)*	The cost for behavioral interventions is likely moderate. The benefits of decreased low birth weight and preterm labor could result in substantially lower costs.	Many women who are motivated to quit smoking during pregnancy would likely be interested in behavioral interventions to quit smoking. There may be some groups of women or some particular types of behavioral interventions that drive women to smoke more, and these should be better understood.	Behavioral interventions can encompass a wide range of types and intensity of interventions. The 5As approach is widely endorsed.
Low birth weight *(Critical outcome)*	<2500 grams: 304/4298 (7.1%) in intervention groups vs. 381/4264 (8.9%) in control groups RR 0.82 (95% CI 0.71 to 0.94) ●●●○ *(Moderate certainty that behavioral interventions are better than usual care)*			
Perinatal/infant death *(Critical outcome)*	Stillbirth: 38/2676 (1.4%) in intervention groups vs. 31/2738 (1.1%) in control groups RR 1.22 (95% CI 0.76 to 1.95) ●●○○ *(Low certainty of equivalence)* Neonatal death: 8/1014 (0.8%) in intervention groups vs. 4/1081 (0.4%) in control groups RR 2.06 (95% CI 0.61 to 6.92) ●●○○ *(Low certainty of equivalence))*			
Tobacco abstinence during pregnancy	All trials: 743/5896 (12.6%) in intervention groups vs. 546/6083 (8.9%) in control groups RR 1.44 (95% CI 1.19 to 1.75)			

Coverage question: Should behavioral interventions be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
(Important outcome)	●●●○ *(Moderate certainty that behavioral interventions are better than usual care)* Trials with biochemical validation: 453/4478 (10.1%) in intervention groups vs. 402/4772 (8.4%) in control groups RR 1.25 (95% CI 1.03 to 1.50) ●●●○ *(Moderate certainty that behavioral interventions are better than usual care)*			
Tobacco abstinence after pregnancy *(Important outcome)*	At 12 to 17 months post-partum: 56/298 (18.8%) in the intervention groups vs. 12/133 (9.0%) in the control groups RR 2.2 (95% CI 1.23 to 3.96) ●●●○ *(Moderate certainty that behavioral interventions are better than usual care)* At >18 months post-partum: 21/466 (4.5%) in the intervention groups vs. 17/468 (3.6%) in the control groups RR 1.25 (95% CI 0.57 to 2.73) ●●●○ *(Moderate certainty of equivalence)*			
Balance of benefits and harms:				

Coverage question: Should behavioral interventions be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Rationale: There is moderate certainty that behavioral interventions increase tobacco abstinence during pregnancy and up to 17 months postpartum. The benefit does not persist beyond 18 months. Behavioral interventions are effective at reducing the incidence of low birth weight and pre-term birth. A potential harm is a paradoxical increase in smoking that occurred in four of the seventy studies, but otherwise the intervention carries little risk. The strength of the recommendation is based on evidence demonstrating the significant impact on morbidity, few harms, moderate cost, and some with strong interest in the intervention.				
Recommendation: Behavioral interventions are recommended for coverage *(strong recommendation).*				

Coverage question: Should ultrasound with high feedback be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Pregnancy complications *(Critical outcome)*	No data	This would involve an increase in reimbursement for additional physician counseling during a prenatal ultrasound and would likely have minimal to modest costs associated with it.	Many women would want to have additional detailed information provided by physicians at the time of an ultrasound, however, the clinical significance of variable findings may be difficult to interpret. ~~.~~ However,	
Low birth weight *(Critical outcome)*	No data			
Perinatal/infant death *(Critical outcome)*	No data			
Tobacco abstinence during pregnancy	Absolute rate (of cessation): 28.4% in ultrasound with high feedback group vs. 8.1% in controls group RR 2.93 (95% CI 1.25 to 6.86)			

Coverage question: Should ultrasound with high feedback be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
(Important outcome)	●●○○ *(Low certainty that ultrasound with high feedback is better than low or no feedback)*		if specific harms to their fetus about the impact of tobacco were shown to the pregnant woman~~them~~ it is possible this could create psychological distress ~~in those unable to quit smoking~~.	
Tobacco abstinence after pregnancy *(Important outcome)*	No data			
Balance of benefits and harms:				
Rationale: There is no evidence available on any of the critical outcomes and on only one of the important outcomes. While the increase in absolute rate of cessation was noteworthy (and higher than any other intervention), it is a single, small RCT with a moderate risk of bias and there is low certainty of the benefit. Additionally, this study was published in 1982 and apparently has not been replicated (or published) which may undermine our confidence in these findings. ~~-~~ However, the cost of this may be quite modest. A recommendation for coverage~~noncoverage~~ is made at this time; it is a weak recommendation because there is potential for this to change, particularly if additional studies confirm the large increase in tobacco abstinence and if associated health benefits or if harms to the mother were demonstrated. ~~as a result of the intervention.~~				
Recommendation: Ultrasound with high feedback is ~~not~~ recommended for coverage (*weak recommendation*).				

Coverage question: Should financial incentives be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Pregnancy complications *(Critical outcome)*	No data	There is a direct, somewhat predictable financial expenditure for the financial incentives. The amounts of incentives used in studies were modest in nature. Performing a contingent model of incentives would lower the overall costs based on individual efficacy (a woman would stop receiving incentives if the intervention failed).	Financial incentives may be quite appealing to many women. One could argue that incentivizing those in poverty raises some ethical concerns, but the clear potential benefit to the woman and the fetus of smoking cessation, with a lack of harm, mitigates those concerns.	
Low birth weight *(Critical outcome)*	No data			
Perinatal/infant death *(Critical outcome)*	No data			
Tobacco abstinence during pregnancy *(Important outcome)*	180/675 (26.6%) in the incentive groups vs. 56/622 (9.0%) in the control groups OR 3.79 (95% CI 2.74 to 5.25) ●●●○ *(Moderate certainty that financial incentives are better than usual care)*			
Tobacco abstinence after pregnancy *(Important outcome)*	Absolute rate (at 10-24 weeks post-partum): 15.4% in the incentive groups vs. 4.8% in the control groups OR 3.60 (95% CI 2.39 to 5.43) ●●●○ *(Moderate certainty that financial incentives are better than usual care)*			
Balance of benefits and harms:				

Coverage question: Should financial incentives be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Rationale: Moderate certainty evidence supports financial incentives improving tobacco abstinence during and after pregnancy. The costs of this are relatively modest, and many women would be interested in participating in this model if motivated to quit for additional financial gain. Contingent financial incentives appear to be the most effective. Therefore, this is recommended for coverage. It is a weak recommendation because of the lack of evidence on critical outcomes.				
Recommendation: ~~Contingent financial~~ Financial incentives (especially those contingent on demonstrated tobacco abstinence) are recommended for coverage (*weak recommendation*). *As financial incentives are provided in clinical settings, but not typically billed as clinical services, this recommendation is listed both in the Coverage Guidance box and in the multisector recommendations box.*				

Coverage question: Should partner support be recommended for coverage for tobacco cessation in pregnancy?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
Pregnancy complications *(Critical outcome)*	No data	Cost would likely be incremental above the cost of behavioral interventions provided to the pregnant woman.	Most patients interested in tobacco cessation would likely desire support from their partners. Partner participation would be variable.	
Low birth weight *(Critical outcome)*	No data			
Perinatal/infant death *(Critical outcome)*	No data			
Tobacco abstinence during pregnancy *(Important outcome)*	Three of four studies found equivalence in maternal smoking cessation. The fourth study found increased quit attempts and smoking cessation, but only at 1 week follow-up. ●●○○ *(Low certainty of equivalence)*			
Tobacco abstinence after pregnancy *(Important outcome)*	No data			
Balance of benefits and harms:				
Rationale: Due to the very limited evidence base and insufficient and mixed evidence of benefit, partner support is not recommended for coverage. The recommendation is weak because more evidence could change the conclusion.				
Recommendation: Partner support for smoking cessation is not recommended for coverage *(weak recommendation)*				

<table>
<tr><td colspan="5">Coverage question: Should clinical interventions to reduce secondhand smoke exposure be recommended for coverage for tobacco cessation in pregnancy?</td></tr>
<tr><td>Outcomes</td><td>Estimate of Effect for Outcome/ Confidence in Estimate</td><td>Resource allocation</td><td>Values and Preferences</td><td>Other considerations</td></tr>
<tr><td>Pregnancy complications
(Critical outcome)</td><td>Preterm birth:
OR 1.24 (95% CI 0.70 to 2.10)
●○○○ (Very low certainty of equivalence)</td><td rowspan="5">Cost would likely be incremental on top of behavioral counseling or regular clinical visits provided to the tobacco user.</td><td rowspan="5">Most patients interested in tobacco cessation would likely desire reduced exposure to secondhand smoke. Preferences of nearby smokers would be highly variable.</td><td rowspan="5">These studies looked at self-report of exposure to second hand smoke.</td></tr>
<tr><td>Low birth weight
(Critical outcome)</td><td>OR 1.31 (95% CI 0.77 to 2.24)
●○○○ (Very low certainty of equivalence)</td></tr>
<tr><td>Perinatal/infant death
(Critical outcome)</td><td>No data</td></tr>
<tr><td>Tobacco abstinence during pregnancy (Important outcome)</td><td>No data</td></tr>
<tr><td>Tobacco abstinence after pregnancy
(Important outcome)</td><td>No data</td></tr>
<tr><td colspan="5">Balance of benefits and harms:</td></tr>
<tr><td colspan="5">Rationale: Clinical interventions to reduce secondhand smoke exposure have very limited quality evidence showing inconclusive results. Therefore, these interventions are not recommended for coverage. The recommendation is weak because additional research may show a benefit.</td></tr>
<tr><td colspan="5">Recommendation: Counseling-based interventions to reduce secondhand smoke exposure are not recommended for coverage (weak recommendation)</td></tr>
</table>

EVIDENCE TABLES FOR MULTISECTOR INTERVENTIONS

Intervention: Smoke-free legislation				
Setting/sector: Local, state and federal governments				
Outcomes	**Estimate of Population Health Effect**	**Resource Impact**	**Public Values and Preferences**	**Other considerations**
Pregnancy Complications *(Critical outcome)*	Smoke-free legislation is associated with an approximately 10% risk reduction for preterm birth (95% CI -18.80 to -2.00) Evidence type: Systematic review of interrupted time series	Limited direct public resource impact to implement legislation; legislation would likely reduce tobacco-related health care and disability-related costs but reduce state tobacco tax revenue due to reduced tobacco use.	Oregon has an existing smoke-free workplace law, including bars and restaurants. Smoke-free legislation has often faced opposition from those with a financial interest in tobacco sales.	
Low birth weight *(Critical Outcome)*	Smoke-free legislation is associated with a -1.70% risk reduction of low birth rate, but the result is not statistically significant (95% CI -5.10 to 1.60) Evidence type: Systematic review of interrupted time series			

Intervention: Tobacco excise taxes				
Setting/sector: Local, state and federal governments				
Outcomes	**Estimate of Population Health Effect**	**Resource Impact**	**Public Values and Preferences**	**Other considerations**
Pregnancy Outcomes *(Critical outcome)* **Preterm birth**	Each $1 increase in tobacco taxes is associated with small reduction (0.07% to 0.08%) in the rate of preterm births Evidence type: Quasi-experimental analysis of US natality files	Increases to tobacco taxes generate revenues to the jurisdiction imposing them and reduce health care costs because of reduced tobacco consumption. Oftentimes, tobacco tax revenue is used to help fund addiction and other health services. Tobacco taxes would reduce tobacco-related healthcare costs to the extent they reduce tobacco use.	Tobacco taxes are common in the United States at the state level, though increases in tobacco taxes face opposition from businesses that generate revenue from tobacco sales. Nonsmokers are generally more in favor of tobacco control policies than smokers. Some argue that tobacco taxes are regressive because low-income and less well-educated populations have higher rates of smoking. Counter arguments are that low-income populations show greater decreases in tobacco use after tax increases, and new tobacco tax revenues can be used to fund tobacco control programs and other health and social services.	
Low birth weight *(Critical Outcome)*	Each $1 increase in tobacco taxes is associated with a small reduction (0.08% to 0.12%) in the rate of low birth weight Evidence type: Quasi-experimental analysis of US natality files			
Perinatal/infant Death *(Critical Outcome)*	Each $1 increase in tobacco taxes is associated with a small reduction (0.19 per 1000) in infant death rate Evidence type: Time series modeling			

Intervention: Tobacco excise taxes				
Setting/sector: Local, state and federal governments				
Outcomes	**Estimate of Population Health Effect**	**Resource Impact**	**Public Values and Preferences**	**Other considerations**
Tobacco abstinence during pregnancy *(Important Outcome)*	Each $1 increase in tobacco taxes is associated with a 2% to 5% reduction in smoking during pregnancy Evidence type: Quasi-experimental and cross-sectional ecological study			
Tobacco abstinence after pregnancy *(Important outcome)*	Each $1 increase in tobacco taxes is associated with a 4% reduction in smoking at 4 months post-partum Evidence type: Cross-sectional ecological study			

MULTISECTOR INTERVENTIONS: TOBACCO PREVENTION AND CESSATION

Benefit coverage for smoking cessation on Line 5 and in Guideline Note 4 TOBACCO DEPENDENCE is intended to be offered with minimal barriers, in order to encourage utilization. To further prevent tobacco use and help people quit, additional evidence-based policy and programmatic interventions from a population perspective are available here:

- Oregon Public Health Division's Health Promotion and Chronic Disease Prevention Section: Evidence-Based Strategies for Reducing Tobacco Use A Guide for CCOs https://public.health.oregon.gov/PreventionWellness/TobaccoPrevention/Documents/evidence-based_strategies_reduce_tob_use_guide_cco.pdf
- Community Preventive Services Task Force (supported by the CDC) - What Works: Tobacco Use http://www.thecommunityguide.org/about/What-Works-Tobacco-factsheet-and-insert.pdf

The Community Preventive Services Task Force identified the following evidence-based strategies:

TASK FORCE FINDINGS ON TOBACCO USE

The Community Preventive Services Task Force (Task Force) has released the following findings on what works in public health to prevent tobacco use. These findings are compiled in The Guide to Community Preventive Services (The Community Guide) and listed in the table below. Use the findings to identify strategies and interventions you could use for your community.

Legend for Task Force Findings: ● Recommended ◆ Insufficient Evidence ▲ Recommended Against (See reverse for detailed descriptions.)

Intervention	Task Force Finding
Reducing Tobacco Use Initiation	
Increasing the unit price of tobacco products	●
Mass media campaigns when combined with other interventions	●
Smoke-free policies	●
Increasing Tobacco Use Cessation	
Increasing the unit price of tobacco products	●
Mass media campaigns when combined with other interventions	●
Mass-reach health communication interventions	●
Mobile phone-based interventions	●
Multicomponent interventions that include client telephone support	●
Smoke-free policies	●
Provider reminders when used alone	●
Provider reminders with provider education	●
Reducing client out-of-pocket costs for cessation therapies	●
Internet-based interventions	◆
Mass media – cessation contests	◆
Mass media – cessation series	◆
Provider assessment and feedback	◆
Provider education when used alone	◆

Intervention	Task Force Finding
Reducing Exposure to Environmental Tobacco Smoke	
Smoke-free policies	●
Community education to reduce exposure in the home	◆
Restricting Minors' Access to Tobacco Products	
Community mobilization with additional interventions	●
Sales laws directed at retailers when used alone	◆
Active enforcement of sales laws directed at retailers when used alone	◆
Community education about youth's access to tobacco products when used alone	◆
Retailer education with reinforcement and information on health consequences when used alone	◆
Retailer education without reinforcement when used alone	◆
Laws directed at minors' purchase, possession, or use of tobacco products when used alone	◆
Decreasing Tobacco Use Among Workers	
Smoke-free policies	●
Incentives and competitions to increase smoking cessation combined with additional interventions	●
Incentives and competitions to increase smoking cessation when used alone	◆

Visit the "Tobacco Use" page of The Community Guide website at www.thecommunityguide.org/tobacco to find summaries of Task Force findings and recommendations on tobacco use. Click on each topic area to find results from the systematic reviews, included studies, evidence gaps, and journal publications.

The Centers for Disease Control and Prevention provides administrative, research, and technical support for the Community Preventive Services Task Force.

General Multisector Interventions

Mayne, et al., 2015

This is a narrative systematic review of natural or quasi-experimental studies conducted to examine the effects of policy and built environment changes on obesity outcomes. The authors identified 37 studies, but only three of these studies measured weight or body mass index (BMI) outcomes (the remaining studies only examined changes in dietary composition or physical activity). One study of school nutrition policy and day care meal standards involving almost 68,000 children in Chile found mixed results for the outcomes of BMI z-score and obesity prevalence and the initial improvements were not sustained at 24 months. The second study examined the effects of changes in food voucher policy among 72,000 low-income immigrant adults in the United States and found no association between the policy change and BMI. The third study, which was designed as a longitudinal within-person study of the effects of a new light rail system in Charlotte, North Carolina found that use of the light rail system was associated with a self-reported BMI reduction of 1.18 kg/m2 (95% CI -2.22 to -0.13) and reduced the odds of incident obesity. The authors did note that weaker study designs are more likely to report positive findings.

Bottom line: There is limited evidence from a study in one community that use of a new light rail system was associated with a small reduction in self-reported BMI and incident obesity. The results of nutritional policy interventions were mixed.

Amiri Farahani, et al., 2015

This is a narrative systematic review of community-based physical activity interventions targeting women ages 18 to 65 years old. The authors identified nine studies including four methodologically rigorous randomized controlled trials (RCTs). Most of the studies were done in the United States and involved multi-component interventions to promote physical activity. Most of the interventions involved social support, goal setting, barrier anticipation, and self-monitoring; these were provided in theoretical constructs of social cognitive theory and social marketing theory. One trial involved a combined exercise program for mothers and daughters and one included a free gym membership. While seven of the nine studies reported positive effects on physical activity, only four studies reported statistically significant improvements. No studies reported on weight or BMI outcomes. The authors concluded that there was "insufficient evidence to assess the effectiveness of community-based interventions for enhancing physical activity among women."

Bottom line: While several programs found improvements in physical activity, there is insufficient evidence for the effectiveness of community-based physical activity promotion programs for weight loss in adult women.

Hillier-Brown, et al., 2014a

This is a narrative systematic review of interventions applied at various levels to reduce socioeconomic disparities in adult obesity. Interventions were classified as occurring at the individual, community, or societal levels. Five studies at the individual level were included; four examined tailored weight-loss

plans delivered via primary care, while the fifth was a long-term study of an educational intervention for obesity prevention. The individually tailored weight-loss plans delivered in primary care appeared to be effective at up 12 months and several of the studies showed greater effects among African-American participants. At the community level, authors identified 12 studies; eight of these examined community-based group health education and counseling interventions, two examined workplace education interventions, and two examined family-based group education programs delivered in schools. Overall, the results of the community-based interventions were mixed, but some of the studies of community-based education and counseling programs showed modest reductions in BMI, but only in the short term (3 to 6 months). At the societal level, the authors identified 3 studies. The first was an initiative involving environmental strategies to encourage healthful eating and physical activity through "social marketing…stairway signs, cafeteria signs, farmer's markets, walking groups, challenges, workshops, educational displays, newsletters, project website, project information centre and print materials." This study showed modest positive results, but only among the higher-educated participants. The final two societal level studies examined the effects of changes in the structure of nutrition assistance programs for poor women; neither study found significant effects on obesity.

Bottom line: There is some evidence of effectiveness for individual level interventions (particularly those involving tailored weight-loss plans in primary care) in reducing inequalities in adult obesity, but there was less evidence for the effectiveness of community and societal level interventions.

Workplace Interventions

Bellicha, et al., 2015

This is narrative systematic review of studies examining the effectiveness of interventions to promote the use of stairs. Fifty studies, conducted in a mix of workplace and public settings, were included. The primary outcome measure was stair climbing (ascent only) or stair use (ascent and descent combined). The interventions consisted of a mix of motivational and directional signs with or without stairwell enhancements. The study designs were nearly all pre-post comparisons and none were judged to be high quality. Modest improvements in stair climbing (absolute median increase of about 4%) were noted in most studies during the intervention period. The combination of motivational and directional signs appeared to be more effective than motivational signs alone. Three of the four studies of stairwell enhancements showed similar results (absolute median increase in stair climbing of 4.4%) to the motivational and directional signs. The authors did note that elements of external validity (i.e. implementation) were "largely underreported" in the literature. No weight, BMI, or health outcomes were reported.

Bottom line: Motivational and directional signs as well as stairwell improvements probably lead to modest increases in stair use, but the external validity of these studies remains uncertain.

Malik, et al., 2014

This is a narrative systematic review of health promotion interventions in the workplace to increase physical activity. The authors identified 58 studies including exercise interventions (6 studies), counseling and support interventions (13 studies), and informational or health promotion message interventions (39 studies). The primary outcomes were measures of physical activity. The exercise intervention studies were mostly RCTs or cluster randomized trials. Two of the six studies showed statistically significant increases in physical activity (increased step counts in both of the positive studies); the remaining studies did not demonstrate an effect. The counseling and support interventions, which included telephonic counseling and peer support programs, used mostly RCT and quasi-experimental designs but there were substantial issues with blinding, use of intention-to-treat, baseline group differences, and attrition. Eight of the thirteen studies showed statistically significant increases in measures of physical activity or total energy expenditure. The informational and health promotion message interventions were diverse and mostly studied using RCT and quasi-experimental designs, but as with other included studies there were methodologic flaws in most trials. Twenty-two of the thirty-nine studies showed statistically significant increases in physical activity; programs that included stage-of-change matched informational materials were more likely to report significant results. Weight, BMI, and health outcomes were not reported. The authors' overall conclusion was that the evidence for workplace health promotion interventions was mixed and inconclusive.

Bottom line: Evidence that workplace health promotion interventions lead to increased physical activity is mixed.

Gudzune, et al., 2013

This is a narrative systematic review of workplace or college-based interventions to prevent weight gain. The authors identified seven workplace and two college-based studies using randomized, cluster-randomized, or quasi-experimental designs. The age, gender, and other participant characteristics varied by study site. The studied interventions were diverse and included environmental changes, health promotion and informational programs, educational programs (including a 4 month college course on preventing weight gain), supported self-management programs, or some combination of the interventions. Five of the workplace studies and both college-based studies reported BMI outcomes at 12 to 24 months.

At 24 months, one of the workplace studies showed intervention group participants had a BMI 0.3 kg/m2 lower than the control group. Another showed the intervention group with a BMI 0.2 kg/m2 higher than the control group at 12 months. Both of these results were statistically significant, while 3 other studies showed no difference between intervention and control groups.

Both of the college-based programs showed lower BMI at 12 months (-0.5 kg/m2 and -1.6 kg/m2) in the intervention group, though only the former result was statistically significant. Overall, the authors deemed the evidence for BMI reduction to be low strength because of issues with bias in the non-randomized trials and inadequate blinding of outcomes assessors. The authors concluded that there was limited evidence for workplace and college-based interventions to prevent weight gain.

Bottom line: There is mixed evidence that workplace interventions are effective to prevent weight gain. There is limited evidence that college-based interventions are effective.

Sugar-sweetened Beverage Taxes

Cabrera Escobar, et al., 2013

This is a systematic review and meta-analysis of the effects of sugar-sweetened beverage (SSB) taxes on SSB demand and obesity. Nine studies, six from the US and one each from Mexico, Brazil, and France were included. The primary outcomes were own-price and cross-price elasticity (measured as the percentage change in quantity demanded), and change in obesity rates or BMI. All studies showed negative own-price elasticity ranging from -0.85 to -4.45 with a meta-analytic estimate of -1.3 (95% CI -1.089 to -1.509). These results suggest that the demand for SSBs is elastic and that SSB price increases are associated with reduced demand. Cross-price elasticities meant to measure effects of SSB price increases on demand for other beverages were studied in five of the nine studies. The overall estimate is that SSB price increases result in slightly increased demand for fruit juice and milk and slightly lower demand for diet beverages. Meta-analysis could not be performed for the effect of SSB taxes on obesity and BMI. One study estimated that a 10% increase in SSB price would lead to a reduction in the point prevalence of obesity of -0.34% for men and -0.05% for women. A second study estimated that a SSB price increase of 20% would reduce the point prevalence of overweight -0.045% and obesity by -0.03%. A third study estimated that a 20% increase in the price of SSBs would reduce BMI by -0.065 kg/m2. A fourth study reported that 1% grocery soda taxes and soft drink vending machine taxes would increase BMI by 0.012 kg/m2 and 0.011 kg/m2 respectively, though neither result was statistically significant. The fifth study found that a 1% increase in SSB price would produce only small effects on BMI of -0.0031 kg/m2 for adults and -0.015 kg/m2 for children and adolescents. Overall, the authors conclude that SSB taxes or price increases may benefit health.

Bottom line: SSB prices are elastic and SSB taxes can reduce demand, but the estimated effects of SSB price increases on obesity prevalence and BMI are modest.

Long, et al., 2015

This is a modeling study of the cost-effectiveness of SSB taxes in the U.S. Key assumptions of the model include an own-price elasticity for SSBs of -1.22 and that a reduction of SSB consumption of 8 oz/day leads to weight loss of about 1 kg in children and 12 oz/day leads to BMI change of -0.39 kg/m2 for adults. Health gains were estimated over 10 years using a Markov cohort model. The model accounts for downstream changes in a variety of obesity-related illnesses to produce estimates of quality-adjusted life years and disability-adjusted life years. The model also estimated differences in healthcare expenditures based on inputs from the Medical Expenditure Panel Survey. Based on the model, a national SSB excise tax of $0.01/oz would lead to a 20% reduction in consumption which, in turn, would reduce average adult BMI by 0.08 kg/m2 and youth BMI by 0.16 kg/m2. The prevalence of obesity among adults and children would drop by 0.99% and 1.38% respectively. Over the 10 year period

between 2015 and 2025, the SSB excise tax would lead to 871,000 QALYs gained and reduce health care costs by $23.6 billion. Thus, the intervention was deemed cost-saving, a finding that was maintained across varied inputs in the sensitivity analysis.

Bottom line: This modeling study suggests that a national SSB excise tax of $0.01/oz would reduce the prevalence of obesity by about 1% and avert nearly $25 billion in health care costs over 10 years.

Financial Incentives

Mantzari, et al., 2015

This is a systematic review and meta-analysis of financial incentives for changing health-related behaviors. The review identified fifteen studies examining the effects of financial incentives on markers of healthier eating and physical activity and two studies on physical activity alone. Most of the studies were done in the U.S. and were conducted in a variety of settings including workplaces, communities, health care, and academia. The magnitude and duration of the financial incentives varied greatly across studies and some studies used financial incentives with other interventions like counseling. The studies were a mix of randomized and cluster randomized designs. Financial incentive targeted at indicators of healthier eating and physical activity showed positive results at up to 12 months (OR for attainment of target behaviors 1.39, 95% CI 1.03 to 1.88), but the improvements were not sustained after removal of the financial incentive (OR 1.11, CI 0.76 to 1.63). Although not observed in the diet and physical activity trials, the authors did observe that use of higher value financial incentives was more effective than lower value incentives when used for smoking cessation.

Bottom line: Financial incentives to change health habits around healthful eating and physical activity are effective at up to 12 months, but the effects are attenuated beyond 12 months and appear not to be sustained once the incentive is removed.

Note: A separate systematic review and meta-analysis (*Giles, et al., 2014*) included studies of financial incentives for smoking cessation, vaccinations, and physical activity, though they identified only one study on physical activity. Across all the studies, the relative risk for attainment of target behaviors was 1.62 (95% CI 1.38 to 1.91), but the authors note that the effect size decreased at post-intervention follow-up. Their overall conclusion is that financial incentives are more effective than usual care.

General Multisector Interventions for Children

Ramsey Buchanan, et al., 2016

This is a systematic review and meta-analysis of interventions to reduce recreational sedentary screen time. It was prepared for the Centers for Disease Control and Prevention (CDC) Community Guide. The

authors identified 49 studies; 12 studies focused on reducing screen time only, while 37 studies examined interventions to reduce sedentary screen time and improve physical activity or nutrition. The interventions in the included studies were diverse and included classroom-based education, tracking and monitoring of screen time, coaching or counseling, and family or peer social support. Additional intervention components were devices to monitor and limit screen time, media and educational campaigns, and contingent rewards (i.e. screen time as a reward for physical activity). The authors defined high-intensity interventions as those that included electronic monitoring and limitation of screen time and at least three personal or computer-based interactions. Reported outcomes of interest included BMI, BMI z-score, and obesity prevalence. For children, two screen time-only and twelve screen time-plus studies showed an aggregate decrease in BMI z-score of -0.13 (interquartile interval [IQI] -0.23 to -0.01). For adults, two studies showed BMI reductions of -0.18 kg/m2 and -0.19 kg/m2. In terms of obesity prevalence, ten high-intensity screen time-plus interventions were estimated to decrease median obesity prevalence by -2.1% (IQI -3.9 to -1.1, baseline obesity prevalence of 10.3%). Four studies of low-intensity screen time interventions were estimated to reduce median obesity prevalence by -4.6% (IQI -7.6 to -1.1, baseline obesity prevalence of 12.3%). Among five studies that stratified analysis according to socioeconomic status (SES), four found greater effectiveness for reducing BMI and obesity prevalence among low income participants.

Bottom line: Interventions to reduce screen time are effective in reducing BMI and obesity prevalence. This effect has been observed mostly in children <13 years old, but a smaller number of studies also support the effectiveness of these interventions in adults. Interventions that include electronic monitoring and control of screen time appear to be more effective. The results also suggest that screen time interventions may reduce disparities in obesity prevalence between high and low SES children.

Kader, et al., 2015

This is a narrative systematic review of studies examining the effectiveness of parental support interventions. The authors identified 35 studies and divided the parental support interventions into four categories: individual counseling, group education, informational-only, and individual telephone counseling. Sixteen of the 35 studies reported on weight outcomes for children, but most of these studies were not powered to detect changes in BMI. One of the four studies of face-to-face counseling found a decrease in the prevalence of obesity among girls but not boys and those results were not sustained at later follow-up. Four of the seven studies involving group education showed improvement in weight-related outcomes. Information-only programs appeared to be ineffective. One of the two studies on telephone counseling showed a reduction in BMI z-score. The authors conclude that for weight-related outcomes, group education programs appear to be more effective than other universal parental interventions. Among five studies that were conducted exclusively in low SES or minority populations, 6 to 12 group education sessions for parents of preschool-age children were associated with “desirable effects on weight status.”

Bottom line: Group education programs appear to be more effective than other types of parental intervention for weight outcomes, especially for low SES and minority children.

Hillier-Brown, et al., 2014b

This is a narrative systematic review of interventions applied at various levels to reduce socioeconomic disparities in childhood obesity. Interventions were classified as occurring at the individual, community, or societal levels. The authors identified four studies at the individual level, seventeen studies at the community level, and one study at the societal level. Among the individual interventions, screen time reduction and mentored health promotion programs showed the most promise for reducing disparities. The authors concluded that the evidence for community level interventions was inconclusive with mixed results in studies of school- and community-based health promotion programs. The single societal level study of environmental changes in Swiss pre-schools showed no significant differences in BMI or overweight prevalence, but there was a "trend towards more beneficial effects in higher SES children." There was no evidence that any of the interventions worsened inequalities in obesity outcomes. The authors conclude that there is limited evidence but that some individual and community level interventions may be effective in reducing disparities in obesity-related outcomes for children.

Bottom line: Some individual interventions (screen time reduction and mentored health promotion programs) show promising results for reducing disparities in childhood obesity, while reported outcomes for community interventions were inconclusive or mixed.

Showell, et al., 2013

This is a narrative systematic review of home-based interventions on childhood obesity. The authors identified six studies including combined physical activity and diet interventions (3 studies), diet only interventions (1 study), interventions spanning home, school and primary care settings (1 study), and interventions with primary care and consumer health informatics components (1 study). Overall, none of the studies showed statistically significant reductions in BMI or obesity prevalence, though three studies showed improvements in diet or physical activity. The authors judged the evidence quality to be low or insufficient and called for better studies of home-based interventions.

Bottom line: There is insufficient evidence that home-based interventions are effective for reducing BMI or obesity prevalence in children.

School-based Interventions

Sun, et al., 2013

This is a narrative systematic review of trials examining school-based direct delivery of physical activity interventions. The authors identified six large, high-quality RCTs of high dose physical activity in schools. Three of the six studies found statistically significant reductions in BMI; the three remaining trials did not find statistically significant effects. Overall, the authors note that high dose direct delivery of physical activity in schools is associated with improved fitness measures, but that the effects on BMI, body fat, and waist circumference are inconclusive.

Bottom line: High dose physical activity interventions in schools improve fitness measures, but do not have a clear effect on weight-related outcomes.

Lavelle, et al., 2012

This is a systematic review and meta-analysis of school-based interventions to reduce BMI. The authors identified 43 RCTs, cluster-randomized, and quasi-randomized trials of school-based interventions that reported on BMI outcomes. These interventions were diverse (targeting physical activity, sedentary behavior, and nutrition) and variably included components of direct physical activity, nutrition and activity education, self-management and self-esteem building, and environmental changes (i.e. school meal changes or removal of vending machines). As expected, there was a high degree of heterogeneity. Two-thirds of the studies showed reductions in BMI with 16 of those demonstrating statistically significant differences. In the meta-analysis, the estimate of BMI reduction was -0.17 kg/m2 (95% CI -0.26 to -0.08). Notably, in the stratified analyses, the results were only statistically significant for girls. Among the studies in which interventions were only targeted at overweight and obese children, the meta-analysis showed a reduction in BMI of -0.35 kg/m2 (95% CI -0.58 to -0.12).

Bottom line: School-based interventions, particularly those that contain a physical activity component, are associated with a statistically significant reduction in BMI and the effect is greatest in overweight and obese children.

Childcare-based Interventions

Zhou, et al., 2014

This is a narrative systematic review of obesity prevention interventions delivered in childcare settings. The authors identified fifteen randomized, cluster randomized and non-randomized controlled trials that reported on adiposity outcomes. The study participants were 2 to 6 year old children in preschool childcare centers in several countries; about half the participants were socioeconomically disadvantaged. The interventions were varied and included structured age-appropriate nutrition education, healthy cooking classes, physical activity, and playful games. Several programs also included a component of parental education. The interventions lasted from six months to two years. Overall, the results were mixed with seven of the fifteen studies reporting improvements in measures of adiposity including BMI, body fat percentage, weight circumference, or decreased prevalence of overweight compared to controls. All of the studies with positive results included both nutrition and physical activity components. Among the remaining studies many reported positive effects on measures of physical activity or nutrition, but did not show improvements in adiposity outcomes.

Bottom line: There is mixed evidence about the effectiveness of interventions delivered in childcare settings in general to reduce obesity. Studies with positive results for this outcome all included combined physical activity and nutrition interventions.

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Section 5.0
Clarification of coverage guidance evidence submission policy

Clarification of coverage guidance evidence submission policy

Question: Clarification of coverage guidance evidence submission policy

Question source: HERC Staff

Issue: For a recent coverage guidance, verbal testimony at HERC caused the coverage guidance to be returned to EbGS, though one of the studies cited by the commenter had already been considered and the other did not meet inclusion criteria in the literature search. The commenter had not been aware that the coverage guidance was under developed until after the written comment period. Referring a coverage guidance back to a subcommittee for additional comment delays our process, and the value of including additional studies needs to be weighed against that delay. In addition, with certain fields (such as devices and genetic tests) manufacturers are creating a large number of new products and continually publishing evidence, which is often of low or very low quality.

Recommendations: Consider adopting the following policy:

For coverage guidances, HERC generally only includes studies during its initial coverage guidance development (before the relevant subcommittee reviews the first draft) or when these studies are submitted during the formal written comment period. In exceptional circumstances, however, the HERC recognizes the need to include late-breaking studies, or studies submitted outside the formal comment process. This policy outlines the circumstances which may justify consideration of new evidence outside the formal comment period.

Decisions about whether to delay the process for a new study will be made by staff, based on where a coverage guidance is in the development process and the importance of the evidence in question.

Staff will presume that an important study would be a new randomized controlled trial or a large registry study showing a new harm. The study would need to have a low risk of bias and moderate or better quality of evidence. The study would need to be determined by staff to be likely to alter a recommendation in a way that would significantly impact cost or quality of care for the population in question.

If staff finds out about a study after the formal comment period ends, staff will make a determination of the importance of the study in question per the criteria above. Staff would delay the process as needed in order to incorporate the study and update its existing literature search to find any other additional studies which may be appropriate to include. For other studies, staff will set them aside until the coverage guidance is complete, then assess whether it should trigger an off-cycle rescan based on the regular coverage guidance monitoring process.

In the case of a coverage guidance which has already been approved by the originating subcommittee, if an important new study arises, it would be referred back to that subcommittee before coming to HERC and VbBS.

Section 6.0

Presenting results in GRADE-informed framework

Presentation of estimates of effect in the HERC Grade-informed Framework

May 12, 2016

After encountering challenges in presenting and interpreting evidence in the GRADE-informed framework for some recent coverage guidance, staff and leadership have explored the presentation of the factors in the GRADE-informed framework.

Staff developed the proposed edits to Appendix A (shown as revisions below) as well as six examples which highlight scenarios for evidence based on a hypothetical trial described below. These examples would be used to inform staff work in developing initial recommendations for EbGS and HTAS.

Hypothetical study:

- **Population is adults with dyslipidemia (white men>55 with comorbid HTN, obesity or some similar high risk group, 10% baseline MACE risk in 5 years). Study quality rating shown in Appendix B.**
- **Diet 1 is control (no intervention)**
- **Diet 2 is a diet for lowering cholesterol**
- **The only outcome on which we have evidence is rate of MI at 5 years. However it is assumed that this diet would be difficult to adhere to as it differs significantly from the diets typically consumed by people in the studied population.**
- **The burden of proof is on Diet 2 since it costs money and is inconvenient for patients. Thus we would need to have evidence of superiority in order to recommend coverage.**
- **A priori, staff determined that clinically significant benefit on MI would be 0.95; clinically significant harm would be 1.02 (for the purposes of discussion…)**

Proposed revisions to Appendix A

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. ~~The narrower the gradient, the higher the likelihood that a weak 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 ~~is confident~~ concludes that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the ~~quality of evidence~~balance of benefits and harms, ~~cost and~~ resource allocation, ~~and~~ values and preferences and other factors.

Against: The subcommittee ~~is confident~~ 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.~~considering the quality of evidence, cost and resource allocation, and values and preferences.~~

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.~~considering the quality of evidence, cost and resource allocation, and values and preferences~~, but ~~is not confident~~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~~quality of evidence~~, cost and resource allocation, and values and preferences, but further research or additional information could lead to a different conclusion~~is not confident~~.

~~Quality or strength of evidence~~Estimate of effect rating across studies for the ~~treatment~~intervention/outcome[1]

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.

[1] Includes risk of bias, precision, directness, consistency and publication bias

Moderate: The subcommittee is moderately confident in the estimate of effect ~~estimate~~: 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 ~~estimate~~ 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 ~~estimate~~: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

Appendix B

Quality Assessment							
Number of studies	**Study design**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
MACE							
White men at high risk for MACE							
6	RCT (n=10,000)	Low	Not serious	Not serious	Not serious	None	High quality ●●●●

Case 1: Statistically significant benefit, not clinically significant

Coverage question: Should diet 2 (including counseling and food) be recommended for coverage for patients with dyslipidemia?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate/Quality of Evidence***	**Resource allocation**	**Values and Preferences**	**Other considerations**
MACE at 5 years *(Critical outcome)*	1,000/10,000[2] (10%; 95% CI=x%-y%) control 980/10,000 (9.8%; 95% CI=x%-y%) diet 2 NNT 500 (95% CI 333-1,000) For 1,000 patients treated, 2 fewer MACE (95% CI 1 to 3) RR 0.98 (95% CI 0.97-0.99) ●●●● *(High confidence/quality[3], based on 6 RCTs, N=10,000)*	Moderate unit cost to health system and a highly prevalent condition.	We believe that most patients would value avoiding an MI more than they would value the burden of diet. However, the benefit of avoiding an MI would likely have to be "clinically significant" to warrant the burden.	Diet 2 will require major lifestyle changes for many patients and their families. Delivery system is not well prepared to offer dietary counseling.
Balance of benefits and harms (for all outcomes)[4]: No known harms of diet 2. Benefits, although statistically significant, are not clinically significant.				
Rationale: Lack of clear clinical benefit, resource allocation, values and preferences and other considerations all support noncoverage. Therefore the recommendation is strong.				
Recommendation: Diet 2 is not recommended for coverage (*strong recommendation*).				

*The ~~Quality of Evidence~~ confidence in estimate rating was assigned by the primary evidence source, not the HERC Subcommittee

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

[2] Absolute risk with 95% CI with NNT is preferred. RR is a fallback but downgrade confidence for RR crossing 1 or for rare events. Downgrading for crossing clinical decision threshold should be discussed with committee unless the threshold is defined ahead of time.

[3] We will use "Confidence" rather than "Certainty" of estimate of effect. We will not use "Quality of Evidence" or "Strength of Evidence" but will use "Quality of Evidence" in the GRADE tables included in the appendix. We will NOT use the word confidence in the balance column, rationale or recommendation. Instead we will state the conclusions, and if there is statistical doubt we will use "clear, likely, suggestion of, sure, unsure or possible" to characterize our understanding.

[4] CeBP to draft this; OHA staff to review and discuss.

Case 2: Statistically and clinically significant benefit

Coverage question: Should diet 2 (including counseling and food) be recommended for coverage for patients with dyslipidemia?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
MACE at 5 years *(Critical outcome)*	1,000/10,000 (10%; 95% CI=x%-y%) control 750/10,000 (7.5%; 95% CI=?%-?%) diet 2 AAR 2.5%, NNT 40 (95% CI 25-67) For 1,000 patients treated, 25 fewer MACE (95% CI 15 – 40) RR 0.75 (95% CI 0.60-0.85) ●●●● *(High confidence, based on 6 RCTs, N=10,000)*	Moderate unit cost to health system and a highly prevalent condition.	We believe there would be significant variability in how patients would weigh the clinically significant risk reduction in MI against the burdens of adopting the diet.	Diet 2 will require major lifestyle changes for many patients and their families. Delivery system is not well prepared to offer dietary counseling.
Balance of benefits and harms (for all outcomes): No known harms of diet 2. Benefits outweigh harms, and the benefit is clinically significant. *(discussion about including last clause)*				
Rationale: Balance of benefits and harms strongly support the intervention but values and preferences are mixed. The clear and meaningful benefit, outweighs cost and variable values and preferences. The recommendation is strong based on the convincing evidence of a very significant effect despite variable values and preferences. *(strong/weak would likely be debated in this case because of variable values/preferences)*				
Recommendation: Diet 2 is recommended for coverage (*strong recommendation*).				

*The confidence in estimate ~~Quality of Evidence~~ rating was assigned by the primary evidence source, not the HERC Subcommittee.

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

Case 3: Statistically significant benefit, however unclear whether benefit is clinically significant

Coverage question: Should diet 2 (including counseling and food) be recommended for coverage for patients with dyslipidemia?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
MACE at 5 years *(Critical outcome)*	1,000/10,000 (10%; 95% CI=x%-y%) control 850/10,000 (8.5%; 95% CI=?%-?%) diet 2 AAR 1.5%, NNT 67 (95% CI 34-1000) For 1,000 patients treated, 15 fewer MACE (95% CI 1-29) RR 0.85 (95% CI 0.71-0.99) ●●●● *(Moderate confidence[5], based on 6 RCTs, N=10,000)*	Moderate unit cost to health system and a highly prevalent condition.	We believe there would be significant variability in how patients would weigh the potentially significant risk reduction in MI against the burdens of adopting the diet.	Diet 2 will require major lifestyle changes for many patients and their families. Delivery system is not well prepared to offer dietary counseling.
Balance of benefits and harms (for all outcomes): No known harms of diet 2. Benefits outweigh harms, but the benefits may or may not be clinically significant. Benefits are **likely/probably** clinically significant. (debate about whether to include green part as the confidence was downgraded for lack of precision, see footnote)				
Rationale: Balance of benefits and harms supports the intervention, though clinical significance of the benefit is not clear (Debate about whether to say moderate confidence the clinical significance of the benefit would warrant the burden of the intervention). Values and preferences are variable; therefore we make a weak recommendation for coverage.				
Recommendation: Diet 2 is recommended for coverage (*weak recommendation*).				

*The confidence in estimate ~~Quality of Evidence~~ rating was assigned by the primary evidence source, not the HERC Subcommittee.

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

[5] Downgrade if RR crosses 1 or if the 95% CI crosses a clinical decision threshold. Staff and subcommittee can discuss clinical decision thresholds after seeing the data, but such decisions should be made by the subcommittee after careful thought about bias.

Case 4: Diet 2 point estimate shows a small positive effect, but the maximum difference would not be clinically significant and the confidence interval crosses 1 (Diet 1 is control, no intervention)

Coverage question: Should diet 2 (including counseling and food) be recommended for coverage for patients with dyslipidemia?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
MACE at 5 years *(Critical outcome)*	1,000/10,000 (10%; 95% CI=x%-y%) control 990/10,000 (8.5%; 95% CI=?%-?%) diet 2 AAR 1.5%, NNT 1,000 (95% CI 333 NNT to 1000 NTH) For 1,000 patients treated, 1 fewer MACE (95% CI 3 fewer to 1 more) RR 0.99 (95% CI 0.97-1.01) ●●●● *(Moderate or high[6] confidence based on 6 RCTs, N=10,000)*	Moderate unit cost to health system and a highly prevalent condition.	We believe patients would weigh the burden of the diet more highly than the benefits.	Diet 2 will require major lifestyle changes for many patients and their families. Delivery system is not well prepared to offer dietary counseling.
Balance of benefits and harms (for all outcomes): No clinically significant benefit or harm.				
Rationale: Given lack of clinically significant benefit, we strongly recommend against this intervention.				
Recommendation: Diet 2 is not recommended for coverage (*strong recommendation*).				

*The confidence in estimate ~~Quality of Evidence~~ rating was assigned by the primary evidence source, not the HERC Subcommittee.

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

[6] Downgraded because RR crosses 1 or if the 95% CI crosses a predetermined clinical decision threshold. Staff and subcommittee can discuss clinical decision thresholds after seeing the data, but such decisions should be made by the subcommittee after careful thought about bias.

Case 5: Diet 2 point estimate shows a small positive effect, but the difference would not be clinically significant with wide CI crossing clinical thresholds of benefit and harm

Coverage question: Should diet 2 (including counseling and food) be recommended for coverage for patients with dyslipidemia?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	**Resource allocation**	**Values and Preferences**	**Other considerations**
MACE at 5 years *(Critical outcome)*	300/10,000 (10%; 95% CI=x%-y%) control 297/10,000 (3.0%; 95% CI=?%-?%) diet 2 AAR 7.0%, NNT 3,333 (95% CI 107 NNT to 114 NTH) For 10,000 patients treated, 3 fewer MI (95% CI 93 fewer to 87 more) RR 0.99 (95% CI 0.69-1.29) ●●●● *(Low[7] confidence based on 6 RCTs, N=10,000)*	Moderate unit cost to health system and a highly prevalent condition.	We believe patients would weigh the burden of the diet more highly than the benefits, given lack of clear benefit.	Diet 2 will require major lifestyle changes for many patients and their families. Delivery system is not well prepared to offer dietary counseling.
Balance of benefits and harms (for all outcomes): Unclear whether there is any benefit or harm on critical outcome, with wide confidence interval.				
Rationale: Given lack of clinically significant benefit, we strongly recommend against this intervention[8].				
Recommendation: Diet 2 is not recommended for coverage (*strong recommendation*).				

*The Confidence in estimate ~~Quality of Evidence~~ rating was assigned by the primary evidence source, not the HERC Subcommittee

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

[7] Think about clinical thresholds in advance here if possible. Downgrade if RR crosses 1 or if the 95% CI crosses a clinical decision threshold. Staff and subcommittee can discuss clinical decision thresholds after seeing the data, but such decisions should be made by the subcommittee after careful thought about bias.

[8] Will vary based on other factors. For instance, tobacco cessation interventions during pregnancy have a lower burden of proof.

Case 6: Diet 2 shows a wide CI, mostly in favor of intervention, but the estimate crosses 1.0

Coverage question: Should diet 2 (including counseling and food) be recommended for coverage for patients with dyslipidemia?				
Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate/Quality of evidence***	**Resource allocation**	**Values and Preferences**	**Other considerations**
MACE at 5 years *(Critical outcome)*	1,000/10,000 (10%; 95% CI=x%-y%) control 850/10,000 (8.5%; 95% CI=?%-?%) diet 2 AAR 1.5%, NNT 150 (95% CI 350 NNT to 20 NTH) RR 0.85 (95% CI 0.65-1.02) For 1,000 patients treated, 15 fewer MI (95% CI 35 would fewer to 2 more) ●●●● *(Low confidence[9], based on 6 RCTs, N=10,000)*	Moderate unit cost to health system and a highly prevalent condition.	Given the evidence, we would expect high variation in how patients value the benefits of the diet against the burden.	Diet 2 will require major lifestyle changes for many patients and their families. Delivery system is not well prepared to offer dietary counseling.
Balance of benefits and harms (for all outcomes): Evidence suggests that the benefit may be quite significant clinically, but the wide confidence interval of the estimate and possibility of harm are concerning[10] Using "quality" would allow us to say "Evidence suggests….but we are not confident…" .				
Rationale: Lack of a clear, clinically significant benefit, cost, mixed values and preferences and other considerations drive the recommendation for noncoverage. Additional evidence showing a clear, clinically-significant benefit could change this conclusion, so the recommendation is weak. **Or …** There is a likely very large benefit in reducing MACE. This outweighs the lack of clear benefit, along with the costs, variability in values and preferences and other factors, so we make a weak recommendation for coverage.				
Recommendation: Diet 2 is not? recommended for coverage (*weak recommendation*).				

[9] *Low confidence based on crossing 2 thresholds. (if defined a priori). Exploring subgroups and sensitivity would be useful here to target intervention to optimal population.*

[10] If baseline evidence quality were low, it would downgrade to very low confidence and we would be unable to draw conclusions in the balance.